Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance

METHOMYL

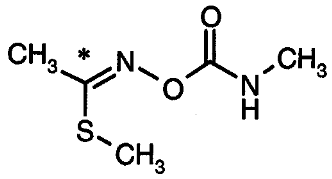
of the second stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 3, Annex B, part 2, B.8 – B.9, Appendices

November 2004

B.8 ENVIRONMENTAL FATE AND BEHAVIOUR

Radiolabelled studies were carried out with methomyl labelled as shown below:



* denotes position of ^{14}C

Representative uses of methomyl are on grapes and fruiting vegetables at recommended maximum field application rate 450 g a.s./ha and up to two applications during a growing season.

This equates to a soil concentration of 0.39 mg a.s./kg, based on the assumptions given in Section B.8.3. All studies where a test substance was used were conducted in accordance with the principles of GLP unless stated otherwise.

B.8.1 Route and rate of degradation in soil (IIA 7.1.1, IIIA 9.1.1)

B.8.1.1 Aerobic and anaerobic studies (II 7.1.1, IIIA 9.1.1)

B.8.1.1.1 Soil microbial studies

a) A study was carried out to US EPA guidelines 162-1 (1982) determine the aerobic metabolism of [1-^{14}C] methomyl in one soil (Madera, California). The study was conducted at 25 C and 75% of field capacity rather than 20°C and 40-50% of MWHC as specified in SETAC (1995).

The study used radiolabelled [1-^{14}C] methomyl with a specific radioactivity of 28.3 μCi/mg and radiochemical purity >97%.

The rate and route of degradation of Methomyl was studied in fresh loam soil, from Madera, California (see Table B.8.1 for physico-chemical characteristics) under aerobic laboratory conditions. Methomyl in dosing solution (0.2 mg/5 ml) was applied to 50 g dry weight of soil to give nominal concentrations of 4.1 mg/kg (rate equivalent to approximately 9.0 kg a.s./ha). Soil samples were incubated under aerobic conditions in the dark at 25±1°C at a soil moisture content of 75% of field capacity for up to 3 months. Provisions were made to trap radiolabelled $^{14}CO_2$ and volatiles. The microbial viability of the soil was demonstrated at the beginning of the study.

At each sampling point, duplicate soil samples were extracted with methanol/water (100mL of 1:1, v:v) then methanol. For each sample, all extracts were combined and aliquots were analysed by liquid scintillation counting (LSC) to determine total extractable radioactivity. Samples were concentrated before HPLC and TLC analysis. Extracted soil samples were combusted to determine levels of unextractable residues. Degradation products were identified by co-chromatography using authentic standards by HPLC and TLC. The rate of degradation of methomyl in soil was determined by fitting the data to a first order rate equation with a linear least squares regression.

Table B.8.1 Physical and chemical characteristics of the test soil

Characteristic	Soil
Origin Location	Madera, California, USA
pH	7.8
% Sand (2000 - 50 µm)	44.9
% Silt (<50 - 2 µm)	41.7
% Clay (<2 µm)	13.4
Texture[a]	Loam
Organic carbon (%)[b]	0.54
Cation exchange capacity	56.3
Field moisture capacity at 1/3 bar (%)	37.6
Microbial biomass (mg microbial C/kg soil)	Not determined
a USDA soil classification system b organic carbon = organic matter/1.72	

Material balance for Methomyl ranged from 92% to 102% (see Table B.8.2 for distribution of radiolabelled components). Table B.8.3 shows the distribution of unextracted residues and Table B.8.4 summarises DT_{50} and DT_{90} values for methomyl in aerobic soil.

Table B.8.2 Average percent distribution of radiolabelled components in aerobic soil after application of [1-^{14}C]Methomyl

Sampling Point (days)	Methomyl	Methomyl oxime	Polar Unknown 1	Polar Unknown 2	$^{14}CO_2$	Unextractable Residue	Total
0	99.0	1.5	0.0	0.1	0.00	0.3	102
1	92.3	2.1	0.6	0.4	0.02	2.4	99
2	87.0	1.4	0.5	0.4	0.82	5.4	96
4	81.1	1.7	1.3	0.6	5.0	9.1	100
8	66.7	1.0	0.7	0.2	15.8	15.1	100
14	43.8	1.0	2.3	0.6	27.7	18.7	95
21	24.7	0.9	2.9	0.5	40.6	24.1	95
30	14.8	0.7	2.8	0.4	51.8	24.2	95
61	2.6	0.3	2.5	0.2	70.9	22.3	99
92	1.3	0.2	0.6	0.1	75.4	13.9	92

Methomyl oxime=Z-methyl N-hydroxyethanimidothioate (INX1177)

Table B.8.3 Distribution of unextractable components in soil organic matter

Soil Fraction	(% of radiolabel)[a] Month 1 % of Applied	Month 2 % of Applied
Fulvic acid	3.2	3.3
β-Humus	0.1	0.3
Hymatomelanic Acid	0.2	0.2
α-Humus	0.7	0.8
Soluble Humin	8.0	8.3
Insoluble Humin	8.5	7.5

[a] Recoveries from organic matter fractionation were 89.6 and 86.1% respectively from Month 1 and Month 2 samples.

Table B.8.4 DT_{50} and DT_{90} values for Methomyl in aerobic soil (linear regression, log normalised)

Analyte	DT_{50} (days)	DT_{90} (days)	r^2	Method of calculation
Methomyl	10.5	35[a]	0.994	First order

[a] The DT_{90} value was calculated from the linear regression equation provided in the report.

(Zwick, T.C., Malik, N. 1990a)

b) A study was carried out in three aerobic soils to EEC 91/414EEC (as amended by Commission Directive 95/36/EC) to determine the rate of degradation of methomyl.

The study used [1-^{14}C] methomyl with a specific radioactivity of 42.96 µCi/mg and radiochemical purity of 95%).

The rate of degradation of Methomyl was determined under laboratory conditions in three field-fresh soils (see Table B.8.5 for physico-chemical characteristics) at 20°C ± 2°C and in one of these soils (Nambsheim) at 10°C ± 2°C. These soils were typical of agricultural soil types. Methomyl was dissolved in 10 mM pH 5 sodium acetate buffer, at a concentration of 180 mg/L and 0.50 or 0.55 ml were applied to 25-g dry weight of soil to give a nominal soil concentration of 3.6 mg/kg (rate equivalent to 2.7 kg a.s./ha assuming incorporation into the top 5 cm and a soil bulk density of 1.5 g/cm^3). Soil samples were incubated under aerobic conditions in darkness at a soil moisture content of 50% of maximum water holding capacity for up to 21 (Speyer 2.2 soil) or 30 days (Mattapex and Nambsheim soils).

Table B.8.5 Physical and chemical characteristics of the test soils

Characteristic	Soil		
Soil Name or Designation	Speyer 2.2	Mattapex	Nambsheim
Origin	Germany	USA	France
pH (in water)	6.4	5.1	7.8
% Sand (2000 - 50 µm)	69.2	43.2	57.2
% Silt (<50 - 2 µm)	24.8	46.8	32.8
% Clay (<2 µm)	6.0	10.0	10.0
Texture[a]	Sandy loam	Loam	Sandy loam
Organic carbon (%)[b]	2.1	0.9	0.7
Cation exchange capacity	10.67	4.44	6.48
Maximum water-holding capacity (%)	45.9	35.2	32.3
Microbial biomass (mg microbial C/kg soil)[c]	392	110	230/189[d]

[a] USDA soil classification system [b] organic carbon = organic matter/1.72 [c] at the final sampling time [d] for Nambsheim soil, the first value refers to the soil incubated at 10°C and the second value to the soil incubated at 20°C

Material balance was >85% at all sampling intervals in all soil groups (Table B.8.6).

Soil was extracted with methanol/water, and analysed by LSC and HPLC. There were four extractable degradation products. None of these represented more than 10% at any time (Table B.8.6). After 30 days, unextractable residue represented 25-32% at 20°C and 23% at 10°C.

DT_{50} and DT_{90} values were calculated assuming first order kinetics (Table B.8.7).

Table B.8.6 Percent distribution of radiolabelled components in aerobic soils after application of [1-^{14}C]Methomyl (mean values from duplicate samples)

Soil and Temperature	Sampling Time (Days)	Methomyl	Methomyl oxime	$^{14}CO_2$	Organic Volatiles	Others [2]	Unextractable Residue [1]	Total
Speyer 2.2 (20°C)	0	91.2	0.5	-	-	2.8	0.8	95.0
	1	82.4	1.4	2.1	nd	4.7	4.3	94.8
	2	74.2	1.4	4.6	nd	5.6	6.8	92.6
	3	65.3	1.3	5.2	nd	6.8	10.9	89.4
	5	50.1	1.3	13.0	nd	8.0	15.7	87.9
	7	36.5	0.9	19.6	nd	7.9	22.2	87.0
	14	10.9	0.4	40.2	nd	6.6	30.4	88.4
	21	3.2	0.1	51.3	nd	6.6	31.0	92.0
Mattapex (20°)	0	91.0	0.5	-	-	2.7	1.0	95.1
	1	86.4	0.7	4.8	nd	2.9	4.1	98.9
	2	80.7	0.8	8.7	nd	3.2	6.5	99.8
	3	75.9	0.6	7.1	nd	3.1	8.3	95.1
	5	67.2	0.6	12.7	nd	3.5	13.5	97.4
	7	51.6	0.7	11.6	nd	3.6	18.0	85.4
	14	28.0	0.6	29.8	nd	3.7	27.2	89.1
	21	12.4	0.4	47.1	nd	4.1	31.3	95.3
	30	7.7	0.4	51.1	nd	4.0	32.2	95.4
Nambsheim (20°)	0	89.9	1.0	-	-	2.8	1.0	94.6
	1	85.1	2.2	2.0	nd	3.8	2.9	95.9
	2	78.3	1.8	5.4	nd	3.9	4.7	94.0
	3	72.0	1.7	9.3	nd	4.5	5.6	93.0
	5	54.9	1.6	20.3	nd	4.5	9.5	90.7
	7	46.1	1.7	26.5	nd	4.7	11.2	90.1
	14	27.5	0.9	41.0	nd	4.5	17.9	91.7
	21	10.2	0.3	54.6	nd	4.0	21.4	90.3
	30	3.5	0.2	61.0	nd	3.6	25.2	93.4
Nambsheim (10°)	0	91.9	0.9	-	-	2.8	0.9	96.4
	1	88.0	1.4	0.6	nd	3.1	1.9	94.8
	2	87.4	1.9	1.3	nd	2.8	3.1	96.4
	3	83.1	1.4	2.6	nd	3.2	3.0	93.1
	5	79.9	2.4	3.3	nd	2.9	4.8	93.2
	7	74.3	2.5	7.4	nd	4.0	5.5	93.5
	14	63.1	1.6	16.3	nd	4.2	8.4	93.4
	21	48.9	1.4	24.6	nd	3.7	13.8	92.1
	30	35.8	0.9	32.7	nd	4.7	22.7	96.6

[1] Unextractable Residue in soil [2] Sum of all unknown polar products (maximum individual peak represented 6.1 % AR) nd = Not detected

Table B.8.7 DT_{50} and DT_{90} values for Methomyl in aerobic soil (linear regression, log normalised)

Soil Name	Texture (pH)	Incubation Temperature (°C)	DT_{50} (days)	DT_{90} (days)	r^2	Method of Calculation
Speyer 2.2	Sandy loam (6.4)	20	4	14	0.996	First order
Mattapex	Loam (5.1)	20	8	26	0.991	First order
Nambsheim	Sandy loam (7.8)	20	6	21	0.992	First order
Nambsheim	Sandy loam (7.8)	10	23	75	0.995	First order

(Shaw, D. 2001a)

c) A study was carried out to US EPA Guideline 162-2 (1982) to determine the anaerobic degradation of methomyl in one soil. The notifier reported that the study was conducted at 25°C rather than 20°C specified in SETAC.

The study used radiolabelled [1-^{14}C] methomyl with a specific radioactivity of 28.3 µCi/mg and radiochemical purity >97%.

The metabolism of Methomyl was studied in fresh loam from Madera, California (see Table B.8.8 for physico-chemical characteristics) maintained under aerobic conditions for 14 days then under anaerobic conditions for an additional 60 days. The microbial viability of the soil was measured before test substance application. Methomyl in dosing solution (0.2mg/5mL) was applied to soil (50 g dry weight) to give nominal concentrations of 4 mg/kg (rate equivalent to 8 pounds active substance per acre or approximately 9 kg a.s./ha). Soil samples were incubated under aerobic flow-through conditions in the dark at 25±1°C at a soil moisture content of 75% of field capacity for 14 days. Provisions were made to trap radiolabelled $^{14}CO_2$ and volatiles. After 14 days, the flasks were purged with nitrogen gas. The samples were incubated under anaerobic conditions in the dark for up to 60 days. Provisions were made to trap radiolabelled $^{14}CO_2$ and organic volatiles.

At each sampling point, soil samples were extracted with methanol/water (100mL of 1:1, v/v) then methanol. For each sample, all extracts were combined and aliquots were analysed by liquid scintillation counting (LSC) to determine total extractable radioactivity. Samples were concentrated for HPLC and TLC analysis. Extracted soil samples were combusted to determine levels of unextractable residues. Degradation products were identified by co-chromatography using authentic standards by HPLC and TLC. The rate of degradation of Methomyl in soil was determined by fitting the data to a first order rate equation with a linear least squares regression.

Table B.8.8 Physical and chemical characteristics of the test soil

Characteristic	Soil
Origin Location	Madera, California, USA
pH	7.8
% Sand (2000 - 50 µm)	44.9
% Silt (<50 - 2 µm)	41.7
% Clay (<2 µm)	13.4
Texture[a]	Loam
Organic carbon (%)[b]	0.54
Cation exchange capacity	56.3
Field moisture capacity at 1/3 bar (%)	37.6
Microbial biomass (mg microbial C/kg soil)	Not determined

a USDA soil classification system b organic carbon = organic matter/1.72

Overall recovery ranged from 85 to 100% of the applied radiolabel under aerobic and nitrogen flow-through anaerobic conditions (Table B.8.9). Table B.8.10 summarises the distribution of unextracted residues and Table B.8.11 summarises DT_{50} and DT_{90} values for methomyl in soil under aerobic followed by anaerobic conditions.

Table B.8.9 Percent distribution of applied radioactivity in soil treated with [1-^{14}C]Methomyl and incubated under aerobic and flow-through anaerobic conditions

Day	Average % of radiolabel							
	Organic Volatiles	Labelled CO_2	Unextrac-table	Methomyl	Methomyl oxime	Unknown 1	Unknown 2	Total Recovered
0	0.0	0.0	0.1	94.9	1.2	0.1	0.1	100
14	0.1	29.5	23.3	35.3	1.5	2.5	0.5	94
Conversion[a]								
7[b]	2.0	37.0	35.6	4.6	0.7	6.9	0.8	89
14	3.9	40.0	34.9	1.9	0.4	3.7	0.7	87
30	3.9	49.7	28.5	1.4	0.6	2.7	0.3	88
60	3.9	52.9	24.5	0.6	0.4	2.0	0.2	85

[a] Time when samples were converted to anaerobic conditions [b] Days under anaerobic conditions

Table B.8.10 Distribution of unextractable components in soil organic matter

Soil Fraction	% of Radiolabel[a]
	Day 14 Anaerobic Flow-Through Sample
Soluble Humin	21.1
Insoluble Humin	3.6
Fulvic acid	5.1
β-Humus	0.7
Hymatomelanic Acid	0.2
α- Humus	0.9

[a] Recovery from organic matter fractionation was 90.6%.

Table B.8.11 DT_{50} and DT_{90} values for Methomyl in soil under aerobic followed by anaerobic conditions (linear regression, log normalised).

	DT_{50} (days)	DT_{90} (days)[a]	r^2	Method of calculation
Aerobic	10	33	Only 2 data points 1	First order
Anaerobic	14.3	48	0.981	First order

[a] Values calculated from the linear regression equations provided in the original report.

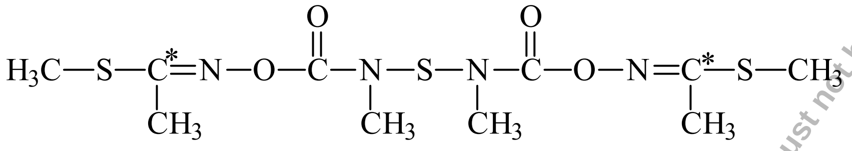
(Zwick, T.C., Malik, N. 1990b)

B.8.1.1.2 Soil rate of degradation studies - laboratory

Thiodicarb studies supplied by Bayer CropScience (formerly Aventis) for that review, for which the UK is also RMS, have been evaluated under this review. Thiodicarb is an active ingredient in its own right (used as a molluscicide and insecticide); methomyl is a metabolite of it.

a) A study was conducted in accordance with SETAC Guidelines (1995) to determine the rate of aerobic degradation of thiodicarb in 3 soils. From these studies degradation rates for its degradation product methomyl were also calculated. The thiodicarb notifier reported that the temperature was outside the specified range of 20°C±2°C for *ca.* 3 hours reaching a maximum of 24.5°C, but that this brief rise in temperature had no impact on the results and conclusions of the study.

The study used [Acetyl-1-^{14}C]-Thiodicarb, with a specific activity of 1419 MBq/mmole and a radiochemical purity of >99.4%. See Figure B.8.1 for position of radiolabel.



* indicates label position

The soil characteristics are outlined in Table B.8.12. Soil samples were treated with ^{14}C-thiodicarb at a nominal rate of 1 kg a.s./ha and maintained under aerobic conditions at approximately 45% of the maximum water holding capacity in the dark at 20°C for 56 days in metabolism flasks. An additional set of clay loam samples was similarly treated but incubated at 10°C for a period of 56 days.

Table B.8.12 Characteristics of 3 UK Soils Used in Aerobic Soil Study

Soil Reference	**High pH clay loam**	**Sandy loam**	**Clay loam**
Textural classification ADAS:	Clay loam	Sandy loam	Clay loam
% Sand	20.35	76.78	23.59
% Silt	52.03	13.56	53.42
% Clay	27.63	9.68	22.99
Organic Carbon (%)	4.7	1.8	1.9
Organic Matter (%)	8.1	3.1	3.3
Cation Exchange Capacity (meq/100g)	126.9	10.6	16.4
pH Water	7.6	6.0	6.9
Moisture holding capacity (%)	94.11	48.26	51.30
Moisture content (%)	31.21	8.28	11.57
Microbial Biomass (μg Cg^{-1} soil):			
Initial[a]	1134	20	248
final	1057	163	238[b]/249[c]
Source	Flint Hall, Royston, Herts. UK	Wilsons Farm Baylham, Suffolk, UK	Boarded Barns Farm, Ongar, Essex, UK

a Determined by fumigation extraction method by Chemex International plc, Bar Hill, Cambridge, Cambridgeshire, UK.
b Final biomass for 20°C samples
c Final biomass for 10°C samples

Following treatment the soil flasks were connected to a series of trapping solutions to collect any volatile products evolved. Immediately after treatment and at 0.25, 1, 2, 5, 7, 15, 28 and 56 days after treatment flasks were removed for analysis. The soils were extracted with methanol and the components present in the extracts were characterised and quantified by HPLC.

In addition, selected extracts were analysed by LC-MS to confirm characterisation and provide confirmation of structural identity. At each sampling interval, the radioactivity in the traps was quantified and the traps were also replenished between sampling intervals as necessary.
The overall recovery of radioactivity throughout the study is summarised in Tables B.8.13 to B.8.16.

Table B.8.13 Recovery and Distribution of Radioactivity-high pH clay loam at 20°C

Time (days)	**% Applied radioactivity**					
	Total extracted	**Volatile traps**			**Unextracted**	**TOTAL**
		Methanol	**KOH**	**Total**		
0	89.43	0.00	0.00	0.00	7.20	96.63
0.25	87.77	0.02	0.15	0.18	6.67	94.62
1	84.00	0.05	0.94	0.99	11.22	96.21
2	74.95	0.08	2.27	2.34	18.05	95.35
3	62.12	0.18	6.22	6.40	23.79	92.31
5	48.31	0.30	19.13	19.44	26.26	94.01
7	35.29	0.33	27.83	28.15	28.50	91.95
15	7.83	0.27	46.53	46.80	34.63	89.27
28	3.67	0.08	40.27	40.35	34.90	78.92
56	2.44	0.29	60.28	60.56	30.22	93.33
		Mean overall recovery				**93.73***

*Flask 58 excluded from mean recovery

Table B.8.14 Recovery and Distribution of Radioactivity-sandy loam at 20°C

Time (days)	**% Applied radioactivity**					
	Total extracted	**Volatile Traps**			**Unextracted**	**TOTAL**
		Methanol	**KOH**	**Total**		
0	94.34	0.00	0.00	0.00	0.70	95.03
0.25	88.57	0.02	0.11	0.13	1.96	90.66
1	91.09	0.01	0.11	0.12	4.68	95.90
2	88.31	0.00	0.04	0.04	6.21	94.55
3	88.09	0.04	1.57	1.61	9.61	99.30
5	68.13	0.09	5.57	5.66	19.92	93.72
7	53.45	0.05	14.86	14.90	19.95	88.31
15	15.41	0.09	41.95	42.04	33.53	90.99
28	3.73	0.12	52.27	52.39	33.89	90.01
56	2.20	0.19	65.56	65.75	26.06	94.00
	Mean overall recovery					**93.25**

Table B.8.15 Recovery and Distribution of Radioactivity-clay loam at 20°C

Time (Days)	**% Applied radioactivity**					
	Total extracted	**Volatile traps**			**Unextracted**	**TOTAL**
		Methanol	**KOH**	**Total**		
0	92.70	0.00	0.00	0.00	3.44	96.14
0.25	86.49	0.03	0.06	0.09	5.62	92.21
1	90.05	0.02	0.37	0.39	9.00	99.43
2	86.00	0.06	1.00	1.06	9.27	96.34
3	79.09	0.09	0.96	1.05	11.25	91.38
5	75.23	0.08	6.00	6.09	13.97	95.28
7	64.30	0.08	13.06	13.14	17.78	95.20
15	36.33	0.04	25.93	25.96	27.22	89.52
28	12.45	0.09	45.01	45.11	34.48	92.38
56	4.13	0.10	59.37	59.47	29.23	93.90
			Mean overall recovery			**94.04**

Table B.8.16 Recovery and Distribution of Radioactivity-clay loam at 10°C

Time (Days)	**% Applied radioactivity**					
	Total extracted	**Volatile traps**			**Unextracted**	**TOTAL**
		Methanol	**KOH**	**Total**		
0	94.16	0.00	0.00	0.00	3.88	98.04
0.25	88.95	0.01	0.04	0.05	4.84	93.85
1	91.47	0.01	0.10	0.11	5.80	97.39
2	89.82	0.01	0.19	0.20	4.21	94.23
3	90.55	0.04	0.01	0.04	5.93	96.52
5	86.70	0.04	0.83	0.88	7.41	94.98
7	87.92	0.22	1.29	1.51	7.48	96.91
15	73.68	0.12	9.44	9.56	15.93	99.17
28	42.16	0.16	20.67	20.83	28.25	91.24
56	19.54	0.21	39.15	39.36	30.42	89.32
		Mean overall recovery				**95.16**

The levels of thiodicarb in the extracts decreased rapidly to form one major metabolite methomyl. Metabolite levels are summarised in Tables B.8.17 to B.8.20.

Table B.8.17 Levels of Thiodicarb and Metabolites in Soil Extracts-high pH clay loam at 20°C

	% Applied radioactivity					
Time (days)	**% in extract**	**Thiodicarb**	**Methomyl**	**Methomyl oxime**	**Unknown**	**Other unknowns**
0	89.43	52.81	36.62	0.00	0.00	0.00
0.25	87.77	24.74	61.28	1.66	0.05	0.05
1	84.00	3.65	79.76	0.20	0.29	0.11
2	74.95	0.00	73.56	0.68	0.68	0.03
3	62.12	0.00	61.27	0.26	0.59	0.00
5	48.31	0.00	45.66	0.61	1.88	0.16
7	35.29	0.00	30.58	0.25	4.04	0.43
15	7.83	0.00	5.85	0.27	1.69	0.02
28	3.67	0.00	0.80	0.00	2.88	0.00
56	2.44	0.00	0.70	0.00	1.69	0.06

Table B.8.18 Levels of Thiodicarb and Metabolites in Soil Extracts-sandy loam at 20°C

	% Applied Radioactivity					
Time (days)	**% in extract**	**Thiodicarb**	**Methomyl**	**Methomyl oxime**	**Unknown**	**Other unknowns**
0	95.03	91.26	1.67	1.12	0.05	0.24
0.25	88.60	80.10	8.00	0.12	0.19	0.18
1	91.10	43.70	47.16	0.10	0.12	0.00
2	88.31	32.79	53.91	0.97	0.42	0.21
3	88.09	28.61	58.78	0.04	0.36	0.29
5	68.13	3.94	62.63	0.23	1.10	0.24
7	53.45	0.75	48.58	0.35	3.02	0.75
15	15.41	0.00	11.00	0.50	3.27	0.65
28	3.73	0.00	1.10	0.00	2.63	0.00
56	2.20	0.00	0.28	0.00	1.88	0.04

Table B.8.19 Levels of Thiodicarb and Metabolites in Soil Extracts-clay loam at 20°C

	% Applied radioactivity					
Time (days)	**% in extract**	**Thiodicarb**	**Methomyl**	**Methomyl oxime**	**Unknown**	**Other unknowns**
0	92.70	81.96	10.63	0.00	0.12	0.00
0.25	86.49	76.37	10.12	0.00	0.00	0.00
1	90.05	28.53	61.40	0.00	0.12	0.00
2	86.00	7.03	77.87	0.49	0.41	0.20
3	79.09	5.18	71.21	0.05	0.15	2.49
5	75.23	1.87	72.41	0.11	0.75	0.09
7	64.30	0.00	61.42	0.29	1.69	0.91
15	36.33	0.27	33.36	0.24	1.86	0.60
28	12.45	0.18	11.06	0.08	1.02	0.10
56	4.13	0.14	2.48	0.02	1.43	0.05

Table B.8.20 Levels of Thiodicarb and Metabolites in Soil Extracts-clay loam at 10°C

	% Applied radioactivity					
Time (days)	**% in extract**	**Thiodicarb**	**Methomyl**	**Methomyl oxime**	**Unknown**	**Other unknowns**
0	94.16	82.34	11.68	0.00	0.00	0.15
0.25	88.95	78.61	10.20	0.03	0.05	0.06
1	91.47	68.94	22.47	0.06	0.00	0.00
2	89.82	36.76	50.62	0.23	0.38	1.83
3	90.55	29.33	60.81	0.12	0.16	0.14
5	86.70	16.83	69.55	0.06	0.17	0.08
7	87.92	8.86	77.78	0.13	0.74	0.41
15	73.68	0.42	72.59	0.17	0.39	0.11
28	42.16	0.57	39.69	0.38	1.00	0.52
56	19.54	0.35	16.39	0.16	2.32	0.32

In order to define the degradation kinetics for both parent thiodicarb and major metabolite methomyl the Parent and Metabolite model was implemented within ModelMaker using Simple First-Order (SFO) kinetics using non linear least squares curve fitting and entering the mean of the replicate data points. The DT_{50} and DT_{90} values for thiodicarb and methomyl were calculated, and are summarised in Table B.8.21 (20ºC) and 8.22 (10ºC)

Table B.8.21 DT_{50} and DT_{90} values for thiodicarb and methomyl (20ºC & 45% MWC) using ModelMaker (simple first order)

		Thiodicarb			Methomyl	
	r^2	DT_{50} (days)	DT_{90} (days)	Conversion percentage	DT_{50} (days)	DT_{90} (days)
Clay loam high pH	0.990	0.13	0.42	90.7	4.6	15.4
		(0.11-0.14)	(0.37-0.47)		(3.9-5.4)	(12.9-17.9)
Sandy loam	0.967	1.2	3.9	99.2	4.9	16.2
		(1.0-1.4)	(3.2-4.7)		(3.0-6.8)	(9.9-27.5)
Clay loam	0.982	0.60	2.0	91.3	9.9	33.0
		(0.50-0.70)	(1.7-2.3)		(7.4-12.5)	(24.6-41.5)

Figures in parentheses are the 95% confidence intervals

Table B.8.22 DT_{50} and DT_{90} values for thiodicarb and methomyl at 10°C & 45% MWC using ModelMaker (simple first order) in the Clay loam soil

Thiodicarb			Methomyl		
DT_{50} (days)	DT_{90} (days)	r^2	DT_{50} (days)	DT_{90} (days)	r^2
1.7	5.7	0.961	23.2	77.0	0.961

(Burr C. M., 2000a)
Bayer Data

b) A second laboratory study was carried out in 1 soil to US EPA Guidelines Subdivision N, 162-1 (1982) to determine the rate of aerobic degradation of thiodicarb. Degradation rates for the metabolite methomyl formed in this study were also calculated

The study used [Acetyl-1-^{14}C]-Thiodicarb, with a specific activity of 20.05 mCi/mmole and a radiochemical purity of 99%.

Sandy loam soil (see Table B.8.23 for characteristics) in metabolism flasks was treated with 10 ppm of ^{14}C-thiodicarb and maintained under aerobic conditions at 75% FMC at 1/3 bar in an environmental chamber in the dark at 25 ± 1 °C for up to 60 days. For each sample, volatile radioactivity was collected in a series of organic traps (containing methanol) and CO_2 traps (containing 2-ethoxyethanol-ethanolamine 2:1). Duplicate samples were taken and analysed at 0, 0.5, 1, 3, 7, 14, 21, 30, and 60 days. Soil was extracted with methanol and with acidified methanol, extracts concentrated and analysed by TLC (thin layer chromatography).

The methanol and acidic extracts of the soil were analysed separately by TLC to determine metabolite distribution. The volatile radioactivity retained in methanol traps was identified as acetonitrile by HPLC and GC/MS analyses. Volatile radioactivity retained in ethoxyethanol-ethanolamine traps was identified as carbon dioxide by re-trapping it in NaOH traps and by precipitating it with barium chloride.

Table B.8.23 Physical Properties of Sandy Loam Soil

Soil classification	**Sandy loam**
pH	5.4
Cation Exchange Capacity (meg/100 g)	6.16
% Organic Matter	0.49
% Water Holding Capacity at 0.33 bar	9.24
% Water Holding Capacity at 15 bar	3.71
% Sand	69.56
% Silt	17.24
% Clay	13.20
Bulk Density (g/cc)	1.36

The material balance of thiodicarb is summarised in Table B.8.24.

Table B.8.24 Material Balance of Thiodicarb Aerobic Soil Metabolism in Sandy Loam Soil

Time (days)	Recovery of applied radioactivity (%)					
	Volatiles		Soil			Total recovery
	Aceto-nitrile	CO_2	Extractables		Un-extractables	
			MeOH Ext.	Acidic Ext.		
0	-	-	98.67	1.16	0.18	100.01
0.5	0.22	0.13	97.58	3.27	1.37	102.57
1	0.20	0.27	95.64	4.04	1.52	101.66
3	0.57	1.01	91.40	5.61	3.68	102.26
7	0.88	3.70	84.35	4.02	4.01	96.96
14	0.60	15.40	65.65	5.46	9.07	96.18
21	0.83	28.83	55.99	6.70	12.44	104.77
30	1.77	33.83	49.25	5.76	9.63	100.22
60	1.82	51.62	22.97	5.19	13.47	95.07

Identity and levels of metabolites are summarised in Table B.8.25.

Table B.8.25 Identity of Thiodicarb Metabolites

Identity		% of applied dose at indicated sampling time (days)								
		0	0.5	1	3	7	14	21	30	60
Unknown 1	%	-	-	-	0.44	0.56	1.68	1.90	2.43	0.53
Unknown 2	%	-	-	-	-	-	-	-	-	0.55
Unknown 3	%	-	-	-	0.66	0.43	0.65	1.32	1.64	1.98
Unknown 4	%	-	-	-	0.46	0.43	0.29	0.20	0.08	0.99
Thiodicarb	%	89.51	86.21	61.91	21.09	6.41	2.17	0.96	0.28	-
Methomyl	%	10.10	11.50	37.31	73.68	79.63	65.98	57.37	50.18	23.91
M. Oxime	%	0.22	3.17	0.45	0.39	0.83	0.27	0.86	0.28	0.24
Unknown 8	%	-	-	-	0.07	0.07	0.06	0.08	0.11	0.12

Degradation times for thiodicarb and methomyl are summarised in Table B.8.26.

Table B.8.26 DT_{50} and DT_{90} values for thiodicarb and methomyl at 25°C and 75% FMC (simple first order kinetics)

Substance	**DT_{50} (days)**	**DT_{90} (days)**	**r^2**
Thiodicarb	3.6	12	0.94
Methomyl	31	100	0.99

(Feung C.S., Weisbach P.J., 1991©)
Bayer Data

c) An aerobic soil degradation study was conducted according to EEC 91/414 EEC guidelines on methomyl oxime (INX1177).

[1-^{14}C]-methomyl oxime with a specific radioactivity of 66.2 µCi/mg; radiochemical purity 95%), was used.

The rate of degradation of methomyl oxime was determined under laboratory conditions in three field-fresh soils (Table B.8.5) at 20±2°C. Methomyl oxime was dissolved in 10-mM sodium acetate buffer, pH 5 at a concentration of 115 mg/L and 0.50 ml were applied to 25-g dry weight of soil to give a nominal soil concentration of 2.3 mg/kg. Soil samples were incubated under aerobic conditions in darkness at a soil moisture content of 50% of maximum water holding capacity for up to 7 days. (See table B.8.5 for soil characteristics except the microbial biomass was 75, 139 and 308 mgC/kg dry soil at the beginning of the incubation increasing to 127, 361, and 549 mgC/kg dry soil at study termination in the Mattapex, Nambsheim and Speyer 2.2 soils respectively). Mean values from duplicate sample analyses were reported throughout the study. Soil samples were extracted with methanol/water before being analysed by HPLC and TLC. Unextracted radioactivity was quantified by combustion then quantification by LSC. Volatiles were trapped in potassium hydroxide (CO_2) and ethyl digol (organic volatiles).

Material balance was >89% at all sampling intervals in all soils. Labelled carbon dioxide was produced from each soil (48 to 59% after 4 to 7 days). No organic volatiles were produced.

Table B.8.27: Percent distribution of radiolabelled components in aerobic soils (20°C, 50%MWHC) after application of [^{14}C]-methomyl oxime (mean values from duplicate samples analysed by HPLC)

Soil	Sampling Time (Days)	Methomyl oxime	$^{14}CO_2$	Organic Volatiles	Others[1]	Unextracted Residue[1]	Total
Speyer 2.2	0	89.5	-	-	3.3	0.6	93.4
	0.25	80.4	0.9	nd	9.7	3.8	94.8
	0.5	74.0	3.5	nd	13.5	10.8	101.7
	1	51.8	12.2	nd	15.6	13.5	93.1
	2	16.8	32.5	nd	15.1	31.0	95.3
	4	1.9	50.6	nd	9.7	37.7	99.8
	7	1.3	48.1	nd	7.5	34.3	91.1
Mattapex	0	86.0	-	-	5.3	2.3	93.5
	0.25	72.4	0.7	nd	14.8	7.0	94.8
	0.5	68.4	2.8	nd	17.0	12.4	100.3
	1	63.2	6.9	nd	13.3	16.9	100.2
	2	21.8	29.3	nd	11.1	41.0	103.1
	4	1.8	48.6	nd	7.9	38.0	96.4
	7	3.1	49.4	nd	5.5	33.3	91.3
Nambsheim	0	90.3	-	-	3.3	0.8	94.3
	0.25	81.4	1.4	nd	8.0	3.1	93.9
	0.5	77.8	3.2	nd	12.2	6.2	99.4
	1	59.4	11.2	nd	12.6	22.4	105.6
	2	36.5	30.2	nd	11.7	21.8	100.0
	4	3.7	58.6	nd	8.1	22.3	92.6
	7	0.7	58.2	nd	6.5	24.2	89.5

[1] Sum of all unknown polar products (maximum individual peak represented 8.1 % AR)
nd = Not detected

There were five extractable degradation products. None of these were identified and none represented more than 10% at any time. The maximum proportion of any individual product was 8.1%.

For those soils in which a plateau was reached, unextractable residue represented 22-41% of the applied radiolabel after 2 to 7 days.

Table B.8.28: DT_{50} and DT_{90} values for methomyl oxime in aerobic soil at 20°C, 50% MWHC (linear regression, log normalised).

Soil Name	Texture (pH)	Incubation Temperature (°C)	DT_{50} (days)	DT_{90} (days)	r^2	Method of Calculation
Speyer 2.2	Sandy loam (6.4)	20	0.7	2	0.988	First order
Mattapex	Loam (5.1)	20	0.7	2	0.962	First order
Nambsheim	Sandy loam (7.8)	20	0.9	3	0.952	First order

Kinetic data were derived from zero-time to day 4 data (6 data points)

(Shaw 2001b)

B.8.1.2 Photolysis in soil

a) A study was carried out to US EPA guideline 161-3 (1982) to determine the photolytic degradation of methomyl in one soil. The study was conducted at between 18ºC – 24ºC instead of the 20ºC ± 3ºC.

The study used radiolabelled [1-^{14}C]Methomyl. Specific radioactivity was not specified, the radiochemical purity was >97%.

The photodegradation of Methomyl was studied under natural sunlight on non-sterile Keyport silt loam soil (Table B.8.29) from Newark, Delaware, USA. Soil thin layers (~1-mm thickness) were treated with Methomyl dissolved in N,N-dimethylformamide (2.80 mg in 2.40 ml) at a rate of 161 µg per test plate which is approximately equivalent to a field application rate of 1 lb a.s./acre (~1 kg a.s./ha). Thin layers were placed on stainless steel heat exchangers in Lucite containers with a quartz glass window in the upper side. The chambers containing non-irradiated samples were shielded from light by aluminium foil. The temperature of the soil thin layers was maintained at 24-28°C with a continuous flow of circulated, temperature-controlled water. Test vessels were continuously irradiated for up to 30 days with natural sunlight at a latitude of 39°40'N at DuPont's Experimental Station, Wilmington, Delaware from July 31 to August 30, 1986. Cumulative energy exposure at sampling intervals (measured by pyranometer) are shown in Table B.8.30. Day length was not stated. Provisions were made for trapping radiolabelled CO_2 with 1M NaOH and organic volatiles with 2-ethoxyethanol. The rate of degradation of methomyl in irradiated and non-irradiated samples was calculated by linear regression.

Soil thin layers were extracted three times with methanol and charcoal volatile traps were desorbed with N,N-dimethylformamide. Extracted soil and desorbed volatile radioactivity was determined by liquid scintillation counting (LSC). Extracted soil samples were combusted to determine levels of unextractable residues.

Soil extracts were analysed by HPLC and/or TLC. Volatiles desorbed from charcoal traps were analysed by GC. Degradation products were identified by co-chromatography using authentic analytical standards.

Table B.8.29 Physical and chemical characteristics of the test soil

Characteristic	Keyport Silt Loam
Origin Location	Newark, Delaware, USA
pH	6.8
% Sand (2000 - 50 µm)	5.0
% Silt (<50 - 2 µm)	67.0
% Clay (<2 µm)	28.0
Texture	Silt Loam
Organic carbon (%)[b]	0.8
Cation exchange capacity	6.25
Maximum water-holding capacity (%)	Not Specified
[a] USDA soil classification system [b] organic carbon = organic matter/1.72	

Recovery of radiolabel ranged from 95 to 110% (Table B.8.30).

Table B.8.30 Recovery and distribution of radiolabel in soil photolysis experiment, and cumulative irradiation levels at sampling points

Sample	Sampling Point (days)	Methomyl[a]	Acetonitrile (IN-07467)[b]	Unextractable Residue	Total	Cumulative irradiation (WH/m^2)
Irradiated	0	96	0	2	98	
	2	90.5	12	2.5	105	10293
	5	84	15	2	102	26135
	8	80	20	3	103	39757
	15	64	38	3	105	79457
	22	54	39	4	98	106038
	30	52.5	40	4	96.5	151954
Non-irradiated	0	96	0	2	98	
	8	103	2	3	109	
	15	100	3	2	105	
	22	99	4	4	107	
	30	98.5	4	4	106.5	

DT_{50} values for Methomyl on irradiated soil are summarised in Table B.8.31.

Table B.8.31 DT_{50} values for Methomyl on irradiated soil (39°N, July/August sunlight)

Sample	k (day^{-1})	half-life (day) (natural sunlight)	Method of Calculation (r^2)[a]
Irradiated	-0.0207	34	First-order (0.980)
Non-irradiated	-0.0001	Stable	First-order (0.003)
[a] Values calculated from data in report			

(Swanson, M.B. 1986)

B.8.1.3 Field studies

No data submitted. Based on the results of the laboratory degradation studies these data are not required.

B.8.1.4 Summary and assessment

The route of degradation of methomyl in soil under aerobic laboratory conditions has been adequately addressed. Data from radiolabelled studies carried out on four different soils at 20°C and one soil at 10°C resulted in the minor metabolite methomyl oxime (Z-methyl N-hydroxyethanimidothioate, INX1177) being identified at up to 2.5% AR. Methomyl and its extractable breakdown products were readily mineralised to carbon dioxide. At study termination, in 20°C experiments carbon dioxide represented 75%AR at 92 days, 51and 61%AR at 30 days and 51%AR at 21 days. In these experiments and at these times unextracted residues accounted for 14%AR, 32 and 25%AR and 31%AR respectively. It should be noted that in the 92 day experiment, unextracted residues had declined from a peak of 24%AR at days 21-30 indicating further mineralisation of unextracted residues might be expected had the 21 day and 30 day studies been of longer duration.

Under anaerobic conditions the route of degradation may also include the production of minor amounts of organic volatile components. In the soil the only minor metabolite identified (as for aerobic incubations) was methomyl oxime (INX1177) but it was formed at lower amounts than under aerobic conditions (it represented a maximum measured amount of only 0.7% AR). Trapped organic volatiles represented up to 3.9%AR and there was some loss of radioactivity from the system (total recoveries were 85-89%AR). In this study these organic volatiles were not characterised but other data (see section B.8.2.4 and B.8.4.4 a) and c)) indicate that under reducing conditions acetonitrile, methanethiol and dimethyl disulfide may be produced. The rate of degradation under anaerobic conditions was comparable to that under aerobic conditions (25ºC first order DT50 14 days under anaerobic conditions compared to 10.5 days under aerobic conditions for this Madera loam soil, see tables B.8.32 and B.8.33).

In a soil photolysis study under natural light conditions at 39°40’N at 18-24°C on a dry viable soil methomyl degraded more rapidly than in dark controls producing the major volatile metabolite acetonitrile (represented 40%AR after 30 days light exposure). As the rate of degradation (photolysis half life of 34 days in this study) was slower than occurs in wetter dark aerobic incubations (first order DT50, 4-22 days at 20°C and field capacity, see table B.8.32), under practical use conditions microbial degradation in soil is likely to predominate over photolytic degradation in soil.

Satisfactory data on the rate of degradation in the dark under aerobic laboratory conditions are available when methomyl was used as test substance on 4 different soils and when methomyl oxime (INX1177) was used as test substance on three of these soils. Data for methomyl when thiodicarb was applied as test substance are available on a further 4 different soils. The resulting first order DT50 calculated from these studies are summarised in Table B.8.32.

The first order DT50 resulting from anaerobic degradation of methomyl in one soil is provided in Table B.8.33.

Table B.8.32 First order DT_{50} & DT_{90} for methomyl and methomyl oxime in aerobic soils under laboratory conditions at 20ºC (unless stated) and first order DT_{50} normalised to reference conditions (20ºC & -10kPa)

Substance	**Soil**	**Moisture content %**	**DT_{50} days**	**DT_{90} days**	**r^2**	***Normalised 1st order DT_{50} days***
Methomyl (25ºC)	Madera (loam, pH 7.8)	75% FMC (37.6%) 0.33 bar	10.5	35	0.99	15.20
Methomyl	Speyer 2.2 (sandy loam, pH 6.4)	50% MWHC (45.9%)	4	14	1.00	4.00
Methomyl	Mattapex (loam, pH 5.1)	50% MWHC (35.2%)	8	26	0.99	6.26
Methomyl	Nambsheim (sandy loam, pH 7.8)	50% MWHC (32.3%)	6	21	0.99	5.35
@Methomyl	Flint Hall (clay loam, pH 7.6)	31.21	4.6	15.4	0.99	4.60
@Methomyl	Wilsons Farm (sandy loam, pH 6.0)	8.28	4.9	16.2	0.97	4.90
@Methomyl	Boarded Barns (clay loam, pH 6.9)	11.57	9.9	33.0	0.98	8.60
@Methomyl (25ºC)	Sandy loam (sandy loam, pH 5.4) (Feung & Weisbach)	75% FMC (9.24%) 0.33 bar	31	100	0.99	22.20
Methomyl geometric mean 1st order DT50 days						7.38
Methomyl oxime	Speyer 2.2 (sandy loam, pH 6.4)	50% MWHC (45.9%)	0.7	3	0.92	0.70
Methomyl oxime	Mattapex (loam, pH 5.1)	50% MWHC (35.2%)	0.7	4	0.81	0.55
Methomyl oxime	Nambsheim (sandy loam, pH 7.8)	50% MWHC (32.3%)	0.9	3	0.98	0.80
Methomyl oxime geometric mean 1st order DT50 days						0.67

*Normalised to -10kPa and 20ºC for groundwater modelling following 'Generic guidance for FOCUS groundwater scenarios (version 1.1 April 2002)' (version control update to SANCO/321/2000 rev.2).
@Test substance applied was thiodicarb

Table B.8.33 First order $DT_{50,}$ and DT_{90} values for methomyl in anaerobic soil at 25ºC under laboratory conditions in the Madera loam.

Substance	**Compartment**	**DT_{50}**	**DT_{90}**	**r^2**
Methomyl	Total System	14 days	48 days	0.98

The longest DT90 in soil for the total extractable residue where methomyl was applied as test substance that is of pertinence to the assessment of residues in following edible crops (see Section 7.1.4) is 43 days (calculated for the Madera loam soil, r^2=0.997). Therefore less than 10% of the methomyl applied and its extractable degradation products remains in soil 100 days after application so the requirement for data to address the potential for residues in following crops is not triggered.

B.8.2 Adsorption, desorption and mobility in soil (IIA 7.1.2, 7.1.3, IIIA 9.1.2)

B.8.2.1 Adsorption and desorption

a) A batch equilibrium adsorption/desorption study was conducted parent methomyl in five soils, in accordance with SETAC (1995) guidelines and OECD Guideline No 106, Adsorption/Desorption studies in soil (1981).

The study used radiolabelled [1-^{14}C]Methomyl with a specific radioactivity of 42.96 µCi/mg and radiochemical purity of >95%.

The adsorption/desorption characteristics of Methomyl on five soils was investigated (Table B.8.34). Initial solution concentrations of 5, 1.0, 0.25, 0.10, and 0.05mg/L were prepared in 0.01M aqueous calcium chloride. Testing was conducted in duplicate (triplicate at the highest concentration) with a solution/soil ratio of 1/1 (20 mL/20 g dry weight of soil). The soil/solution mixtures were equilibrated for 24 hours (8 hours for methomyl on Speyer) at 20-22°C under non-sterile conditions in the dark. Two 24-hour desorption cycles were conducted on the 5-mg/L samples (except for methomyl on Speyer) after the adsorption cycle by removing the supernatant after centrifugation and adding an equivalent volume of fresh 0.01M calcium chloride solution. Sorption data were analysed using the Freundlich isotherm equation expressed in its log form: $\log x/m = 1/n \cdot \log C_e + \log K_f$. Linear distribution coefficients (K_d) were calculated from the mean ratios of x/m to C_e.

The supernatants and soil extracts were analysed by TLC and LSC.

Table B.8.34 Characteristics of Test Soils used in adsorption/desorption studies

Characteristic	Soil				
Soil Name or Designation	Speyer 2.2	Mattapex (Rock Hall)	Drummer (Rochelle)	Nambsheim	Flakkebjerg
Origin Location	Germany	USA	USA	France	Denmark
pH (in water)	6.2	5.1	6.0	8.1	6.6
% Sand (2000 - 50 µm)	70.4	44.4	14.4	52.4	44.4
% Silt (<50 - 2 µm)	24.4	42.8	48.8	36.8	38.4
% Clay (<2 µm)	5.2	12.8	36.8	10.8	17.2
Texture[a]	Sandy Loam	Loam	Silty clay loam	Sandy loam	Loam
(%) Organic carbon [b]	2.09	0.99	2.27	1.05	1.10
Cation exchange capacity (meq/100g) units	9.66	4.41	29.5	5.61	9.97
Maximum water-holding capacity (%)	Not reported	Not reported	Not reported	Not reported	Not reported

[a] USDA soil classification system
[b] organic carbon = organic matter/1.72

Time to equilibration of methomyl between soil and solution was judged to be ~24 hours. Speyer soil was equilibrated for 8 hours as pilot studies indicated methomyl was not stable in this soil for 24 hours.

Total recoveries of radioactivity after adsorption equilibration ranged from 91 to 108% for methomyl.

The Freundlich isotherm regressions correlated well with the soil adsorption data although correlation coefficients were not included in the report. Analysis based on the data presented in the report resulted in r^2 values > 0.98 for methomyl sorption.

Results are shown in Table B.8.35. Mean K_{foc} values ranged from 13.3 to 42.8. These sorption values reflect weak adsorption of methomyl. Methomyl that adsorbed was also poorly desorbed: Only 1-30% of adsorbed radioactivity was desorbed. Apparent desorption constants (K_{des}) after the second desorption ranged from 2.3 to 16.9 ml/g.

Table B.8.35 Adsorption of [1-^{14}C]Methomyl on a Range of Soils

Soil, Origin	Soil Type	pH	% Organic Carbon	K_f (ml/g)	K_{foc} (ml/g)	1/n	r^2
Speyer,Germany	Sandy loam	6.2	2.09	0.277	13.3	0.86	0.982
Rock Hall, MD USA	Loam	5.1	0.99	0.201	20.3	0.88	0.987
Rochelle, IL USA	Silty clay loam	6.0	2.27	0.809	35.6	0.82	0.991
Nambsheim, France	Sandy loam	8.1	1.05	0.145	13.8	0.83	0.981
Flakkebjerg, Denmark	Loam	6.6	1.10	0.471	42.8	0.89	0.993
			Average	*0.381*	*25.2*	*0.86*	

(Aikens, P.J. 2001a)

b) A further batch equilibrium adsorption/desorption study was conducted for the metabolite of methomyl, methomyl oxime (Z-methyl N-hydroxyethanimidothioate, INX1177) in five soils, in accordance with SETAC (1995) guidelines and OECD Guideline No 106, Adsorption/Desorption studies in soil (2000).

The study used [1-^{14}C] methomyl oxime with a specific radioactivity of 66.2 µCi/mg (radiochemical purity >95%).

The soil characteristics and study methodology were as outlined at B.8.2.1 a). Methomyl oxime was judged to have an equilibration time of 24 hours and no significant degradation was seen over this time period.

Total recoveries of radioactivity for methomyl oxime (INX1177) after adsorption equilibration ranged from 84 to 100%. The low recovery from one soil was due to the loss of a portion of the Drummer sample during processing. Adsorption constants are summarised in Table B.8.36.

Table B.8.36 Adsorption of [1-^{14}C] methomyl oxime on a range of soils

Analyte	Soil, Origin	Soil Type[a]	pH	% Organic Carbon[b]	Kf (ml/g)	Kfoc (ml/g)	1/n	r^{2c}
Methomyl oxime	Speyer, Germany	Sandy loam	6.2	2.09	0.186	8.9	0.73	0.992
	Rock Hall MD USA	Loam	5.1	0.99	0.090	9.1	0.95	0.976
	Rochelle, IL USA	Silty clay loam	6.0	2.27	0.454	20.0	0.84	0.996
	Nambsheim, France	Sandy loam	8.1	1.05	0.070	6.6	0.71	0.964
	Flakkebjerg, Denmark	Loam	6.6	1.10	0.139	12.6	0.68	0.941
				Average	*0.188*	*11.4*	*0.78*	

[a] USDA soil classification system [b] organic carbon = organic matter/1.72 [c] R^2 values calculated from data presented in original reports

(Aikens, P.J., 2001b)

B.8.2.2 Column leaching

a) A column leaching study using [1-^{14}C] methomyl (radiochemical purity >98.0%) was carried out to BBA guidelines part IV, 4-2. The only deviation from SETAC were that three soils were used instead of the four specified. A clay textured soil was not investigated.

Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 46.0 µCi/mg was used (radiochemical purity >98%). A soil column leaching study was performed with Speyer 2.1 sand, Speyer 2.2 loamy sand, and Speyer 2.3 sandy loam (Table B.8.37). Test solutions of 50 µg/ml methomyl were prepared in a formulation containing inert ingredients to simulate a water soluble powder formulation. Treatment solution (2 ml) was applied to the top of duplicate HPLC grade water-saturated columns previously filled to a depth of approximate 30 cm with packed with soil. The application rate is equivalent to a field application rate of approximately 500 g as/ha.

Columns were eluted with the equivalent of 200 mm HPLC grade water (390-397 ml) over 2 days. The leachate was collected then analysed by LSC and chromatography versus authentic standards. After elution, the columns were separated into three 10-cm segments and each segment was extracted with methanol/water (2:1 v/v) and analysed chromatographically and by LSC. The extracted soil segments were combusted to determine the amount of unextracted radioactivity.

Table B.8.37 Characteristics of soils used in column leaching experiments

Characteristic	Soil		
Soil Name or Designation	Speyer 2.1	Speyer 2.2	Speyer 2.3
Origin Location	Germany	Germany	Germany
pH	5.9	5.6	6.4
% Sand (2000 – 53 μm)	90.93	82.07	64.72
% Silt (53 - 2 μm)	5.88	11.07	24.7
% Clay (<2 μm)	3.19	6.86	10.58
Texture[a]	Sand	Loamy sand	Sandy loam
Organic carbon (%)[b]	0.62	2.32	1.22
Cation exchange capacity	5.0	10.9	10.2
Maximum water holding capacity (%)	n.d.	n.d.	n.d.
Microbial biomass (mg microbial C/kg soil)	n.d.	n.d.	n.d.
Bacteria (cfu/g)	4.60×10^6	1.02×10^6	7.20×10^6
Bacterial spores (cfu/g)	2.75×10^6	3.75×10^5	6.80×10^6
Actinomycetes (cfu/g)	1.38×10^5	6.15×10^5	8.25×10^5
Fungi (cfu/g)	9.00×10^2	1.10×10^3	9.00×10^3

[a] USDA soil classification system
[b] Organic matter = 1.73 × % organic carbon
n.d. = not determined

The overall recovery was approximately 98-106% applied radiolabel for duplicate Speyer 2.1 and Speyer 2.3 soil columns (Table B.8.38). Recovery from four replicate Speyer 2.2 soil columns was 69-84% of the applied radiolabel.

Radiolabel was found in all column segments and in the leachate

The major component in the soil extracts and leachate was identified as methomyl. In soil 33.8, 44.7, and 71.9 & of the applied radioactivity was present a methomyl after elution in Speyer 2.1, Speyer 2.2, and Speyer 2.3 soils, respectively (Tables B.8.39, B.8.40, B.8.41). Only minor amounts (<4%) of other compounds were detected. Methomyl oxime (INX1177) was observed at a maximum amount of

2.2% of the applied radioactivity. The low recovery of radiolabel from Speyer 2.2 during leaching suggests rapid metabolism of methomyl to volatile components.

The radiolabel recovered in the leachate was lower for the Speyer 2.2 loamy sand columns and Speyer 2.3 sandy loam columns, accounting for 2-14% and 8-9% of the applied radiolabel, respectively. The leachate of the Speyer 2.1 sandy soil columns contained 49-57% of the applied radiolabel (Table B.8.38).

Methomyl observed in the leachate was lower for the Speyer 2.2 loamy sand columns and Speyer 2.3 sandy loam columns, accounting for 7-11.8% and 5.4-6.6% of the applied radiolabel, respectively (Table B.8.42). The leachate of the Speyer 2.1 sandy soil columns contained 46.2-54.7% of the applied radiolabel identified as methomyl (Table B.8.42). Methomyl oxime (INX1177) was less than 1.7% of the applied radioactivity in all leachates.

Table B.8.38 Recovery and distribution of radiolabel in column leaching experiment. Results expressed as % applied radioactivity

Soil Segment:	Speyer 2.1 Sand	Speyer 2.2 Loamy Sand	Speyer 2.3 Sandy loam
0-10 cm			
Extracted	3-7	6-13	9-10
Unextracted	1-2	3-4	3-4
10-20 cm			
Extracted	7-16	11-16	19-25
Unextracted	2	5-7	4-5
20-30 cm			
Extracted	26-28	22-32	43-48
Unextracted	1-2	8-13	8
Leachate	49-57	2-14	8-9
Total ^{14}C recovered	98-106	69-84	99-101

Results from duplicate Speyer 2.1 and 2.3 columns and 4 replicate Speyer 2.2 columns

Table B.8.39 Proportions of radioactive components characterised in column soil segments in Speyer 2.1 Sand. Results expressed as % applied radioactivity

Component	0-10 cm	10-20 cm	20-30 cm	0-30 cm
1	<0.2	<0.1	0.3	0.3
2	<0.2	<0.1	<0.2	<0.5
3	<0.2	<0.1	<0.2	<0.5
Methomyl oxime	<0.2	<0.1	0.4	0.4
Methomyl	2.8	6.4	24.6	33.8
Others	0.2	0.9	1.0	2.1

Others: Radioactivity distributed on chromatograms containing no discrete components

Table B.8.40 Proportions of radioactive components characterised in column soil segments in Speyer 2.2 loamy sand. Results expressed as % applied radioactivity

Component	0-10 cm	10-20 cm	20-30 cm	0-30 cm
1	0.3	0.9	1.6	2.8
2	<0.1	<0.2	<0.2	<0.5
3	<0.1	<0.2	0.7	0.7
Methomyl oxime	0.2	0.3	0.9	1.4
Methomyl	11.5	11.9	21.3	44.7
Others	0.9	1.0	2.1	4.0

Others: Radioactivity distributed on chromatograms containing no discrete components

Table B.8.41 Proportions of radioactive components in column soil segments in Speyer 2.3 sandy loam. Results expressed as % applied radioactivity

Component	0-10 cm	10-20 cm	20-30 cm	0-30 cm
1	<0.2	0.2	<0.2	0.2
2	<0.2	<0.1	<0.2	<0.5
3	<0.2	0.1	<0.2	0.1
Methomyl oxime	0.2	0.6	1.4	2.2
Methomyl	8.1	23.0	40.8	71.9
Others	0.7	0.7	1.0	2.4

Others: Radioactivity distributed on chromatograms containing no discrete components

Table B.8.42 Proportions of radioactive components in column leachate. Results expressed as % applied radioactivity

	Speyer 2.1 Sand		Speyer 2.2 Loamy Sand			Speyer 2.3 Sandy loam	
Component	A	B	A	B	C	A	B
1	<0.1	<0.06	<0.1	<0.2	<0.06	<0.05	<0.06
2	<0.1	<0.06	<0.1	<0.2	<0.06	<0.05	<0.06
3	0.5	0.7	0.7	0.4	0.2	0.2	0.1
Methomyl oxime	1.1	1.2	0.9	0.9	0.8	1.7	1.6
Methomyl	46.2	54.7	10.0	11.8	7.0	5.4	6.6
Others	0.9	0.7	0.8	0.7	0.3	0.3	0.2

b) An aged column leaching study using [1-^{14}C] methomyl (radiochemical purity >98.0%) was carried out to BBA guidelines part IV, 4-2 on a single sand soil.

Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 46.0 µCi/mg was used.

The soil was Speyer 2.1 sandy soil (For properties see Table B.8.37 above). Test solutions of 50 µg/ml methomyl were prepared in a formulation containing inert ingredients. Eight 100-g dry weight samples of Speyer 2.1 soil were each treated with 100 µg methomyl and incubated in flasks under aerobic conditions at 40% of maximum water-holding capacity at 20°C in darkness. Traps were used to collect volatiles. Samples were analysed 0, 1, 3, 8, 10, and 14 days after application to determine DT_{50}. Two soil samples aged for 13 days were transferred to the top of duplicate HPLC grade water-saturated columns previously filled to a depth of approximate 30 cm with packed with German 2.1 standard sandy soil. Columns were eluted with the equivalent of 200-mm HPLC grade water (393 ml) over 2 days. The leachate was collected and analysed as one fraction.

After elution, the columns were separated into three 10-cm segments and each segment was extracted with methanol/water (2:1 v/v) and analysed both chromatographically and by LSC. The extracted soil segments were combusted to determine the amount of unextracted radioactivity.

The overall recovery was approximately 94% prior to leaching and 85-90% after column leaching (see Table B.8.43). The difference is probably due to further mineralisation during the two-days of the leaching experiment.

After 13 days of ageing, about 20-24% of the applied radioactivity was trapped as volatiles. After column leaching, the largest proportion of the radioactivity was retained on the soil columns (58-59%). The largest proportion of the applied radioactivity was found in the top 0-10-cm soil column segment (30-34%) with much of that radioactivity unextractable (B.8.43).

In soil aged for 13 days and eluted during a period of 2 days methomyl represented the largest portion of the observed radioactivity (25% of the applied radioactivity). radiolabelled CO_2 was the major degradation product observed (22% of the applied radioactivity). In soil minor degradation products were observed not accounting for more than 2.5% of the applied radioactivity. Methomyl oxime (INX1177) was observed below 1% of the applied radioactivity in soil and leachate.

Less than 7% of the applied radioactivity was found in the leachate. The major radioactive component in the leachate was methomyl, accounting for 4.7-5.3% of the applied radioactivity.

Table B.8.43 Recovery and distribution of radiolabel in aged column leaching experiment

	Results expressed as % applied radioactivity		
Soil Segment:	**0-10 cm**	**10-20 cm**	**20-30 cm**
Total Soil Residues	30.1-34.2	9.9-9.4	17.1-15.6
Component 1	1.3	0.3	0.9
Component 2	<0.3	<0.08	<0.2
Component 3	<0.3	<0.08	<0.2
Methomyl	6.8	6.6	11.9
Methomyl oxime	<0.3	0.2	0.7
Others	1.4	0.5	0.6
Unextractables	21.3	2.24	3.01
Volatile Traps	20.1-23.7		
Leachate	6.70-6.71		
Total ^{14}C recovered	85-90		

Others: Radioactivity distributed on chromatograms containing no discrete components

Table B.8.44 Proportions of radioactive components in column soil segments in Speyer 2.1 sand after ageing and elution. Results expressed as % applied radioactivity

Component	0-10 cm	10-20 cm	20-30 cm	0-30 cm
1	1.3	0.3	0.9	2.5
2	<0.3	<0.08	<0.2	<0.6
3	<0.3	<0.08	<0.2	<0.6
Methomyl oxime	<0.3	0.2	0.7	0.9
Methomyl	6.8	6.6	11.9	25.3
Others	1.4	0.5	0.6	2.5

Others: Radioactivity distributed on chromatograms containing no discrete components

Table B.8.45 Proportions of radioactive components in column leachate. Results expressed as % applied radioactivity

	Speyer 2.1 Sand	
Component	C	D
1	0.3	<0.07
2	<0.06	<0.07
3	0.4	0.2
Methomyl oxime	0.9	0.8
Methomyl	4.7	5.3
Others	0.5	0.4

Others: Radioactivity distributed on chromatograms containing no discrete components

(Langford-Pollard, A.D. 1994)

B.8.2.3 Modelling of leaching (IIIA 9.2.1)

See section B.8.6.3-Calculation of PEC_{gw}

B.8.2.4 Degradation in the saturated zone (IIA 7.2.1.4)

a) In a published study carried out by research workers in the Netherlands degradation in subsoils from the saturated zone was investigated in the laboratory under anaerobic conditions. The study was not carried out to GLP, however it was completed before 1993, was relatively well reported and can be considered as supporting information. The substances aldicarb sulphoxide, aldoxycarb, oxamyl and methomyl were investigated. Only the results for methomyl are summarised below.

The rate of methomyl degradation under anaerobic laboratory conditions was studied in four subsoils from below the water table (Table B.8.46) taken from agricultural locations in the Netherlands.

Table B.8.46: Physical and chemical characteristics of the test soils

Characteristic	Soil			
Origin Location	Lisse	Breezand	Wieringerwerf	Emmercompascuum
Depth (m)	1.2-1.6	1.1-1.5	1.3-1.7	1.3-1.7
pH (KCl)	7.6	7.5	7.8	4.5
% Silt (50 - 2 µm)	0.8	11.9	11.4	6.4
% Clay (<2 µm)	1.3	8.0	4.0	2.4
Texture	Sand	Loamy fine sand	Loamy fine sand	Fine sand
Organic matter (%)	0.5	2.3	1.0	0.1
$CaCO_3$ (%)	0.4	5.7	8.7	-

These soil samples taken from below the water table (0.75 – 1 m) were stored under a layer of groundwater. Soil samples were gently mixed, then 100 g water-saturated soil samples were transferred to glass jars. The soils were flooded with 25-mL ground water and the jars were purged with nitrogen before being sealed. After a pre-incubation period of 7-11 day at 10°C, nitrogen-purged aqueous solutions of analytical grade methomyl (4 ml of 50 µg/ml) were added to the soil samples. Treated soil samples were incubated in the dark at 10±1°C.

At each sampling point, the flooded soil samples were extracted with distilled water and analysed by HPLC with UV detection. Recoveries of methomyl from 4 hr 2°C aerobic soils ranged from 76 to 90%. The half lives calculated by the study authors in each subsoil are summarised in Table B.8.47. Note only the half lives were reported. The rapporteur was unable to independently assess the validity of these half lives as neither the results at individual time points nor the frequency of sampling were reported.

Table B.8.47: Laboratory DT_{50} values for methomyl in subsoil samples from the saturated zone incubated under anaerobic conditions at 10°C

Location	Sampling Depth	Experimental Conditions	DT_{50} (days) methomyl	Method of Calculation
Lisse	1.2-1.6	Anaerobic	<0.2	First-order log normalised linear regression
Breezand	1.1-1.5	Anaerobic	<0.2	First-order log normalised linear regression
Wieringerwerf	1.3-1.7	Anaerobic	<0.2	First-order log normalised linear regression
Emmercompascuum	1.3-1.7	Anaerobic	0.3	First-order log normalised linear regression

(Smelt, J. *et al.*, 1983)

b.) In a published study carried out by research workers in the UK and the Netherlands degradation in subsoils from the saturated zone was investigated in the laboratory under anaerobic conditions. The study was not carried out to GLP, however it was completed before 1993, was relatively well reported and can be considered as supporting information. The substances aldicarb (and its oxidation products), oxamyl and methomyl were investigated. Only the results for methomyl are summarised below.

The rate of methomyl degradation was studied under laboratory conditions in suspensions of two anaerobic subsoils (Table B.8.48) taken from agricultural locations in the Netherlands and in aqueous solutions in the absence and presence of Fe^{2+}.

Soil samples, taken from below the water table, were stored under a layer of groundwater at 10°C. Wet subsoil was added (80-200-g dry soil equivalents) to flasks previously purged with nitrogen and partially filled with groundwater. The soil/water mixtures were purged with nitrogen before the flasks were sealed. Nitrogen-purged aqueous solutions of analytical grade methomyl (5 mg in 5 ml) were added by syringe to the soil suspensions, resulting in a final concentration in the soil water of 40-50 µg/ml. Treated soil suspensions were incubated at 19-24°C. At sampling, aliquots of the water were removed, acidified with glacial acetic acid (2.5 µL/ml water) and analysed by HPLC with UV detection. In addition, water samples were extracted with organic solvents while headspace was analysed directly by GC with flame-photometric detection.

Aqueous solutions of methomyl (20 µg/ml) were prepared in 0.05 M piperazine-N,N'-bis-2-ethanesulphonic acid buffer and incubated at 30±1°C in the absence or presence of 250 µg/ml Fe^{2+} as $FeSO_4$. Solutions were deoxygenated under nitrogen before addition of the metal ion as the solid salt. Solutions were incubated in sealed glass tubes under nitrogen. Immediately after opening the tubes, aqueous and headspace samples were analysed by direct GC and HPLC injections, respectively.

Table B.8.48: Characteristics of test subsoils and soil water samples

	Location			
Characteristic	**Westmaas**		**Emmercompascuum**	
	Soil	Soil Water	Soil	Soil Water
pH	7.7	6.7	4.6	5.7
% Silt (50 - 2 µm)	301		47	
% Clay (<2 µm)	43		32	
Organic matter (%)	22		1.0	
Total iron (g/kg)	13		2.6	
Redox potential (mV)	-60 to 60		50 to 130	
Fe^{2+} (µg/ml)		41		27
Fe^{3+} (µg/ml)		4.7		0.3

The DT_{50} values for methomyl incubated under anaerobic conditions at 20-24°C ranged from <0.2 to 1 hour (Table B.8.49). Two degradants, methanethiol and dimethyl disulfide, were detected in the headspace and in the soil water.

The DT_{50} values for methomyl maintained in aqueous buffer solutions at 30°C in the presence and absence of ferrous ions were 4.1 hours and >2000 hours, respectively (Table B.8.50). Methanethiol was identified as a volatile degradation product. Note only the half lives calculated were reported. The rapporteur could not independently assess the validity of these half lives as neither the results at individual time points or the frequency of sampling were reported.

Table B.8.49: DT_{50} values for methomyl in anaerobic subsoil samples

Location	DT_{50} (hours) methomyl	Method of Calculation
Emmercompascuum	1.0	First-order
Westmaas	<0.2	First-order

Table B.8.50: DT_{50} values for methomyl in solutions with and without Fe^{2+}

0.05 M PIPES Buffer	DT_{50} (hours) methomyl	Method of Calculation
Fe^{2+} (absent)	>2000	First-order
Fe^{2+} (250 µg/ml)	4.1	First-order

Methomyl degrades rapidly in anaerobic subsoils and in the presence of ferrous ions with half-lives of below 0.2 hours to 4 hours. The degradation rate in anaerobic soils was faster than in an aqueous solution with a higher concentration of ferrous ions.

(Bromilow, R. *et al.*, 1986)

B.8.2.5 Summary and assessment

In guideline laboratory batch adsorption studies methomyl weakly adsorbed to all five soils tested. The mean K_{foc} value was 25.2 ml/g (from a range of 13.3 – 42.8 ml/g). Methomyl demonstrated a non-linear sorption behaviour over the tested range of concentrations (5 to 0.05 ppm). The mean 1/n value was 0.86 (from a range of 0.82 – 0.89).

Again in guideline laboratory batch adsorption studies the minor soil degradation product methomyl oxime (Z-methyl N-hydroxyethanimidothioate, INX1177) was weakly adsorbed to all five soils tested. The mean K_{foc} value was 11.4 ml/g (from a range 6.6 – 20.0 ml/g). Methomyl oxime demonstrated a non-linear sorption behaviour over the tested range of concentrations (5 to 0.05 ppm). The mean 1/n value was 0.78 (from a range of 0.68 – 0.95).

In a laboratory column leaching study carried out using 3 soils, methomyl in leachate represented 46-55%AR in the Speyer 2.1 sand soil. This proportion was lower in the Speyer 2.2 loamy sand and 2.3 sandy loam at up to 11.8 and 6.6% AR respectively. Methomyl oxime was observed up to 2.2% of the applied radioactivity in soil and up to 1.7%AR in leachate. One-13% of the applied radioactivity was unextractable from the soil after leaching.

An aged residue laboratory column leaching study on a single soil was also evaluated for methomyl. Methomyl oxime (INX1177) was observed below 1% of the applied radioactivity in soil and leachate. About 58% of the applied radioactivity was unextractable from the soil. The major radioactive component in the leachate (5% AR) co-chromatographed with methomyl.

All these data indicate that methomyl and its minor soil metabolite methomyl oxime (INX1177) have the potential to be mobile in soil. There is no evidence to suggest that soil pH affects adsorption potential, although adsorption is low. However the aged column leaching study provides evidence that due to the relatively rapid degradation of both compounds that occurs in soil, the potential for leaching to deeper soil layers may not be realised under practical intended use conditions.

This is confirmed by the results of first tier FOCUS groundwater modelling for the 7 FOCUS scenarios where grapes and 5 scenarios where tomatoes are defined as a pertinent crop (see section B.8.6).

FOCUS PRZM2.2.1 predicted 80^{th} % annual average concentrations (as defined by FOCUS) <0.001µg/l for methomyl oxime (INX1177) (both crops) and methomyl on tomatoes at all the pertinent scenarios. On grape vines this value was calculated to be up to 0.003µg/l (Hamburg scenario).

FOCUS PEARL 1.1.1 predicted 80^{th} % annual average concentrations passed 1m depth (as defined by FOCUS) of up to 0.002µg/l on tomatoes and 0.005µg/l on vines for methomyl oxime (INX1177) at all the pertinent scenarios. For parent methomyl on tomatoes this value was predicted to be up to 0.04µg/l (Piacenza) at all the pertinent scenarios. Again for parent methomyl but on grape vines this value was calculated to be up to 0.084µg/l (Piacenza) at all the pertinent scenarios.

In conclusion, from the intended representative uses, based on the results from first tier FOCUS groundwater modelling, contamination of vulnerable shallow groundwater above 0.1µg/l would not be expected for parent methomyl or its minor soil degradation product methomyl oxime (INX1177).

However even in more vulnerable situations than represented by the FOCUS scenarios, groundwater contamination by parent methomyl would be unlikely in practice because data on degradation in the saturated zone indicate that any methomyl that was to leach to the saturated zone would be degraded relatively rapidly under the reducing conditions that are likely to be present (Half lives in 4 anaerobic subsoils incubated in the laboratory at 10°C were ≤8 hours).

B.8.3 Predicted environmental concentrations in soil (PECs) (IIIA 9.1)

The PECsoil provided by the notifier was not used as they chose a mean DT50 value from the laboratory studies available to them. The use of the longest value is more appropriate. PEC calculated on this basis are presented below.

PECsoil values were calculated from 2 applications at 450g/ha assuming first-order degradation of the parent compound in soil as recommended by FOCUS (FOCUS, 1996. Soil Persistence models and EU registration. The longest DT50 appropriate for use in calculating PEC soil was 22 days at 20°C and pF2 (calculated from a DT_{50} at 25 °C and 75% FMC). The application interval assumed was 14 days. The initial and time-weighted-average concentrations for methomyl were estimated in the top 5-cm layer of the soil with a soil bulk density of 1.5g/cm^3 after the second application assuming 60% crop interception in grape vines as applications are unlikely to be made before leaf development (BBCH 50) using the crop interception tables in the FOCUS groundwater scenarios (SANCO/321/2000rev2 version control 1.1) report (see Table B.8.51).

Table B.8.51: Calculated PEC_{soil} values

Days after last appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.394	0.394
1	0.382	0.388
2	0.370	0.382
4	0.348	0.371
7	0.316	0.354
14	0.254	0.319
28	0.163	0.262
50	0.082	0.199
100	0.017	0.120

When applications are made to vines at later growth stages higher crop interception will occur. For example if applications are made after flowering FOCUS guidance (SANCO/321/2000 rev 2 version control 1.1) indicates 70% crop interception would occur. In this situation the maximum PEC soil is 0.296 mg/kg.

For the 350 g/ha rate to grape and 60% crop interception, the maximum soil PEC is lower, at 0.187 mg/kg

When applications are made to vegetable crops with the 2x450g/ha application rate assuming 50% crop interception the maximum initial PEC soil is 0.493mg/kg.

B.8.4 Fate and behaviour in water (IIA 7.2.1, IIIA 9.2.1, 9.2.3)

B.8.4.1 Aqueous hydrolysis

a) The hydrolytic stability of methomyl was studied according to U.S. EPA guidelines (560/6-82-003). The study was not GLP compliant but was completed before 1993, was acceptably reported and is therefore considered acceptable.

Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 16.0 µCi/mg was used (radiochemical purity >98%).

The hydrolytic stability of radiolabelled methomyl was studied in aqueous solutions buffered at pH values of 5, 7, and 9. Test solutions at nominal concentrations of 10 µg/ml and 100 µg/ml were prepared and incubated for up to 30 days at 25°C under sterile conditions in the dark. Samples were analysed by LSC and reversed phase HPLC with authentic standards.

During the test period 2% of the radiolabel volatilised. The major pH 9 degradation product was methomyl oxime (INX1177), accounting for up to 44% of the radiolabel (Table B.8.52). At pH 5 and 7, methomyl was stable for 30 days (93% of radiolabel as methomyl). At pH 9, methomyl hydrolysed with a DT_{50} of 37 and 35.6 days in the 100 and 10 µg/ml replicate, respectively (Table B.8.53).

Table B.8.52: Hydrolytic degradation of [1-^{14}C]methomyl in sterile buffer at pH 9

Days	% of applied ^{14}C as:			
	10 µg/ml		100 µg/ml	
	Methomyl	Methomyl oxime	Methomyl	Methomyl oxime
0	90	2	94	2
0.17	89	1	94	2
1	90	3	92	3
2	87	6	90	5
3	86	8	89	6
6	80	11	84	11
9	80	16	79	17
14	67	27	71	24
21	60	34	64	32
30	50	44	54	41

Table B.8.53: Hydrolytic half-lives and rate constants for methomyl

Analyte	pH	DT_{50} (day)	Method of Calculation
Methomyl	5 7 9	Stable Stable 37 / 35.6 *average 36*	-- -- Graphical

(Friedman, P., 1983)

b) The hydrolytic stability of methomyl was studied according to SETAC 1995 guidelines. (This study is also summarised in section B.7.8.1).

The hydrolysis of radiolabelled methomyl, [1-^{14}C]methomyl with a specific radioactivity of 42.96 µCi/mg (radiochemical purity 100% based on HPLC with radiochemical detection) was studied at a nominal concentration of 10 µg/ml in buffered solutions of pH 4, 5, and 6 to simulate representative processing conditions: pasteurisation at 90°C (pH 4) for 20 minutes; baking, brewing, boiling at 100°C (pH 5) for 60 minutes; and sterilisation at 120°C (pH 6) for 20 minutes, in order to determine the nature of residues in processed commodities under these conditions.

The solutions used in these experiments were 0.01M acetate (pH 4), 0.01M acetate (pH 5), and 0.01M phosphate (pH 6) buffers. Sterile conditions were not employed due to the short-term nature of the study (20 – 60 minutes). The total amount of methanol co-solvent present in each test systems was approximately 0.2%. Each condition was studied in an individual test system consisting of the treated buffer solutions contained in a sealed glass ampoule and excluded from light with aluminium foil. After heating, samples were allowed to cool in a freezer before subsamples were taken for analysis for total radioactivity, for the parent (methomyl), and for major hydrolysis products.

Reversed phase HPLC with UV or radiochemical detection was used for analysis. Degradation products were identified by co-chromatography with analytical reference standards. The detection limit for this method was 46 ng, less than 5.7% of the initial mass injected.

Recovery of total radioactivity expressed as a percent of applied [1-^{14}C]methomyl ranged from 97 to 101% for all test systems. These recoveries indicate that neither adsorption of test substance to test containers nor formation of volatiles were significant processes during this study (Table B.8.54).

Table B.8.54: Mean overall recovery of total ^{14}C, percent recovery of [1-^{14}C]methomyl and methomyl oxime under simulated processing conditions

Hydrolysis Solution Type	**Pasteurisation pH 4, 90°C**		**Baking, brewing, boiling pH 5, 100°C**		**Sterilisation pH 6, 120°C**	
	% of Time-zero AR[a]		**% of Time-zero AR**[a]		**% of Time-zero AR**[a]	
	%Methomyl (mean±S.D.)	**%methomyl oxime** (mean±S.D.)	**%Methomyl** (mean±S.D.)	**%methomyl oxime** (mean±S.D.)	**%Methomyl** (mean±S.D.)	**%methomyl oxime** (mean±S.D.)
Control (room temperature)	99.0		98.3		97.1	
	100.0 ± 0	0.0 ± 0	100.0 ± 0	0.0 ± 0	100.0 ± 0	0.0 ± 0
Treated	99.1		98.5		100.9	
	93.7 ± 0.8	4.3 ± 0.5	86.5 ± 2.5	13.5 ± 2.5	58.2 ± 0.5	39.5 ± 1.4

[a] AR = [1-^{14}C]methomyl applied radioactivity

The only degradation product detected under these conditions greater than 10% of the applied radioactivity was the hydrolysis product methomyl oxime (INX1177).

The proportion of methomyl oxime formed as a percentage of the applied radioactivity (AR) increased with increasing pH and temperature reaching 4.3% of AR at pH 4 and 90°C, 13.5% of AR at pH 5 and 100°C, and 39.5% of AR at pH 6 and 120°C.

No further degradation of the metabolite methomyl oxime was observed during the study period. Methomyl oxime can be considered as stable to hydrolysis.

No degradation of methomyl was observed in the room temperature control at any level of acidity.

(Pedersen, 2001)

B.8.4.2 Aqueous photolysis

a) A study was carried out in accordance with EPA OPPTS Series 830.7050 (1996) and OECD 101 (1981) guidelines to determine the aqueous photochemical degradation of methomyl.

The UV/visible absorbance spectra were measured for acidic, neutral, and basic aqueous solutions of methomyl (purity 99.8%). Duplicate test solutions (25.63 µg/ml) were prepared at pH 1.68, 6.98, and 10.90 just before use. UV/visible absorption measurements were taken at approximately 10, 20 and 30 minutes using a diode array spectrophotometer with 1-cm quartz flow cell. Higher concentrations of methomyl in methanol (30, 998 and 1000 µg/ml) were tested in a longer cell (100 mm).

The absorbance maximum at 25ºC of methomyl in duplicate acidic, neutral, and basic aqueous solutions was 234 nm. The molar extinction coefficient, ε, ranged from 8.89-9.01 x 10^3 at 234 nm. There were no absorption maxima beyond 290 nm in the aqueous solutions or in the higher concentration methanol solutions. The molar extinction coefficient for methomyl in the methanol solutions was not greater than 10 at 290 nm. Direct photolysis of methomyl can therefore be excluded.

(Moore, LA 1999)

b) The indirect photolytic stability of [1-^{14}C]methomyl with a specific radioactivity of 45.24 µCi/mg (99% radiochemical purity) was studied in sterile aqueous solutions buffered at pH 7 in the presence and absence of nitrate ions and in sterile natural water. Natural water was collected from a spring-fed pond (West Grove, PA, USA) receiving no runoff or other agricultural inputs.

Solutions containing [1-^{14}C]methomyl were prepared at nominal concentrations of 1 mg/L and were continuously irradiated for up to 15 days using a xenon arc simulated sunlight source (spectral cut off<290nm, 270watt-hours/m^2/day equivalent to 42 days of summer sunlight at a latitude of 39° 40'N) at 25°C under sterile conditions. Dark controls were also prepared and maintained at 25°C. The effect of hydroxyl radicals was studied by irradiating buffered solutions of 0.02 mM each methomyl and acetophenone with varying concentrations of hydrogen peroxide.

For ^{14}C-methomyl, LSC and reversed phase HPLC with UV detector and fraction collector were used to analyse the water samples.

Material balance was not reported for all samples but recovery for the dark controls ranged from 91 to 103% and recovery for irradiated buffer samples in the absence of nitrate ranged from 89 to 101% (Table B.8.55). No significant degradation was observed in the dark controls or in irradiated pH 7 buffers without nitrate. Methomyl degraded in the presence of nitrate ions and in natural water. Methomyl degraded most rapidly in solutions containing the higher molar excess of nitrate.

Table B.8.55: Photochemical degradation of [1-^{14}C]methomyl in sterile aqueous systems

Time (Days)	pH 7 Buffer	Average pH 7 Buffer with 1000 Molar Nitrate Excess	Average pH 7 Buffer with 100 Molar Nitrate Excess	Average Natural Water
0	100	100	100	100
0.2		79.3		
0.3	101		92.4	98.7
0.5				
1.0	99.2	52.2	86.6	95.8
2.0	97.9	36.5	80.6	89.4
3.0	96.0		75.8	88.7
5.5		15.9		
7.0	89.3	10.3	56.2	77.2
15.0	97.9	4.3	50.9	55.6
0 (Dark)	100	100	100	100
7 (Dark)	101	90.9	99.6	98.0
15 (Dark)	98.3	103	97.7	95.7

Only the loss of methomyl was monitored so no degradation products were identified in the report. DT_{50} values for methomyl in buffers and pond water are shown in Table B 8.56. These data indicate that indirect photolysis may be a significant degradation pathway in water containing nitrate and in natural water.

Table B 8.56: DT_{50} values and rate constants for indirect photolysis of methomyl

Exposure	Sample	DT_{50} continuous exposure (days)	k (day^{-1})	DT_{50} natural sunlight (day)	Method of Calculation (r^2)
Irradiated	**pH 7 (no nitrate)**	Stable			
	pH 7 (1000 molar excess nitrate)	3.4	0.204	9.5	First-order (0.919)
	pH 7 (100 molar excess nitrate)	16	0.044	45	First-order (0.872)
	Natural pond water	18	0.038	50	First-order (0.995)
Non-irradiated	**pH 7 (no nitrate)**	Stable			
	pH 7 (1000 molar excess nitrate)	Stable			
	pH 7 (100 molar excess nitrate)	Stable			
	Natural pond water	Stable			

Hydroxyl radicals were also shown to react with methomyl by competition kinetics versus the reference compound acetophenone whose reactivity toward hydroxyl radicals is documented.

Methomyl would be susceptible to degradation by indirect photolysis processes with half-lives ranging from 10 to 50 days in natural shallow or near-surface waters.

(Armbrust, K., 1995)

B.8.4.3 Ready biodegradation

Ready biodegradation of methomyl was studied according to OECD guidelines (No. 301/B, 1992).

Methomyl was dissolved in nutrient medium at concentrations of 10 and 20 mg/L and inoculated with activated sewage sludge bacteria and incubated for 28 days at 22°C with aeration. Samples were taken at intervals and the residual dissolved organic carbon (DOC) was measured to assess the percent of biodegradation. Sodium acetate was used as a positive control.

No biodegradation was seen with methomyl. Levels of CO_2 evolution were lower than background controls. Sodium acetate reached a level of 98% biodegradation. Sodium acetate was readily biodegradable as defined by this test.

Methomyl is not readily biodegradable as defined by this test.

(Aldred, D., 1992)

B.8.4.4 Water/sediment studies

a) An aerobic sediment water study was carried out to BBA IV 5-1 (1990), 59 NOHSAN NO. 3850 guidelines. There was no major variation from recommended guideline SETAC however a 2-2.5 cm sediment layer was below a 6-cm water layer, rather than a sediment/water ratio of 1:4 to 1:10.

Degradation of methomyl was studied in two different water/sediment systems (See Tables B.8.57 and B.8.58). Water/sediment systems were filtered and placed in test vessels (2-2.5 cm sediment and 6-cm water). Test vessels were allowed to acclimatise at 20°C in the dark for 28 days to allow stabilisation of oxygen concentration, pH and redox potentials. Humidified air was drawn across the surface of the water during the entire course of the study. Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 44.8 µCi/mg (radiochemical purity >97%) in methanol was applied to the aqueous phase in each test system at a nominal rate of 0.45 mg/L (0.1 ml). The test vessels were connected to a series of traps for volatiles (methanol for neutral organics such as acetonitrile, ethanolamine/ethoxyethanol for acidic organics and KOH for CO_2).

The systems were sampled up to 102-days after application.

Overlying water was decanted from duplicate sediment samples prior to initiation of extraction. Radioactivity in water, soil extracts, and volatile trap samples was quantified by liquid scintillation counting. Soil samples were extracted with methanol/water. The water, soil extracts, and pooled methanol traps were analysed by HPLC and/or TLC. Extracted soil samples were combusted to determine levels of unextractable residues. Transformation products were identified by co-chromatography with authentic standards.

Table 8.57 Characteristics of the water/sediment systems: water

System:	Auchingilsie, Scotland	Hinchingbrooke, England
Location/Source	Ditch carrying hill catchment flow	Still freshwater pond
pH	6.8	7.62
Total N[a]	0.003	0.76
Total P[b]	<10	112
Dissolved Organic C[c]	0.1	<1.0
Hardness[d]	15	605

[a] Total nitrogen (mg/L)
[b] Total phosphorus (mg/L)
[c] Dissolved organic carbon (mg/L)
[d] Hardness (mg equivalents $CaCO_3$/L)

Table 8.58 Characteristics of the water/sediment systems: sediment

System:	Auchingilsie, Scotland		Hinchingbrooke, England	
Location/Source	Ditch carrying hill catchment flow		Still freshwater pond	
pH	6.8		7.62	
% Organic Matter	5.0		10.0	
Cation Exchange[a]	10.8		32.6	
Total N[b]	0.16		0.53	
Total P[c]	1900		1250	
% Sand	41		44	
% Silt	37		31	
% Clay	22		25	
Texture	Clay loam		Silty clay loam	
Microbial activity (colony forming units/g)	**Initiation of study**	**Termination of study**	**Initiation of study**	**Termination of study**
Bacteria	2.23-2.96 × 10^6	1.06-1.26 × 10^6	1.71-1.77 × 10^6	1.34-1.46 × 10^6
Bacterial Spores	0.875-3.85 × 10^5	3.35-7.4 × 10^5	6.55-8.30 × 10^5	0.615-1.29 × 10^6
Actinomycetes	1.40-2.05 × 10^5	3.16-3.30 × 10^5	1.90-4.45 × 10^4	1.64-3.10 × 10^5
Fungi	1.75-1.80 × 10^3	9.00 × 10^2.	7.00-7.50 × 10^2	1.90-2.00 × 10^3

[a] Cation Exchange Capacity (meq/100 g)
[b] Percent total nitrogen
[c] Total phosphorus (ppm)

Overall recoveries were greater than or equal to 90% of the applied radiolabel up to 7 days after application. At this time, approximately 70% of the applied methomyl was degraded in the total system, thus the study allowed determination of the DT_{50} based on actually measured degradation. Recoveries decreased to a minimum of 63% applied radiolabel at day 14 for the Hinchingbrooke system and 72% of applied radiolabel at day 29 for the Auchingilsie system. The low recoveries were attributed to incomplete recovery of volatile radioactivity despite extensive efforts to trap volatile degradates (see table 8.59)

Radiolabel in neutral volatile traps increased rapidly to 19-23% of applied radiolabel by 14 days; after which the increase was more gradual (24-26% applied radiolabel at

29 days). At 102 days, the acidic volatile traps ($^{14}CO_2$) contained 32-46% of the applied radiolabel.

The majority of the applied radiolabel at application was found in the water (79-85% mean values). The applied radiolabel moved from the water to the sediment and by 14 days, only 10 to 15% of the applied radiolabel remained in the aqueous phase, with 23 to 28% in the sediment (Table 8.59). At 102 days, applied radiolabel remaining in the water was only 0.4-2%. Radiolabel in the sediment declined to 11-15% applied radiolabel by 102 days.

Unextractable residues in the sediment peaked at 16-21% of the applied radiolabel at day 14 and then slowly declined to 10-15% applied radiolabel at day 102.

In the acidic volatile traps, $^{14}CO_2$ reached a maximum of 32-46% applied radiolabel by the end of the study. In the neutral volatile traps, [1-^{14}C]acetonitrile was identified as the only degradate and accounted for up to 24-27% of the applied radiolabel.

Acetonitrile and carbonate were also degradation products found in both water (Table 8.60) and sediment (Table 8.61). A polar fraction, identified as Component 1, was also found in both water and sediment. It reached a maximum average 12% of the applied radiolabel at Day 7 (Auchingilsie water) and declined to less than 6% applied radiolabel by Day 29. Component 1 in Day 7 samples (both >10% of the applied radioactivity) from both water phases was further resolved into 2 or 3 components, one of which co-chromatographed with [1-^{14}C]acetamide accounting for 5.4% and 8.8% of the applied radioactivity in water from the Auchingilisie and Hinchingbrooke systems, respectively (Table 8.60).

Acetonitrile, carbonate and other polar compounds accounted for maximum levels of 7.4%, 8.6%, 7.1% and 6.5% of the applied radioactivity at any sampling date in water phases of the two systems, respectively (Table 8.60).

In both sediments acetonitrile, carbonate, methomyl oxime (INX1177) and other polar compounds accounted for a maximum of 10.9%, 4.0%, 3.8%, and 3.2% of the applied radioactivity at any sampling date (Table 8.61). Acetamide was determined in Day 7 samples of the Auchinglisie sediment at 1.8% of the applied radioactivity after further analysis of the extracts. Acetonitrile levels rapidly declined after the observed peak values in both sediments. In the Auchingilisie sediment, levels declined from 10.9% of the applied radioactivity on Day 7 to less than 2% of the applied radioactivity seven days later. In the Hinchingbrooke sediments the acetonitrile levels declined to 50% of the maximum value observed on Day 0 (10.9 of the applied radioactivity on day 0 to 4.7% of the applied radioactivity on Day 2). The presented data include simultaneous formation and decline of acetonitrile; as an approximation a half-life of 2 days can be estimated for acetonitrile in sediments.

Methomyl declined to below detection limits in both the water and sediment by day 29. First-order equations (linear regression, log normalised) were used to calculate DT_{50} and DT_{90} (see Table 8.62).

Table 8.59 Percent distribution of applied radioactivity and mass balance in aerobic 20°C water/sediment systems treated with methomyl

System	Day	Average % of radiolabel[a]					
		Volatiles[b]	Labelled CO_2	Water	Sediment Extractable	Sediment Unextractable	Total Recovered
Auchingilsie	0	-	-	84.8	16.5	0.4	101.7
	.25	0.98	0.02	87.5	14.2	0.6	103.3
	1	1.14	0.02	88.3	11.2	0.5	101.1
	2	1.71	0.02	82.5	14.9	1.2	100.3
	7	19.0	1.2	48.9	48.9	8.0	90.8
	14	23.0	14.1	15.3	8.0	14.6	75.0
	29	26.4	22.1	7.8	3.6	12.4	72.3
	60	27.0	37.55	1.5	1.4	11.9	79.3
	102	27.0	46.2	1.7	1.1	10.0	86.1
Hinching-brooke	0	-	-	78.5	22.3	1.4	102.2
	.25	0.7	<0.03	73.5	25.2	2.5	101.8
	1	0.9	<0.07	72.2	24.9	2.0	100.1
	2	1.4	<0.09	85.1	11.9	1.4	99.8
	7	9.25	0.5	53.7	19.3	6.9	89.7
	14	18.9	5.9	10.0	7.8	20.1	62.6
	29	23.65	18.5	8.0	3.4	17.0	70.6
	60	23.65	28.1	1.1	0.9	15.6	69.5
	102	23.65	32.1	0.4	0.7	14.7	71.6

[a] Average values calculated from data for individual samples provided in the original report.
[b] Neutral volatile traps were discontinued at day 35 since <1% applied radiolabel was observed in traps between Days 29 to 35. Acetonitrile (IN-07467) was the only degradate found in this trap

Table 8.60 Percent distribution of applied radioactivity in the water phase of aerobic 20°C aquatic systems treated with [1-^{14}C] methomyl

System	Day	Average % of radiolabel[a]							Total Recovered
		Methomyl	Acetonitrile	Carbonate	methomyl oxime	Component 1[b]	Component 2	Others	
Auchingilsie									
	0	79.3	2.6	0.2	0.4	0.5	0.2	1.9	84.8
	0.25	82.3	1.6	0.3	0.6	0.6	0.3	2.0	87.5
	1	81.1	1.6	0.3	1.1	1.1	0.3	2.3	88.3
	2	73.8	2.9	0.3	1.0	1.7	0.3	2.6	82.5
	7	21.7	6.0	6.1	1.1	11.9	0.5	1.8	48.9
	14	<0.1	0.3	8.6	<0.1	5.4	0.3	0.7	15.3
	29[c]	<0.1	0.2	6.6	<0.1	0.6	<0.1	0.8	7.8
Hinchingbrooke									
	0	73.3	2.0	0.3	0.4	0.5	0.3	1.9	78.5
	0.25	68.8	1.6	0.2	0.4	0.5	0.2	2.0	73.5
	1	66.6	1.2	0.2	0.8	1.1	0.3	2.3	72.2
	2	70.7	2.6	0.3	7.1	1.6	0.3	2.6	85.1
	7	27.9	7.4	3.0	1.4	11.3	0.9	1.8	53.7
	14	<0.1	<0.1	8.3	0.2	0.6	0.2	0.7	10.0
	29[c]	<0.1	<0.1	6.9	<0.1	0.2	<0.1	0.8	8.0

[a] Average values were calculated from data for individual samples provided in the original report
[b] Polar degradant 1 was further resolved in day 7 samples was further resolved into two compounds:
Auchingilisie: 11.9% resolved into average of 5.4% acetamide (IN-09066) and 6.5% polar compound
Hinchingbrooke: 11.3% resolved into average of 8.8% acetamide (IN-09066) and 2.6% polar compound
[c] Samples were not analysed chromatographically after Day 29 as they accounted for <2% of radiolabel

Table 8.61 Percent distribution of applied radioactivity in the sediment phase of aerobic 20°C aquatic systems treated with [1-^{14}C] methomyl

System	Day	Average % of radiolabel[a]								
		Methomyl	Acetonitrile	Carbonate	methomyl oxime	Component 1[b]	Component 2	Others	Unextractable	Total Recovered
Auchingilsie										
	0	6.2	7.9	<0.4	<0.4	0.9	<0.4	1.6	0.4	16.9
	0.25	4.2	7.4	<0.3	<0.3	1.1	0.4	1.5	0.6	14.8
	1	3.4	5.7	<0.2	<0.2	0.7	<0.2	1.5	0.5	11.7
	2	4.2	5.8	<0.2	0.2	2.5	0.6	2.0	1.2	16.0
	7	1.4	10.9	<0.3	<0.3	6.6	<0.3	3.2	8.0	21.7
	14	<0.3	1.7	2.3	<0.3	2.7	<0.3	1.6	14.6	22.6
	29[c]	<0.3	0.7	2.3	<0.3	0.5	<0.3	0.2	12.4	16.1
Hinchingbrooke										
	0	8.6	10.2	<0.3	3.8	2.1	<0.3	1.5	1.4	23.7
	0.25	8.7	9.9	<0.4	<0.4	4.4	<0.4	2.2	2.5	27.6
	1	11.4	9.0	<0.2	0.2	2.4	<0.2	2.0	2.0	26.9
	2	4.5	4.7	<0.2	<0.2	1.5	<0.2	1.4	1.4	13.3
	7	2.5	8.4	1.4	0.3	4.5	<0.2	2.6	6.9	26.3
	14	<0.4	<0.4	4.0	<0.4	1.5	<0.4	2.3	20.1	27.8
	29[c]	<0.2	0.4	2.3	<0.2	0.4	<0.2	0.6	17.0	20.5

[a] Average values were calculated from data for individual samples provided in the original report
b Polar degradant 1 was further resolved in Day 7 samples was further resolved into three compounds:
Auchingilsie: 6.6% resolved into average of 1.8% acetamide (IN-09066) and 2.4% and 2.4% polar compounds
[c] Samples were not analysed chromatographically after Day 29 as they accounted for <2% of radiolabel

Table 8.62 First order DT_{50} and DT_{90} values for methomyl in aerobic aquatic systems (linear regression, log normalised)

Analyte	System	DT_{50} (days)	DT_{90} (days)	r^2
Methomyl	Auchingilsie			
	Water	3.5	12	0.952
	Total system	3.5	12	0.957
	Hinchingbrooke			
	Water	5.0	17	0.930
	Total system	4.8	16	0.954
	Average total system	*4.2*	*14*	

Note: Values were calculated using data from 0 – 7 days where ^{14}C recovery was >90%. On Day 7, 70% of the applied methomyl was already degraded, thus a DT_{50} could be reliably established.

(Mayo, B.C., 1994);

b) An aerobic sediment / water study was conducted in accordance with SETAC (1995) guidelines.

The study used radiolabelled [^{14}C]-methomyl, specific activity 1779 MBq/mmol and radiopurity >98% and applied at a rate equivalent to 0.40 kg a.s./ha to surface water. Two contrasting water/sediment systems at 20°C were studied over a period of 44 days. The incubation was performed in glass flasks maintained in the dark at 20°C ± 2°C. The water/sediment systems were incubated for approximately 4 weeks to enable acclimatisation prior to [^{14}C]-methomyl application to the surface of the water. The incubation flasks were attached to a system through which moist air was passed into the water layer in each flask at a constant rate to maintain an oxygenated water layer. The effluent air passed through an ethylene glycol trap to capture volatiles, followed by 2x2M potassium hydroxide traps to capture CO_2.

See Table B.8.63 for sediment physical-chemical properties and Table B.8.64 for the properties of the associated water. The water/sediment systems contained the equivalent of oven dried sediment: water in an average ratio of 1:7 (sandy silt loam) and 1:5 (clay loam). Water and sediment depths were not stated.

Throughout the study the sediments of both systems were regularly monitored for redox potential and the water phases for oxygen content, pH and redox potential.

Table B.8.63 Physical-Chemical Properties of the Sediment

Property	**Sediment Reference**	
Sediment Reference	**Sandy silt loam**	**Clay loam**
Ordinance Survey Grid Reference	**TM100302**	**TL566048**
%Sand (63µm-2 mm)	32.98	48.46
% Silt (2-63 µm)	49.21	26.07
% Clay (< 2 µm)	17.81	25.47
pH in water	7.2	7.9
in 1 M KCl	7.0	7.0
in 0.01M $CaCl_2$	7.0	7.0
$Ca_{exchangeable}$	15.5	39.0
$Mg_{exchangeable}$	3.3	1.3
N.a. $_{exchangeable}$	0.3	0.3
$K_{exchangeable}$	0.4	0.6
$Mn_{exchangeable}$	<0.05	0.1
Total Cation Exchange Capacity (mEq/100g)	19.5	41.3
% Moisture Content	165.2	107.8
Microbial Biomass (µg C/g soil) **initial**	248	56
Microbial Biomass (µg C/g soil) **final**	217	38

Table B.8.64 Analysis of Sediment Associated Water

Analysis of Associated Water	**Sandy silt loam**	**Clay loam**
Total Nitrogen (ppm)	20.0	12.0
Total Phosphorous (ppm)	0.6	0.2
Total Organic Carbon (ppm)	3.8	5.3
Water Hardness (ppm as $CaCO_3$)	327	443
At time of collection: **Temperature °C**	15	10.9
pH	6.49	7.86
Redox Potential (mV)	403	106
Oxygen content water surface level (%)	54	85

At each sampling point (Day 0, 2,4, 7, 10, 14, 31 and 44) duplicate samples were taken for analysis. The water layer was decanted off by pouring and the sediment layer taken for solvent extraction with methanol. Solvent and water extracts were chromatographically analysed by HPLC, using certified reference standards as putative metabolites. See Table B.8.65 for distribution of radioactivity in the two systems.

Table B.8.65 Distribution of Radioactivity in Water Sediment Systems

	% Applied radioactivity					
Time	**Water**	**Sediment**	**Total**	**CO_2**	**Unextracted**	**total**
(days)		**Extract**	**extracted**			
Manningtree Sandy silt loam system						
0	95.28	0.63	95.91	NA	0.00	95.91
2	74.83	5.26	80.09	2.30	5.05	87.44
4	54.47	3.25	57.72	16.40	11.46	85.58
7	31.05	3.07	34.12	26.56	14.87	75.55
10	17.99	3.26	21.25	44.40	15.90	81.55
14	8.98	2.18	11.16	64.76	16.28	92.21
31	4.45	1.15	5.60	72.34	15.49	93.44
Ongar Clay loam system						
0	97.74	0.90	98.64	NA	0.01	98.66
2	93.50	1.52	95.02	0.39	2.33	97.73
4	99.12	0.99	100.11	2.47	11.96	114.54
7	83.85	0.96	84.81	0.47	19.01	104.29
10	25.84	1.77	27.61	38.17	15.76	81.55
14	13.89	1.21	15.09	44.47	16.60	76.16
31	10.74	0.76	11.50	50.37	14.60	76.47
44	1.76	0.40	2.16	59.65	15.25	77.06

NA=not applicable

The total recovery of radioactivity from each sample was initially good being in excess of 90%. However, concurrent with the increase in volatile radioactivity collected in the potassium hydroxide traps there was a decrease in the total recovery of radioactivity in both systems. This can be clearly ascribed to the substantial presence of dissolved carbon dioxide formed in the water phase which was most likely lost during the separation of the water phase from the sediment during the analysis. That there was a likely loss of radioactivity from the water phase is evidenced by significant variability between replicates at some time points. HPLC analysis of the samples where the carbon dioxide was not all removed by precipitation clearly showed its presence in the form of carbonate (see Table B.8.66). Analysis of potassium hydroxide traps by HPLC showed a peak at the same retention time as the peak in the water samples inferring the presence of dissolved carbonate.

See Table B.8.66 for composition of radioactivity in the two systems.

Table B.8.66 Composition of Radioactivity in Water by HPLC

		% Applied radioactivity						
Time,	Flask ID	Total % applied in water	PPT Carbonate	Remaining radioactivity	Carbonate	Methomyl oxime	Methomyl	Total
days					RRT= 0.28	RRT=0.60	RRT=1	
Manningtree Sandy silt loam system								
0	1 and 2	95.28			2.15		93.13	95.28
2	3 and 4	74.83	12.37	62.45	4.68	1.94	55.83	62.45
4	5 and 6	54.47	22.52	31.96	5.47	0.81	25.67	31.96
7	7 and 8	31.05	12.96	18.08	3.37	0.13	14.58	18.08
10	9 and 10	17.99	8.17	9.82	1.95	0.20	7.67	9.82
14	11 and 12	8.98	1.15	7.83	1.73	0.59	5.51	7.83
31	12 and 13	4.45		4.45	1.29	0.75	2.41	4.45
Ongar Clay loam system								
0	1 and 2	97.74			1.75		96.02	97.74
2	3 and 4	93.50		93.50	7.68	3.28	82.55	93.50
4	5 and 6	99.12	48.76	74.74	11.80	1.94	61.00	74.74
7	7 and 8	83.85	10.44	73.41	23.94	0.26	49.22	73.41
10	9 and 10	25.84	12.78	13.06	4.13	0.50	8.43	13.06
14	11 and 12	13.89	6.68	7.20	3.12	0.05	4.03	7.20
31	13 and 14	10.74		10.74	1.16	1.72	7.86	10.74

The extractable radioactivity recovered from the sediment remained low. It never exceeded 6% and 2% in the sandy silt loam and clay loam systems respectively. Only samples from the sandy silt loam, which had 5% of the applied radioactivity present at Day 2, were analysed by HPLC (see Table B.8.67). The samples contained <1% methomyl and methomyl oxime (INX1177) and <4% dissolved carbonate.

Table B.8.67 Composition of Radioactivity in Manningtree Sandy Silt Loam Sediment Extracts by HPLC

		% Applied radioactivity				
Time,	Flask ID	% applied in extract	Carbonate	Methomyl oxime	Methomyl	Total
Days			RRT= 0.28	RRT=0.60	RRT=1	
2	3	5.44	4.57	0.56	0.31	5.44
	4	5.08	4.28	0.48	0.32	5.08
	MEAN	5.26	4.43	0.52	0.32	5.26

The unextracted sediment radioactivity which represented up to 16(day 14) and 19% AR (day 7)was subjected to soil fractionation. This process producing soil fractions of Fulvic Acid, Humic Acid and Humin released of 2.75%, 2.51% and 10.37% of applied radioactivity in the sandy silt loam system and 3.36%, 1.99% and 12.46% in the clay loam system respectively. At study end unextracted radioactivity had declined to 15.5% (day 31) and 15.2%AR (day 44) respectively.

The half-life, DT_{50} and DT_{90} values for methomyl in the water were calculated. It was not possible to calculate values for methomyl in the sediment or the total system due to the small quantity of radioactivity in the sediment.

Assuming first order decay using Excel, the half-life and DT_{90} values for methomyl in the water were calculated by linear regression using the natural logarithm (ln) of methomyl as % of applied. However this did not show a good description of data with r^2 values *ca* 0.83.

Using one, two and three compartment decay and the power rate models within the kinetic modelling program (KIM), the data showed a good description of the experimental data for the clay loam system water using the power rate model. However the best fit for the sandy silt loam system water was achieved with the two-compartment decay model. The Timme-Frehse program did not show a good description of the experimental data and was only used in the sandy silt loam system (see Table B.8.68).

Table B.8.68 DT_{50} and DT_{90} Calculations for Methomyl in the water phases of two sediment/water systems

		Water/Sediment Systems			
Program	**Model**	**Applied to degradation in**	**DT_{50} (days)**	**DT_{90} (days)**	**'Goodness of Fit'***
Excel	**Log normalised linear regression first order**	Water sandy silt loam	6.21	20.62	0.817
		Water clay loam	4.80	15.96	0.852
Timme-Frehse	**Log normalised linear regression first order**	Water sandy silt loam	0.93	10.31	0.933
		Water clay loam	Not calculated	Not calculated	Not calculated
KIM v 1.0	**Two Compartment**	Water sandy silt loam	2.36	8.85	0.996
	Power Rate	Water clay loam	5.66	11.10	0.951
Excel	**Non linear least squares first order**	Water sandy silt loam	2.5	8.2	0.989
		Water clay loam	4.5	14.9	0.846

*Note: These figures are all a measure of the "goodness of fit", but are not equivalent from analysis to analysis. In all cases, a value of ±1.000 would represent a perfect fit to the experimental data.

(Oddy A.M. and Roach S. 1999a)

Bayer Data

c) The fate and behaviour of methomyl in various natural sediments was investigated to support registration, the work was not carried out to any agreed guidelines (pertinent guidelines to address the aims of the experiments do not exist). This report summarised additional information to that already provided by the guideline studies summarised at a) and b) above. Investigations covered:

- the fate of [1-^{14}C]methomyl in natural sediments incubated under anaerobic conditions (test system 1),
- the fate of [1-^{14}C]methomyl in a ferrous ion solution (test system 2),
- the fate of [1-^{14}C]methomyl in frozen samples of natural sediments (test system 3),
- the fate of [1-^{14}C]methomyl in samples of natural sediments stored at ambient temperature (test system 4).

Some of the work (test system 1) was carried out before October 1989. This work was not completed in accordance with GLP. This is acceptable as the pre 1989 experimental work relating to test system 1 predates the 1993 EU GLP requirement for these studies and the work was satisfactorily reported. All the other work described here (test systems 2,3 and 4) was GLP compliant.

Test system 1:

A mixture of sediment and water was obtained from a backwater in a slow-moving creek that drained a cedar swamp near Princeton, Maine, USA. Samples of the sediment (110 g) and the filtered water (100 ml) were placed in centrifuge bottles, purged with nitrogen, sealed, and equilibrated for 30 days in the dark. In addition two agricultural soils (Flanagan & Fallsington) were made anaerobic by flooding with water (90 ml containing 10 ml of the Maine creek water), purging with nitrogen, and equilibrating with 1 g of powder-dry alfalfa, which used up oxygen in the systems as it decomposed.

[1-^{14}C]Methomyl was added to each system and incubated for 14 days. As a control [1-^{14}C]methomyl was also incubated with soils that were prepared as above, but not made anaerobic. Sampling was done on days 0, 2, 7, and 14. The aqueous sediments were centrifuged to remove solids, which were extracted three additional times with water and twice with methanol. The aqueous extracts were combined and extracted with an equal portion of ethyl acetate. The ethyl acetate extract was concentrated. Radioactivity in each fraction was determined by LSC. Analysis of the ethyl acetate concentrates for methomyl was carried out by HPLC. In addition, selected samples of head space were analysed by gas chromatography using the mass spectrometer as a single ion monitor and trapping the GC peak effluent on scintillation cocktail and analysing by LSC. [^{14}C]carbon dioxide was monitored in the flooded sediment mixture over time by the addition of excess barium chloride and precipitation of insoluble barium carbonate.

Poor recovery of total radioactivity was observed in ethyl acetate extracts from the sediments incubated under anaerobic conditions. This loss in recovery was especially apparent after concentration, indicating the presence of volatile metabolites. No methomyl (<0.1% of the applied radioactivity) was found in the day 0 extracts from the anaerobic samples, and essentially all of the radioactivity was found to be volatile.

In comparison, recovery of total radioactivity in the ethyl acetate samples was good in the aerobic control samples, with no apparent loss of radioactivity on concentration. Most of the radioactivity in early samples was recovered as methomyl.

In the headspace samples above methomyl and flooded sediment samples acetonitrile was observed in early stages of incubation. Definite evidence was obtained by analysing the GC peak effluent by LSC. It appeared that the initial volatile metabolite [1-^{14}C]acetonitrile was readily mineralised in the sediment system, so that by 8 days essentially all of the radioactivity in the water was radiolabelled carbon dioxide (Table B.8.69). It was concluded in this study that the complete breakdown of methomyl to small, volatile radiolabelled fragments was extremely rapid in the presence of active anaerobic micro-organisms.

TableB.8.69: Conversion of total radioactivity in aqueous phase to [^{14}C] carbon dioxide (Maine sediment/Maine water)

Incubation Time	dpm in 5 ml Aqueous Phase	dpm in Aqueous Phase after $BaCO_3$ Precipitation	Percentage ^{14}C Precipitated as $BaCO_3$
90 min	93.6 * 10^3	93.0 * 10^3	0.6
3 hours	96.6 * 10^3	91.9 * 10^3	4.8
24 hours	97.3 * 10^3	80.9 * 10^3	16.9
4 days	53.6 * 10^3	29.3 * 10^3	45
6 days	35.8 * 10^3	8.1 * 10^3	77
7 days	33.0 * 10^3	2.1 * 10^3	94
8 days	32.8 * 10^3	0.6 * 10^3	98

dpm: ^{14}C disintegrations per minute

Test system 2:

An aqueous solution of ferrous ions was prepared at a concentration of 200µg Fe^{2+}/mL. [1-^{14}C]methomyl (0.1 mg/ml) was added and the solution incubated at room temperature. Sampling was done at time 0 and 6 hours. Analysis for methomyl and acetonitrile was carried out by HPLC.

Methomyl degraded with a half-life of approximately 12 hours, with the major degradation product identified as [^{14}C]acetonitrile by HPLC.

Test system 3:

Three natural aquatic sediments sampled in the U.S.A. were used in this study. The characteristics are given in Table B.8.70

TableB.8.70: Sediment characterisation for frozen natural sediments

Characteristics	Georgia	Florida	Michigan
Origin	Pond	Field canal	Pond
pH	5.5	7.2	7.3
% Sand	80	84	84
% Silt	14	12	4
% Clay	6	4	8
Texture	loamy sand	loamy sand	loamy sand
% Organic matter	4.1	16.6	2.8
Redox Potential (mV)	412	192	238
Soluble iron (ppm)	307	70	74

The sediments were fortified with [1-^{14}C]methomyl and incubated immediately at about –20°C for up to 369 days. Samples were taken on days 0, 7, 15, 29, 90, and 201 (Georgia sediment); days 0, 1, 7, 32, 94, 185, 273, and 369 (Florida sediment) and days 0, 1, 3, 7, 29, 90, and 278 (Michigan sediment). Extraction of 10g sediments was done with acetone/water (9:1, v:v). From the combined extracts the radioactivity was determined using LSC. An aliquot of extract was evaporated with nitrogen to 0.5mL volume and radioactivity measured with LSC. This extract was reconstituted to 2mL volume using the mobile phase of the HPLC and from this sample 0.25mL were injected into the HPLC. In addition, from the combined acetone/water extracts of the Michigan pond and Florida field canal sediments a 0.5mL extract was directly injected into the HPLC to determine both methomyl and acetonitrile.

[1-^{14}C]Methomyl degraded in laboratory-fortified Michigan, Georgia, and Florida sediment samples stored frozen with half-lives of approximately 204, 54, and 340 days, respectively (Table B.8.72). A loss of volatile radiolabelled degradate was apparent from the decline in recovery after the concentration of the extracts for HPLC analysis.

During analysis of non concentrated sediment extracts a radioactive peak eluting with the same retention time as [1-^{14}C]acetonitrile was observed in Michigan and Florida sediment extracts and. Other extracts were not examined, but it can be assumed that [1-^{14}C]acetonitrile (IN-07467) is the volatile component that was lost on concentration.

Test system 4:

Three natural aquatic sediments sampled in the U.S.A. were used in this study. The characteristics are given in Table B.8.71

Table B.8.71: Sediment characterisation for natural sediments

Characteristics	Georgia	Alabama	Michigan
Origin	Pond	Mesocosm	Pond
pH	5.5	5.9	7.3
% Sand	80	61	84
% Silt	14	22	4
% Clay	6	17	8
Texture	loamy sand	sandy loam	loamy sand
% Organic matter	4.1	0.9	2.8
Redox Potential (mV)	412	-190	238
Soluble iron (ppm)	307	70	74

Sediments were fortified with [1-^{14}C]methomyl and incubated at ambient room temperature for 240 days. Samples were taken on days 0, 30, 60, 120, and 240 (Georgia & Michigan sediment); and Days 0, 10, 20, 40, 60, 120, and 240 (Alabama sediment). Extraction of sediments was done twice with acetone/water (9:1, v:v). From the combined extracts the radioactivity was determined using LSC. A 5mL extract aliquot was evaporated with nitrogen to 0.5mL volume and radioactivity measured with LSC. This extract was reconstituted to 2mL volume using the mobile phase of the HPLC and from this sample 0.25 ml were injected into the HPLC. From the combined acetone/water extracts of the Georgia pond and Alabama mesocosm sediments a 0.5mL extract was directly injected into the HPLC to determine not only methomyl, but also acetonitrile.

[1-^{14}C]Methomyl degraded rapidly in laboratory fortified Georgia pond, Alabama microcosm and Michigan pond sediments stored at ambient room temperatures with half-lives of 98, 342, and 322 minutes, respectively. Generally, most of the radioactivity (90%) was extracted from the sediments, but a loss occurred during the concentration of the extract prior to HPLC analysis.

During analysis of non-concentrated sediment extracts a radioactive peak eluting with the same retention time as [^{14}C]acetonitrile was observed in Georgia pond and Alabama mesocosm sediment extracts and. Other extracts were not examined, but it can be assumed that [^{14}C]acetonitrile is the volatile component being lost on concentration.

TableB.8.72: Half-lives of [1-^{14}C]methomyl in natural sediments stored frozen (test system 3) or at ambient temperature (test system 4).

Sediment	Storage condition (temperature)	DT_{50} (days)	r^2	Calculation
Michigan pond, USA	frozen	204	0.93	First-order
Georgia pond, USA	frozen	54	0.98	First-order
Florida canal, USA	frozen	340	0.91	First-order
Georgia pond, USA	ambient	<0.1	0.98	First-order
Alabama mesocosm, USA	ambient	0.24	0.92	First-order
Michigan pond	ambient	0.22	0.86	First-order

Overall picture from the 4 test systems:

Anaerobic micro-organisms present in natural aquatic sediments can rapidly degrade methomyl to small volatile fragments within a day.

Presence of ferrous ions at a concentration of 200µg Fe^{2+}/mL catalyses breakdown of methomyl to acetonitrile with an approximate half-life of 12 hours.

During analysis of natural sediment samples fortified with [1-^{14}C]methomyl stored at ambient temperatures, methomyl was degraded with half-lives < 0.3 days.

[1-^{14}C]acetonitrile was the volatile compound accounting for the losses of radiolabel during concentration of extracts.

(Ryan, D., 1995)

d) The rate of dissipation of [1-^{14}C]methomyl from the water phase of a simulated pond with aquatic plants present was carried out. There is no recognised guideline available for a study of this type.

The study determined the rate of dissipation of methomyl from the water column of the simulated pond and determined the distribution of total radioactivity between the water, sediment and plant material.

Water, sediments, and plants were sampled from a natural pond located on the DuPont Stine-Haskell Research Center in Newark, Delaware (USA) on 25-Sep-2001 and 01-Oct-2001 (approximate latitude 39° 41'N). Polycarbonate tubes (28 cm × 4.4 cm i.d., core samplers) were manually inserted through the water into the sediment to harvest a core with an approximate 3-to-1 ratio of water to sediment by height, (i.e. water column ca. 13.1cm overlying ca. 4.4cm sediment depth). The average amount of plant material per test vessel was 0.09 g plant material (wet weight)/ml of water in the water column. After sampling, a rubber stopper was inserted into the bottom of the core samplers (test vessels), which was then sealed with tape to prevent leakage of water from the system. Several aquatic plants (*Potamogeton* sp) were placed into the water column of each test system. The tops of the test vessels were open. The water/sediment/plants in the polycarbonate tube were the test system for the study. Day 0 test systems contained only 200 ml of pond water, to allow for more accurate determination of the methomyl concentration in the water phase.

The test systems (except for Day 0) were moved to an outdoor plot at the Stine-Haskell Research Center. Over the 48 hour of the study the air temperature was in the range 8.8-28°C, water temperatures were 11.9-43.7°C. The water level was adjusted to the appropriate height prior to test substance application. The water level was maintained during the course of the study by addition of pond water. The test systems were acclimatised outdoors for 1 day prior to test substance application.

Radiolabelled methomyl was dissolved in methanol and applied directly to the water column of each test system at a concentration of approximately 0.45 µg methomyl g^{-1} water. The percent of methanol in the water column was less than or equal to 0.05% (v/v). Day 0 samples contained only water, and were analysed as soon as possible after dosing. Duplicate test systems were sampled from the outdoor plots at 2, 4, 6, 24, 42, and 48 hours after application. A total of 4 samples were taken at the 24-hour time point.

Following the separation of the water and sediment, the volume of the water was measured and recorded in the study records. The total radioactivity in the water phase was determined by liquid scintillation counting in triplicate. The water phase was analysed by high performance liquid chromatography (HPLC) with on-line radioactivity detection to determine the amount of ^{14}C-methomyl in the sample. Sediments were extracted with 100 ml of methanol. The sediment and extractant were mixed for 30 minutes on a wrist-action shaker and separated by centrifugation (15 minutes at 6000-rpm). The sediment extract was decanted and the extraction process repeated. Total radioactivity of each extraction was determined by liquid scintillation counting. The amount of unextractable radioactivity remaining in the sediment was determined by combustion of the post-extraction solid.

Table B.8.73: Material balance of methomyl in simulated pond system

Distribution[B]	Sampling Times[A] (% applied radiolabel)							
	Day 0[C]	2 Hour	4 Hour	6 Hour	24 A Hour	24 B Hour	42 Hour	48 Hour
Aqueous Phase	100	83.5	76.6	77.2	71.7	69.1	58.4	45.6
Sediment Extractable Radioactivity	0	0.2	0.1	0.1	0.3	0.3	0.5	0.5
Non-Extractable Radioactivity	0	0.9	1.1	0.9	2.1	1.8	2.6	2.9
Total Radioactivity in Plants	0	8.2	5.9	16.5	15.8	7.1	20.6	38.2
Total recovery	100	92.7	83.7	94.8	89.9	78.2	81.9	87.2

A Two sets of 24-hour samples were taken. To differentiate the samples, they are designated as 24 A Hour and 24 B.
B Values are an average of the replicates taken for each sampling time.
C 0 Hour samples consisted of water only to allow an accurate measurement of methomyl in the aqueous phase after test substance application

The recovery of applied radioactivity (AR) in the simulated pond system ranged from 100 to 78.2%. Since volatiles were not trapped in this study, the loss of radioactivity was probably due to formation of $^{14}CO_2$. Radiolabelled CO_2 was generated in the water/sediment study performed with methomyl incubated in the dark at 20°C (see a) and b) above).

The total quantity of radioactivity in the water phase decreased rapidly and continually from 100% AR initially after methomyl application to 45.6% AR at the end of the study (48 hour) (Table B.8.74). The total quantity of radioactivity in the sediment phase (i.e., extractable and non-extractable residues) was not significant during the course of the study (≤3.4%). Extractable radioactivity in the sediment never accumulated to any significant amount, remaining less than 0.5% AR throughout the entire study. Due to the low amount of extractable radioactivity, sediment extracts were not analysed by HPLC. Total radioactivity in the plant material increased over the course of the study to a maximum of 38.2% AR in 48 hours. The radioactivity in the plant material was not characterised further.

All water samples were analysed by HPLC with radiochemical detection to determine the amount of methomyl present in each sample. Duplicate samples were analysed at each time point. At Day 0, approximately 100% AR in the water was methomyl. Methomyl dissipated rapidly in the water column and by 48 hour, only 29.5% AR was methomyl.

No attempts were made to characterise degradation products in this short-term study.

The calculated DT values for methomyl in the water phase of the simulated pond system are summarised in Table B.8.74.

Table B.8.74: DT_{50} and DT_{90} values for methomyl from the water phase of a simulated outdoor pond system with aquatic plants present (non linear least squares fit using ModelMaker), air temperature ca. 9-28 °C in the autumn at 39°N.

Analyte	Phase	DT_{50} (days)	DT_{90} (days)	r^2	Method of calculation
Methomyl	Water	1.4	4.6	0.901	Simple first-order

Methomyl dissipated rapidly from the water phase of a simulated pond system in the presence of sediment and aquatic plants under outdoor conditions, (note the DT90 quoted is extrapolated beyond the study duration).

(Koch Singles, S. and Theilacker, W.,2002)

B.8.4.5 Summary and Assessment

Methomyl is stable to hydrolysis at environmentally relevant pH and temperatures. It is also stable to direct aqueous photolysis. Methomyl was demonstrated to photolyse under sterile laboratory aqueous photolytic conditions in a natural water and in buffer solution in the presence of nitrate (i.e by indirect photolysis). The study design did not identify breakdown products. At 25°C with summer sunlight *ca*. 40°N first order DT50 were 10-50days. (No degradation was observed in dark controls). Whilst this degradation rate could occur in the top layers of natural surface waters in a real water body, indirect photolysis is unlikely to contribute significantly to dissipation in real aquatic situations as this degradation rate is slower than has been shown to occur in non sterile systems (see below).

Guideline (20°C) laboratory sediment water studies were carried out on 4 different natural sediment water systems. In these studies methomyl dissipated relatively rapidly, with first order DT50 in the whole systems of 2.5-4.8 days (r^2, 0.95-0.99). First order DT50 in the water phase alone were 2.5-5 days (r^2, 0.85-0.99). In 3 of the 4 systems, whilst partitioning of radioactivity to sediment occurred, the sediment extractable radioactivity present as methomyl was negligible with methomyl staying almost entirely in the water phase (maximum sediment concentrations of methomyl at any time point were in the range <1% -6.2% AR). The exception to this was in the 5.8% organic carbon Hinchingbrooke silty clay loam water / sediment system, where 2 days after application to the water column methomyl reached 11.4%AR in sediment. However this methomyl sediment residue declined rapidly to <0.4%AR by day 14 of the experiment. The only breakdown products identified (other than CO_2 and CO_3) were acetonitrile acetamide and methomyl oxime (Z-methyl N-hydroxyethanimidothioate, INX1177) which had maximum concentrations of 6-7.4, 5.4-8.8 and 1.1-7.1%AR respectively in water and 10.2-10.9, 1.8 and <0.2-3.8%AR respectively in sediment.

These data demonstrate that in natural sediment water systems, in the aerobic water phase no major >10%AR breakdown products will be formed. In sediment (where conditions can become anaerobic) acetonitrile was detected above 10%AR (at only 1 sampling date in any system) at maxima of 10.2%AR (immediately after application Hinchingbrooke system, only 2.7% on a mass basis) and 10.9%AR (at day 7 Auchingilsie system, only 2.8% on a mass basis). These levels in sediment declined relatively rapidly being <0.4%AR (<0.1% by mass) 13 days later and 0.7%AR (0.2% by mass) 22 days later in each system respectively. 14 days after the test substance was applied, concentrations of acetonitrile in sediment were <10% AR (<0.4 and 1.7%AR in the Hinchingbrooke and Auchingilisie systems respectively). In the Manningtree sandy silt loam and Ongar clay loam systems acetonitrile was not detected in sediment extracts.

In these guideline (20°C) laboratory sediment water studies, by the end of the experiments mineralisation to CO_2 accounted for 32-46%AR (102 days) and 72% at 31 days and 60% at 44 days in the different systems. In two of the systems significant quantities of acetonitrile was recovered from volatile traps (24-27%AR by day 102). This was not the case in the other two experiments, where total recoveries were reasonable but the only volatile trapped was CO_2. An explanation for this may have been that the sediment of the Manningtree and Ongar systems remained largely aerobic, whereas in the Hinchingbrooke and Auchingilisie sediments, anaerobic conditions occurred (evidence from differences in redox potential measurements). Levels of unextracted residue in sediment peaked at 15-20%AR (days 7 and 14), declining marginally after this to 10-15%AR at study ends (31-102 days).

In a non guideline outdoor natural sediment water study carried out in September and October at *ca.* 40°N where water temperatures were in the range 11.9-43.7°C, methomyl was applied to water columns of 13.1cm depth overlying 4.4cm of sediment with aquatic plants present (*ca.* 0.09g/ml). Methomyl dissipation from the water column was faster than in the dark 20°C guideline laboratory sediment water studies with a first order DT50 of 1.4 days (r^2=0.9, non linear least squares). In the study sorption to plants was a major sink for the applied methomyl accounting for up to 38%AR after 48 hours.

In addition, a body of data (not guideline studies) was provided that demonstrates that under reducing conditions (anaerobic conditions in sediment, anaerobic conditions in saturated subsoil, (see section B.8.2.4) or when ferrous ions are present in solution) methomyl is rapidly degraded and forms the volatile breakdown products acetonitrile or in saturated subsoil methanethiol. Under these conditions breakdown of methomyl has been shown to be very rapid (half lives in hours).

Methomyl degrades in the aquatic environment by a number of processes. Under aerobic conditions methomyl will be degraded to methomyl oxime (INX1177) which will be rapidly mineralised to carbon dioxide. This will be the dominating degradation process in the water phase of natural aquatic environments due to the aerobic nature of this compartment. In sediments, anaerobic conditions might be present at times. Under such conditions, micro-organisms degrade methomyl to acetonitrile, which is further degraded to carbon dioxide and/or acetamide. In the guideline laboratory sediment water studies all these identified metabolites were only formed at low levels.

Only acetonitrile in sediment ever represented > 10%AR (up to 10.9%AR only 2.8% on a mass basis) and this declined rapidly. Following the criteria in the aquatic guidance document (Sanco/3268/2001 rev 4, 17 October 2002) because of the fate and behaviour profile of these metabolites in the guideline studies only an aquatic risk assessment for parent methomyl is required.

In the calculation of PEC for the subsequent aquatic risk assessment it is considered appropriate to use the longest 20°C dark guideline aerobic sediment water study water phase first order DT50 of 5 days, this representing a conservative but realistic value.

B.8.5 Impact on water treatment procedures(IIIA 9.2.2)

When applied in to the intended supported crops in accordance with Good Agricultural Practice, exposure to water treatment facilities should be negligible. Data to address this point are therefore not required.

B.8.6 Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw) (IIIA 9.2.1, 9.2.3)

Spatial analyses of the proximity of vineyards and vegetable production areas to surface water bodies

As methomyl requires no spray zones to manage the risk to aquatic life from spray drift (see below and section B.9.2.3), the notifier has investigated the spatial relationship between the cropping intended to have methomyl applied and water bodies.

a) In this study the proximity of surface water adjacent to typical grape growing areas in France was quantified. Three regions within France were selected for spatial analysis based on their known importance for grape production as well as the known proximity of vineyards in these regions to surface water due to the topography of these settings. The selected study sites and related topographic maps for each site were:

1. Bordeaux region: Bordelais vineyards, located northwest of the city of Bordeaux and south of Medoc along the Garonne River; between Castelnau-de-Medoc and St-Laurent-Medoc to the north (French Institut Geographique National (IGN) Série Bleue 1:25,000 topographic maps, IGN #1434 Est (Castelnau-De-Médoc, St-Laurent-Médoc))

2. Burgundy region: Côte d'Or vineyards located south of the city of Beaune; west of the Saône River (IGN Série Bleue 1:25,000 topographic maps, IGN #3024 Ouest (Beaune))

3. Champagne region: Vallée de la Marne vineyards near the city of Dormans, located along the Marne River, west of Epernay [IGN Série Bleue 1:25,000 topographic maps, IGN #2713 Ouest (Dormans)]

Two data categories, or layers, were manually extracted from the IGN maps, the extent of vineyards (internal boundaries were occasionally omitted) and the extent of surface water (including permanent streams, lakes and cisterns). Due to the presence of numerous small "point" sources of water indicated on the map for the Champagne region, a third layer was extracted for this area, namely the extent of "point source" surface water (fountains, springs, reservoirs). The digitisation was performed by drafting the data layers onto clear Mylar film using a permanent pen. Map corner points (registration marks) and geographic locations (majors roads and towns) were also added to each Mylar sheet to assist in subsequent alignment of each map.

After the individual Mylar films outlining the vineyards and water bodies were created for each location, each film was manually digitised using Arc/Info® GIS software. This process involved manually tracing each line on a digitising table, which registered each point along each line as a digital location within Arc/Info®. The accuracy of the digitisation was assessed through determination of the root mean square (RMS) spatial error coefficient. This coefficient determines the highest resolution with which the map can be interpreted. Based on these analyses, the minimum distance between the crop and adjacent water bodies which can be calculated accurately is 4.0-6.7 m. The resulting digitised data layers for each site were error checked and categorised for use in subsequent data analyses.

After the vineyard and water body data layers had been digitised in Arc/Info®, a distance measurement or buffer operation was conducted using the hydrology data layer for each site. A series of fixed-distance buffers were calculated for each hydrology data layer using the following distances for each site:

Site	Distance from permanent surface water
Bordeaux:	10, 15, 25, 100 meters
Burgundy:	25, 50, 100 meters
Champagne:	10, 15, 25, 100 meters

The Burgundy site was the first site analysed and only three distances were used for this location, as listed above. The discretisation was changed for the Bordeaux and Champagne sites to provide additional information for distances closer to the edge of the water body (i.e., 10, 15, 25, and 100 meters instead of 25, 50, and 100 meters). Following calculation of the various buffer widths around each water body, overlay analyses were performed which combined the distance from water categories from the hydrology maps with the location of the corresponding vineyard maps for each study location. These analyses determined how many hectares of vineyards are located within each distance category as well as where they are located.

Bordeaux region: The Bordeaux study site encompassed an area of 23,741 ha with vineyards occupying 4,103.7 ha or 17% of the total surface area. The results of the spatial analyses for the Bordeaux region indicate that only 0.96% (39 ha) of vines are grown closer than 25 m to from the closest surface water while only 0.34% (14ha) of vines are grown closer than 10m from surface water.

Burgundy region: The Burgundy study site extends over an area of approximately 13,000 ha with vineyards present in 3108.5 ha or 24% of the study area. The results of these analyses indicate that only 0.57% (18ha) of vines in the Burgundy region are grown closer than 25 m from the closest surface water.

Champagne region: The Champagne study site encompasses an area greater than 26,000 ha with vineyards present in 2460 ha or 9.3% of this total. Due to the presence of many small, discrete water bodies within the borders of the Champagne region, the proximity of vineyards to surface water was calculated for two cases:

(1) Proximity of vineyards to permanent streams and rivers only

(2) Proximity of vineyards to all water bodies present, including streams, rivers, fountains, springs and reservoirs

The proximity of vineyards to permanent streams and rivers within the Champagne region was assessed and a cumulative assessment of vineyard proximity's to surface water indicate that only 2.18% (54ha) of all vines in this region are grown closer than 25 m from the closest streams and rivers and only 0.88% (22ha) of all vines are grown closer than 10 m from streams and rivers. The proximity results when all water bodies present are considered indicate that only 2.41% (59ha) of vines are grown closer than 25 m from surface water, while only 0.92% (23ha) of vines are grown closer than 10 m from adjacent surface water.

Overall in the grape growing areas of Bordeaux, Burgundy, and Champagne covered by the maps assessed only 1-2.4% (96.7-232.1ha) of all vines are grown at distances closer than 25 m from surface water bodies (permanent streams, rivers, fountains, springs, and reservoirs). In addition only 0.3-0.9 % (19-59ha) of all vines (no assessment was made for the Burgundy region) are grown closer than 10 m from the closest adjacent surface water.

Based on these results, it is concluded that the treatment of vineyards with crop production chemicals will most typically (i.e., >98-99% of the time) be performed at distances of at least 25 m from adjacent surface water. As a result, potential aquatic impacts from spray drift are naturally mitigated in many French locations due to the normal distances maintained between vineyards and adjacent surface water bodies.

(Russell, M., 2002)

b) In this study the aim was to characterise and assess the relative proximity of aquatic systems associated with vegetable and vine crop production (hereafter referred to as "crop") in southern France, southeastern Spain and southern Italy in order to provide information that can help inform assessment of the significance of no spray zone restrictions.

Spatial technologies were used to map water bodies and to examine their locations relative to potentially-treated crop. Eighty high-resolution aerial photographs encompassing approximately 50,000 hectares with a ground resolution of 0.5 meters were obtained in agricultural portions of the French *départements* of Hérault, Gard, Vaucluse and Bouches-du-Rhône near Beziers and Avignon (40 photos), the Italian province of Puglia near Foggia (23 photos), and the Spanish province of Murcia near Lorca (17 photos).

The following aspects of the agricultural landscape were examined:

- Locations of water bodies in the landscape
- Their relative sizes, numbers, and types
- Distribution of various crop as well as other potentially significant land cover types

Each individual water body was examined using the GIS to quantify:

- The presence of crop and other land cover types in areas immediately adjacent to the water bodies (defined by nominal "margins" 5, 10, 15, 20, 25, 30, 40, 50, 60, 65, 70, and 80 meters from the perimeter)

- The distance between the water body and crop in each of the eight cardinal compass directions (i.e., N, NE, E, SE, S, SW, W and NW)

- The amount of perimeter of each water body that was potentially exposed to drift from nearby crop, as well as that which was not subject to potential drift exposure

- The presence of other land cover types in the area between crop and water; in particular, their width and the presence of vegetation that might reduce the transport of spray drift droplets

France:

A spatial analysis of approximately 25,000 hectares of intensely agricultural land near Beziers and Avignon in southern France has confirmed the occurrence of high crop production and high surface water density, making this area a reasonable scenario for high potential exposure of water bodies to spray drift.

Listed below are the key findings from the landscape level analyses based on information about the specific locations of water relative to crop in the study area:

- Arable cropland (potential vegetables) accounted for 5522 hectares (22.5%), and vine crops (grapes) accounted for 6339 hectares (25.8%) of the total area analysed.

- Approximately 752 kilometres of flowing water and 26 hectares of static water bodies (total of 2639 water bodies) were analysed in the study area.

- Manmade canals are the most potentially exposed class. This is due to the fact that canals exist almost exclusively in agricultural areas in order to provide irrigation water and drainage for cropland. Most canals are concrete lined and maintained regularly to prevent sediment build up and plant growth.

- Almost all ponds in this study were small (<0.5 ha) retention ponds for providing irrigation water. They are above ground and have earthen walls 2-5 m tall covered with grass and brush, effectively creating a barrier to most spray drift and all runoff.

Vegetables:

- This study identified all arable cropland as potentially producing vegetables and is therefore conservative in its estimate of potential exposure from applications to vegetables since not all of the cropland will be planted in vegetables simultaneously.

- Of the 5522 hectares of potential vegetable cropland, approximately 3121 hectares or 57% of the total was within 80 m of a water body. Stated conversely, 43% of the total potential application area for pesticides on vegetables was further than 80 m from a water body.

- Approximately 33% of the 2639 water bodies in the study area did not have any potential vegetable crop within 60 meters. Therefore, for approximately one-third of individual water bodies, the impact of spray drift following the application of fungicides and insecticides on vegetables is likely to be negligible.

- In looking at the area within 60 m of all natural flowing water bodies (streams and rivers), over 85% (85% for streams and 90% for rivers) of the 60 m margin was composed of land covers other than arable cropland (potential vegetables).

- When considering only those water bodies that have crop within 60 m, 75% of streams and rivers had more than 61% (streams) and 74% (rivers) of their margins composed of land covers other than arable cropland.

- Very little of the perimeter of natural flowing water bodies were directly adjacent (<1m) to potential vegetable cropland. Rivers have no direct adjacency at all, and 90% of streams have 2% or less of their perimeter directly adjacent to crop.

- When there is crop within 60 m of a water body but not directly adjacent to it (i.e., a natural buffer >1 m wide exists), the average buffer width for natural flowing water bodies is 24 m for streams and 40 m for rivers. The average buffer width for ponds is 37 m and the average buffer width for canals is 17 m.

Vines:

- Of the 6339 hectares of vine cropland, approximately 4063 hectares or 64% of the total is within 80 m of a water body. Stated conversely, 36% of the total potential application area for fungicides and insecticides on vines is further than 80 m from a water body.

- *Ca*. 37% of the 2639 water bodies in the study area do not have any vine crop within 60 meters. Therefore, for just over one-third of individual water bodies, the impact of spray drift following the application of fungicides and insecticides on crop is likely to be negligible.

- In looking at the area within 60 m of all natural flowing water bodies (streams and rivers), over 77% (77% for streams and 93% for rivers) of the 60 m margin is composed of land covers other than vine cropland.

- When considering only those water bodies that have crop within 60 m, 75% of streams and rivers have more than 23% (streams) and 92% (rivers) of their margins composed of land covers other than arable cropland.

- Unlike vegetables, vines are more closely associated with streams with 90% of all streams having 32% or less of their perimeters directly adjacent to vines. Rivers still have no direct adjacency at all.

- When there is crop within 60 m of a water body but not directly adjacent to it (i.e., a natural buffer >1 m wide exists), the average buffer width for natural flowing water bodies is approximately 15 m for streams and 45 m for rivers. The average buffer width for ponds is approximately 29 m, and the average buffer width for canals is approximately 12 m.

Italy:

A spatial analysis of approximately 14,375 hectares of intensely cultivated agricultural land in the province of Puglia in southern Italy confirmed the occurrence of high crop production and high surface water density, making this area a reasonable scenario for high potential exposure of water bodies by spray drift.

Listed below are the key findings from the landscape level analyses based on information about the specific locations of water relative to crop in the study area.

Vegetables:

- Arable cropland (potential vegetables) accounted for 10,149 hectares (71.1%). This study identified all arable cropland as potentially producing vegetables and is therefore conservative in its estimate of potential exposure from applications to vegetables since not all of the cropland will be planted in vegetables simultaneously.
- Approximately 212 kilometres of flowing water and 46 hectares of static water bodies (total of 594 water bodies) were identified in the study area.
- Manmade canals were the most potentially exposed class. This is due to the fact that canals exist almost exclusively in agricultural areas in order to provide irrigation water and drainage for cropland. Most canals are concrete lined and maintained regularly to prevent sediment build up and plant growth.
- Almost all ponds in this study were small (<0.5 ha) retention ponds for providing irrigation water. They are above ground and have earthen walls 2-5 m tall covered with grass and brush, effectively creating a barrier to most spray drift and all runoff.
- Of the 10,149 hectares of potential vegetable cropland, approximately 2866 hectares or 28% of the total was within 80 m of a water body. Stated conversely, 72% of the total potential application area for vegetables was further than 80 m from a water body.
- Almost all of the 594 water bodies in the study area had some amount of vegetable crop within 60 meters. However, in looking at the area within 60 m of all natural flowing water bodies (streams and rivers), over 38% (38% for streams and 97% for rivers) of the 60 m margin was composed of land covers other than arable cropland.
- When considering only those water bodies that have crop within 60 m, half of all streams and rivers had more than 23% (streams) and 97% (rivers) of their margins composed of land covers other than arable cropland.
- Despite the intensely agricultural landscape, virtually none of the perimeter of natural flowing water bodies was directly adjacent (<1 m) to potential vegetable cropland. Rivers have no direct adjacency at all, and 90% of streams have 4% or less of their perimeter directly adjacent to crop.
- Rivers appear to have significant natural protections in this landscape, with virtually no direct adjacency, large natural buffers, and small amounts of cropland within 60 m of the rivers.

- When there is crop within 60 m of a water body but not directly adjacent to it (i.e., a natural buffer >1 m wide exists), the average buffer width for natural flowing water bodies was 15 m for streams and 48 m for rivers. The average buffer width for ponds was 14 m and the average buffer width for canals was 7 m.

Vines:

- Vine crops accounted for only 474 hectares (3.3%) of this area. No further assessment of the proximity of water bodies to vines was carried out.

Spain:

A spatial analysis of approximately 10,625 hectares of intensely cultivated agricultural land in the province of Murcia in south-eastern Spain confirmed the occurrence of high crop production and high surface water density, making this area a reasonable scenario for high potential exposure of water bodies by spray drift.

Listed below are the key findings from the landscape level analyses based on information about the specific locations of water relative to crop in the study area

Vegetables:

- Arable cropland (potential vegetables) accounted for 6558 hectares (62.3%). This study identified all arable cropland as potentially producing vegetables and is therefore conservative in its estimate of potential exposure from applications to vegetables since not all of the cropland will be planted in vegetables simultaneously.

- Approximately 187 kilometres of flowing water and 150 hectares of static water bodies (total of 1005 water bodies) were analysed in the study area.

- Manmade canals are the most potentially exposed class. This is due to the fact that canals exist almost exclusively in agricultural areas in order to provide irrigation water and drainage for cropland. Most canals are concrete lined and maintained regularly to prevent sediment build up and plant growth.

- Almost all ponds in this study were small (<0.5 ha) retention ponds for providing irrigation water. They are above ground and have earthen walls 2-8 m tall covered with grass and brush, effectively creating a barrier to most spray drift and all runoff.

- Of the 6558 hectares of potential vegetable cropland, approximately 3083 hectares or 47% of the total is within 80 m of a water body. Stated conversely, 53% of the total potential application area for fungicides and insecticides on vegetables was further than 80 m from a water body.

- Almost all of the 1005 water bodies in the study area had some amount of vegetable crop within 60 meters. However, in looking at the area within 60 m of all natural flowing water bodies (streams and rivers), over 60% (59% for streams and 78% for rivers) of the 60 m margin is composed of land covers other than arable cropland.

- When considering only those water bodies that have crop within 60 m, half of all streams and rivers have more than 67% (streams) and 79% (rivers) of their margins composed of land covers other than arable cropland.

- Virtually none of the perimeter of natural flowing water bodies is directly adjacent (<1 m) to potential vegetable cropland. Rivers have no direct adjacency at all, and 90% of streams have 1% or less of their perimeter directly adjacent to crop.

- When there is crop within 60 m of a water body but not directly adjacent to it (i.e., a natural buffer >1 m wide exists), the average buffer width for natural flowing water bodies is 30 m for streams and 40 m for rivers. The average buffer width for ponds is 17 m and the average buffer width for canals is 11 m.

Vines:

- Vine crops accounted for only 62 hectares (0.6%) of this area. No further assessment of the proximity of water bodies to vines was carried out.

(Kay, S. and Holmes, C., 2003)

Surface Water

The intended representative uses are 2 spray applications at 14 day intervals of 450g methomyl / ha to grapes and vegetables.

For taller growing vegetables (tomatoes) and applications post flowering to grapes at a baseline distance to the water body of 3m, agreed drift tables in Sanco/3268/2001 (1 October 2001, overall 90^{th} % values) identify that 7.23% spray drift can be assumed when 2 applications are made. Assuming this drift input goes to a 30cm deep static water body in which a first order DT50 (longest from 4 water sediment systems) of 5 days occurs, the following PEC are calculated. (Concentrations calculated for a single application and 8.02% drift at 3m are lower):

Table B.8.75 PECsw for the intended use on grapes post flowering and tomatoes with the base distance to a 30cm deep water body of 3m (7.23% drift).

Days after last appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	12.40	12.40
1	10.80	11.58
2	9.40	10.83
4	7.12	9.52
7	4.70	7.94
14	1.78	5.47
28	0.27	3.13
50	0.01	1.79
100	0.00	0.89

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 15m no spray zone (0.65% drift with 1 application, concentrations calculated for 2 application and 0.56% drift at 15m are lower) the following PEC are calculated.

Table B.8.76 PECsw for the intended use on grapes post flowering and tomatoes to a 30cm deep water body with a 15m no spray zone (0.65% drift).

Days after appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	0.97	0.97
1	0.85	0.91
2	0.74	0.85
4	0.56	0.75
7	0.37	0.62
14	0.14	0.43
28	0.02	0.25
50	0.00	0.14
100	0.00	0.07

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 50m no spray zone (0.1% drift with 1 application, concentrations calculated for 2 application and 0.08% drift at 50m are lower) the following PEC are calculated.

Table B.8.77 PECsw for the intended use on grapes post flowering and tomatoes to a 30cm deep water body with a 50m no spray zone (0.1% drift).

Days after appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	0.15	0.15
1	0.13	0.14
2	0.11	0.13
4	0.07	0.11
7	0.06	0.07
14	0.02	0.07
28	0.00	0.04
50	0.00	0.02
100	0.00	0.01

For the intended representative use on grapes with early applications before flowering, using the assumptions above at a baseline distance to the water body of 3m (2.53% drift, 2 application drift figure gives the highest PEC) the following PEC are calculated.

Table B.8.78 PECsw for the intended use on grapes before flowering to a 30cm deep water body with a 3m baseline distance (2.53% drift).

Days after last appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	4.34	4.34
1	3.78	4.05
2	3.29	3.79
4	2.49	3.33
7	1.64	2.78
14	0.62	1.91
28	0.09	1.09
50	0.004	0.63
100	0.00	0.31

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 10m no spray zone (0.35% drift) the following PEC are calculated.

Table B.8.79 PECsw for the intended use on grapes before flowering to a 30cm deep water body with a 10m no spray zone (0.35% drift).

Days after last appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	0.60	0.60
1	0.52	0.56
2	0.45	0.52
4	0.34	0.46
7	0.23	0.38
14	0.09	0.26
28	0.01	0.15
50	0.00	0.09
100	0.00	0.04

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 30m no spray zone (0.06% drift) the following PEC are calculated.

Table B.8.80 PECsw for the intended use on grapes before flowering to a 30cm deep water body with a 30m no spray zone (0.06% drift).

Days after last appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	0.10	0.10
1	0.09	0.10
2	0.08	0.09
4	0.06	0.08
7	0.04	0.07
14	0.01	0.04
28	0.002	0.03
50	0.0	0.01
100	0.0	0.007

For the intended representative use on low growing vegetables (courgette and aubergine), using the assumptions above but for a single application at a baseline distance to the water body of 1m (2.77% drift) the following PEC are calculated. (Concentrations calculated for 2 application and 2.38% drift at 1m are lower).

Table B.8.81 PECsw for the intended use on courgette and aubergine to a 30cm deep water body with a 1 m baseline distance (2.77% drift).

Days after appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	4.15	4.15
1	3.62	3.88
2	3.15	3.63
4	2.39	3.19
7	1.57	2.66
14	0.60	1.83
28	0.09	1.05
50	0.004	0.60
100	0.00	0.30

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 10m no spray zone (0.29% drift) the following PEC are calculated.

Table B.8.82 PECsw for the intended use on courgette and aubergine to a 30cm deep water body with a 10m no spray zone (0.29% drift).

Days after appl'n	PECsw (µg/l)	Time weighted average (µg/l)
0	0.43	0.43
1	0.38	0.41
2	0.33	0.38
4	0.25	0.33
7	0.16	0.28
14	0.06	0.19
28	0.009	0.11
50	0.00	0.06
100	0.00	0.03

Larger buffer zones reduce surface water exposure. Using the assumptions above and a 30m no spray zone (0.1% drift) the following PEC are calculated.

Table B.8.83 PECsw for the intended use on courgette and aubergine to a 30cm deep water body with a 30m no spray zone (0.1% drift).

PECsw values are the same as in table B8.77

Sediment

In the available studies partitioning to sediment of methomyl was relatively limited. In 3 of the 4 guideline laboratory sediment water studies and in the non guideline outdoor study, partitioning to sediment was negligible with methomyl staying almost entirely in the water phase (maximum concentrations at any time point were in the range <1% - 6.2% AR). The exception to this was in the 5.8% organic carbon Hinchingbrooke silty clay loam water / sediment system, 2 days after application to the water column where methomyl reached 11.4%AR. This value of 11.4%AR had declined to <0.4%AR by day 14 of the experiment (i.e. accumulation in sediment from 2 applications 14 days apart would not occur). These results from the sediment water studies (by day 14 methomyl in sediment represented significantly <10%AR) means that according to the criteria set out in Sanco/3268/2001 rev 4 final (17 October 2002), separate testing of toxicity to a sediment dwelling species and a separate risk assessment for sediment dwellers are not required. The risk assessment to free living aquatic invertebrates is considered sufficient to cover the risk to sediment dwellers.

However for completeness to enable the fate endpoints to be completed as required by the EU Peer review procedures, PECsed are calculated below.

For the intended use pattern of late applications to vines or tomatoes with a base distance to a water body of 3m resulting in 8.02% drift; assuming a 30cm deep static water body overlaying a 5cm depth sediment, with even incorporation of methomyl over this 5cm and a wet sediment bulk density of $1.3 g/cm^3$, a worst case maximum

PECsed of 6.3µg/kg 2 days after application is calculated declining to <0.22µg/kg 12 days later.

With a 15m no spray zone (0.65% drift) these calculated worst case concentrations are 0.51µg/kg 2 days after application declining to <0.02µg/kg 12 days later.

With a 50m no spray zone (0.1% drift) these calculated worst case concentrations are 0.08µg/kg 2 days after application declining to <0.003µg/kg 12 days later.

For the intended use pattern on courgette and aubergine with a base distance to a water body of 1m (2.77% drift) these worst case concentrations are 2.19µg/kg 2 days after application declining to <0.08µg/kg 12 days later.

For the intended use pattern on courgette and aubergine and a 10m no spray zone (0.29% drift) these worst case concentrations are 0.23µg/kg 2 days after application declining to <0.008µg/kg 12 days later.

For the intended use pattern on courgette and aubergine and a 30m no spray zone (0.1% drift) these worst case concentrations are 0.08µg/kg 2 days after application declining to <0.003µg/kg 12 days later.

For a risk assessment to sediment dwellers if water spiking ecotoxicity tests had been carried out, the PECsw calculated above could have been used directly. (A pseudo PECsw for use in sediment dweller risk assessment would not be required, as the rapid dissipation of methomyl in sediment means that there is no accumulation of methomyl in sediment from the intended use pattern with an application interval of 14 days).

Groundwater

The notifier submitted groundwater modelling using FOCUS PRZM 2.2.1 and FOCUS PEARL 1.1.1. for the intended uses grapes and tomatoes for the pertinent FOCUS scenarios. As the laboratory soil degradation database for methomyl includes data not owned by the main notifier for methomyl the rapporteur has re-run the simulations using all the available information (which includes data submitted for the review of the related active substance thiodicarb). The results of these simulations gave marginally higher calculated maximum annual average concentrations than those presented in the applicants report (Dust, M., 2001b). In addition for completeness the rapporteurs simulations included leaching estimates for the minor soil metabolite methomyl oxime (INX1177).

The modelling described below was that carried out by the rapporteur.

FOCUS PRZM 2.4.1 and FOCUS PEARL 1.1.1 were run for all pertinent scenarios for the crops vines and tomatoes. Applications (2 every year) were simulated at a rate of 450 g a.s./ha (225g a.s./ha modified for 50% crop interception for tomatoes and 180g a.s./ha modified for 60% crop interception for vines) with a 14 day application interval with the first application being made 65 days after ‘emergence’ for grapes and 30 days after ‘emergence’ for tomatoes (‘emergence’ dates as defined by FOCUS for each pertinent scenario). The pesticide properties used as input were as summarised in table

B.8.84 Default Q10 of 2.2 / Arrhenius activation energy of 54 kj mol^{-1} and Walker equation exponent of 0.7 were utilised.

Table B.8.84 Summary of input parameters used for methomyl and methomyl oxime FOCUS groundwater modelling

Input parameter	Unit	methomyl	Methomyl oxime
Physico-chemical parameters			
Vapour pressure	Pa	7.2×10^{-4} (25°C)	No information 0 input
Molecular mass	$g.mol^{-1}$	162.2	105.16
Water solubility	$mg.l^{-1}$	54600 (25°C)	No information 0 input to PRZM, 100 input to PEARL
Plant uptake factor		0	0
Degradation parameters			
*Half-life (First order DT50)	days	7.38	0.67
Formation assumed from methomyl	%	-	100
Sorption parameters			
$^{@}Kf_{OC}$ K_{OM}	$cm^3.g^{-1}$	25.2 14.6	11.4 6.6
@Freundlich sorption exponent (1/n)		0.86	0.78

* geometric mean value normalised to 20°C and –10kPa see table B.8.32
@ arithmetic mean values see section B.8.2.5

Model outputs as prescribed by FOCUS recommendations and provided by the FOCUS PRZM and FOCUS PEARL shells for methomyl are tabulated in Table B.8.85. The model outputs for methomyl oxime (INX1177) gave 80th percentile annual average concentrations past 1m depth of <0.001µg/l for both crops and all the pertinent scenarios except with PEARL at Piacenza where the concentration was 0.005µg/l on vines and 0.002µg/l on tomatoes.

Table B.8.85 80th percentile annual average concentrations of methomyl from FOCUS PRZM 2.4.1 and FOCUS PEARL 1.1.1 modelled flux values past 1m depth

	PRZM	**PEARL**
Scenario[1]	**80th % annual average** (µg/l)	**80th % annual average** (µg/l)
Grape vines		
Chateaudun	<0.001	0.003
Hamburg	0.003	0.001
Kremsmunster	0.001	0.001
Piacenza	<0.001	0.084
Porto	<0.001	<0.001
Sevilla	<0.001	<0.001
Thiva	<0.001	<0.001
Tomatoes		
Chateaudun	<0.001	0.003
Piacenza	<0.001	0.042
Porto	<0.001	<0.001
Sevilla	<0.001	<0.001
Thiva	<0.001	<0.001

B.8.7 Fate and behaviour in air (IIA 7.2.2, IIIA 9.3)

The vapour pressure and Henry Law Constant for methomyl are reported in Section B.2. The following values were obtained.

Vapour pressure	7.2×10^{-4} Pa at 25°C	(§ B.2.1.5)
Henry's Law Constant	2.1×10^{-6} pascals-m³/mole	(§ B.2.1.6)

a) The volatility of methomyl from soil and plant surfaces was studied according to BBA Guidelines (Part IV, 6-1, 1990).

The volatilisation of methomyl, applied to the surface of a sandy soil and to the surface of French beans, was studied in a volatilisation chamber for 24 hours. Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 45.244 µCi/mg (radiochemical purity 99%) was dissolved in methanol then added to unlabeled Lannate® L formulation in 27 ml water. The final methomyl application rate was approximately 50 mg/0.5m^2, equivalent to an application rate of 4 kg Lannate® L/ha using a spray volume of 300 L/ha.

Treated samples were maintained in dark volatilisation chambers maintained at 20°C with a relative humidity of 50 ± 10%. In duplicate experiments, the radiolabel present at 24 hours was quantified on the soil or plants, in polyurethane volatile traps, and in other volatile [water, acetonitrile, carbon and CO_2] traps subsequent to the foam plugs.

[1] Scenarios as defined in SANCO/321/2000 rev2

The soil, plants, and polyurethane plugs were extracted with methanol. Combined extracts were analysed by liquid scintillation counting (LSC) and by TLC.

Table B.8.86: Physical and chemical characteristics of the test soil

Origin Location	Speyer, Germany
pH ($CaCl_2$)	5.3
% Sand (2000 - 50 µm)	78.9
% Silt (<50 - 2 µm)	**18.3**
% Clay (<2 µm)	**2.8**
Organic carbon (mg/100 g dry soil)	**920**

Soil

After 24 hours, total recovery of radiolabel ranged from 83-88%. The soil and polyurethane foam plugs contained 80-84% and 3% of the radiolabel, respectively. No radiolabel was found in the traps for water, acetonitrile, carbon or CO_2. Methomyl accounted for >90% of the radioactivity extracted from the foam plugs and the soil. Supplementary experiments indicated that the loss of radioactivity may have occurred during soil homogenisation.

Plants

After 24 hours, total recovery of radiolabel was 81%. The plants and polyurethane foam plugs contained 54-60% and 21-27% of the radiolabel, respectively. No radiolabel was found in the traps for water, acetonitrile or CO_2. Supplementary experiments indicated that the loss of radioactivity may have occurred during homogenisation and extraction of the plants.

Methomyl volatilisation from bare soil after 24 hours in a volatilisation chamber was low (3% applied radiolabel). From bean surfaces, 21-27% volatilised. No degradates were found.

(Kubiak, R., 1994)

b.) The study of volatilisation of ^{14}C-methomyl formulated according to Lannate® L with a content of 250 g/L methomyl from polyethylene film under laboratory conditions was made.

The volatilisation of methomyl from polyethylene film was studied in a volatilisation chamber for 24 hours. Radiolabelled [1-^{14}C]methomyl with a specific radioactivity of 45.244 µCi/mg (radiochemical purity 99%) was dissolved in 200 µL methanol then added to unlabeled Lannate® L formulation in 27 ml water. The final methomyl application rate to polyethylene film was approximately 60 mg/0.5m^2. In duplicate experiments, samples were maintained in dark volatilisation chambers maintained at 20 ± 2°C with a relative humidity of 50 ± 10%. The radiolabel present at 24 hours was quantified on the film, in polyurethane volatile traps, and in other volatile (water, acetonitrile, and CO_2) traps subsequent to the foam plugs.

The film and polyurethane plugs were extracted with methanol. Combined extracts were analysed by liquid scintillation counting (LSC) and by TLC.

After 24 hours, total recovery of radiolabel ranged from 98.8 to 100.5%. The majority of radiolabel (70-75%) remained on the polyethylene film while 22-24% of the radiolabel was found in the polyurethane foam plugs. Low levels of radiolabel (2-7%) passed through the film to filter paper beneath the film. No radiolabel was found in the traps for water, acetonitrile or CO_2. Only methomyl was present on the film and in the polyurethane plugs.

After 24 hours in a volatilisation chamber, 23% of methomyl applied to polyethylene film volatilised. No degradates were found.

(Ellssel, H. and Kubiak, R., 1993)

c.) The potential stability in the upper atmosphere of methomyl was assessed (Atkinson calculation).

A rate of photochemical oxidative degradation of methomyl was estimated using the Syracuse Research Corporation (SRC) Atmospheric Oxidation Program (Version 1.83).

The overall OH rate constant calculated was 6.6481×10^{12} cm^3/molecule-s. Hydrogen abstraction and reaction with both nitrogen and sulphur are predicted to contribute to the photochemical degradation rate. The half-life of methomyl for reaction with average daily air concentrations of hydroxyl radicals (12-hr day, 1.5×10^6 OH radicals per cm^3) is 19.037 hours.

The half-life of methomyl via indirect phototransformation in the gas phase in the troposphere is therefore calculated to be19 hours.

(Jeffery, D., 2001)

Summary and Assessment

The vapour pressure of 7.2×10^{-4} Pa at 25°C, Henrys law constant of 2.1×10^{-6} pascals-m^3/mole and dimensionless Henrys law coefficient at 20°C of 8.6×10^{-10} indicate that methomyl due to its high water solubility (54.6 g/l at 25°C) is unlikely to volatilise from water / soil water. This was confirmed by the study on volatility from soil and the available laboratory sediment water studies. A volatility experiment using bean leaves indicates volatilisation from plants will occur (up to 27% volatilised within 24 hours at 20°C with a relative humidity of 50 ± 10%). The Atkinson calculation indicates that volatilisation losses to the upper atmosphere will be degraded by indirect phototransformation with a half life calculated at 19 hours. Long range transport of methomyl is therefor not likely to be very significant.

B.8.8 Predicted environmental concentrations in air (PECa) (IIIA 9.3)

Any potential losses of methomyl to the atmosphere after application will be diluted through mixing and diffusion in air and eliminated in the upper atmosphere by indirect phototransformation. Concentrations in air can therefore be assessed as likely to be negligible.

B.8.9 Definition of the residue (IIA 7.3)

In soil parent methomyl only was the major (>10% Applied) component of the residue.

In surface water methomyl only was the major (>10% Applied) component of the residue.

In sediment parent methomyl and acetonitrile were the major (>10% Applied) components of the residue. Acetonitrile was a very transient metabolite.

In groundwater, parent compound only is considered to have the potential to be detected and this is considered unlikely from the representative use pattern assessed in this document.

It is proposed the relevant residue for monitoring should just be parent methomyl in the environmental compartments: soil, water, sediment, groundwater and air.

B.8.10 References relied on

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protection Claimed (Y/N)	Owner
Aikens, P.J.	IIA, 7.1.2.1./01	2001a	Adsorption/desorption of [^{14}C]methomyl in five soils Huntingdon Research Centre (UK) DuPont-4501 GLP: Yes Published: No	Y	DuPont
Aikens, P.J.	IIA, 7.1.2.2./01	2001b	Adsorption/desorption of [^{14}C]IN-X1177, a metabolite of methomyl, in five soils Huntingdon Research Centre (UK) DuPont-4502 GLP: Yes Published: No	Y	DuPont
Aldred, D.	IIA, 7.2.1.3.1./01	1992	Determination of the ready biodegradability of methomyl by the modified Sturm test Euro Laboratories Limited AMR 2337-92 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protection Claimed (Y/N)	Owner
Armbrust, K.L., Rielly, D.	IIA, 7.2.1.2.1./02	1995	Indirect photodegradation of methomyl in aqueous solutions DuPont Experimental Station AMR 2975-94 GLP: Yes Published: No	Y	DuPont
Bromilow, R.H., Briggs, G.G., Williams, M.R., Smelt, J.H., Tuinstra, L.G.M.T., Traag, W.A.	IIA, 7.2.1.4./02	1985	The role of ferrous ions in the rapid degradation of oxamyl, methomyl, and aldicarb in anaerobic soils. Rothamsted Experimental Station METH/ENV 3 GLP: No Published: Yes	N	Public information
Burr, C.M.	IIA 7.1.1.1.1/01	2000a	(14C)-thiodicarb: rate of degradation in three soils at 20 degress C and one soil at 10 degrees C. Generated by: Aventis CropScience UK Ltd, GBR Document No: C019338 GLP/GEP: Yes unpublished	Yes	Aventis Crop Science
Feung, C.S.; Wesibach, P.J.	IIA 7.1.1.1.2/01	1991c	Aerobic soil metabolism of thiodicarb:. Generated by: Rhône-Poulenc Ag Company, USA Document No: R008592 GLP/GEP: Yes unpublished	Yes	Aventis Crop Science
Friedman, P.L.	IIA, 7.2.1.1.1./01	1983	Hydrolysis of [1-^{14}C]methomyl DuPont Experimental Station AMR 109-83 GLP: No Published: No	Y	DuPont
Jeffery, D.J.	IIA, 7.2.2./03	2001	The stability in air of methomyl (DPX-X1179): Atkinson calculation Stine-Haskell Research Center DuPont-4653 GLP: No – calculation Published: No	Y	DuPont
Kay, S., Holmes, C.	IIA, 7.2./02	2003	Spatial analysis of vineyards and vegetable production areas in France, Italy and Spain Waterborne Environmental Inc. DuPont-11542 GLP: No Published: No	Y	DuPont
Koch Singles, S., Theilacker, W.M.	IIA, 7.2.1.3.2./03	2002	Rate of dissipation of [1-^{14}C]methomyl from the water phase of a simulated pond Stine-Haskell Research Center DuPont-7474 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protec-tion Claimed (Y/N)	Owner
Kubiak, R.	IIA, 7.2.2./01	1994	Volatilization of ^{14}C-methomyl formulated according to Lannate® L with a content of 250 g/L methomyl from plant and soil surfaces under laboratory conditions Fachbereich Phytomedizin in SLFA AMR 2516-92 GLP: Yes Published: No	Y	DuPont
Langford-Pollard, A.D.	IIA, 7.1.3.1./01; IIA, 7.1.3.2./01; IIA, 7.1.1.1.1./03	1994	The soil column leaching of [1-^{14}C]methomyl Huntingdon Research Centre (UK) AMR 2778-93 GLP: Yes Published: No	Y	DuPont
Mayo, B.C.	IIA, 7.2.1.3.2./01	1994	Degradability and fate of [1-^{14}C]methomyl in water/sediment systems Huntingdon Research Centre (UK) AMR 2590-92 GLP: Yes Published: No	Y	DuPont
Moore, L.A.	IIA, 7.2.1.2.1./01	1999	UV/visible absorption of methomyl DuPont Experimental Station DuPont-3116 GLP: Yes Published: No	Y	DuPont
Oddy, A.M.; Roach, S	IIA 7.2.1.3.2.2/01	1999a	(14C)-methomyl: degradation in two water sediment systems. Generated by: Rhône-Poulenc Ag Ltd, Ongar, UK Document No: R014194 GLP/GEP: Yes unpublished	Yes	Aventis Crop Science
Pedersen, C.T.	IIA, 7.2.1.1.2./01	2001	Hydrolysis of [1-^{14}C]methomyl (DPX-X1179) technical in pH 4, 5, and 6 buffer solutions at high temperatures Stine-Haskell Research Center DuPont 5772 GLP: Yes Published: No	Y	DuPont
Russell, M.H.	IIA, 7.2./01	2002	Spatial analysis of vineyards in the Bordeaux, Burgundy, and Champagne regions of France Stine-Haskell Research Center DuPont-11541 GLP: No Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protec-tion Claimed (Y/N)	Owner
Ryan, D.L.	IIA, 7.2.1.3.2./02	1995	Behavior of methomyl in stream, canal, ditch and pond sediments DuPont Experimental Station AMR 3381-95 GLP: Yes Published: No	Y	DuPont
Shaw, D.	IIA, 7.1.1.1.1./02; IIA, 7.1.1.2.1.1./01	2001a	[^{14}C]methomyl: rate of degradation in three aerobic soils Huntingdon Research Centre (UK) DuPont-5511 GLP: Yes Published: No	Y	DuPont
Shaw, D.	IIA, 7.1.1.2.1.1./03	2001b	[^{14}C]-Methomyl oxime: rate of degradation in three aerobic soils Huntingdon Research Centre (UK) DuPont-5512 GLP: Yes Published: No	Y	DuPont
Smelt, J.H., Dekker, A., Leistra, M., Houx, N.W.H.	IIA, 7.2.1.4./01	1983	Conversion of four carbamoyloximes in soil samples from above and below the soil water table Institute for Pesticide Research METH ENV 2 PAP GLP: No Published: Yes	N	Public information
Swanson, M.B.	IIA, 7.1.1.1.2.2./01	1986	Photodegradation of [1-^{14}C]methomyl on soil DuPont Experimental Station AMR 611-86 GLP: Yes Published: No	Y	DuPont
Zwick, T.C., Malik, N.	IIA, 7.1.1.1.1./01; IIA, 7.1.1.2.1.1./02	1990a	Aerobic metabolism of [1-^{14}C]methomyl in Madera, California, soil Battelle (Ohio) AMR 1543-89 GLP: No Published: No	Y	DuPont
Zwick, T.C., Malik, N.	IIA, 7.1.1.1.2.1./01; IIA, 7.1.1.2.1.2./01	1990b	Anaerobic metabolism of [1-^{14}C]methomyl in Madera, California, Soil Battelle (Ohio) AMR 1544-89 GLP: Yes Published: No	Y	DuPont

Plant Protection Product – Methomyl 20SL

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protection Claimed (Y/N)	Owner
Dust, M.	IIIA, 9.2.1./01	2001b	Model assessment of the potential groundwater concentrations of methomyl (DPX-X1179) after use of Methomyl 20SL in grapes and vegetables in Europe DuPont de Nemours (Deutschland) GmbH DuPont-7537 GLP: No Published: No	N	DuPont

Pages 387-389 do not exist.

B.9 Ecotoxicology

Background

Methomyl is an insecticide used in the control of biting and sucking insects. It is formulated as the product 'Methomyl 20SL' containing 200 g a.s./l. The representative uses are summarised in Table B.9.1 (see **Note** below).

Table B.9.1 Summary of proposed uses for methomyl formulated as 'Methomyl 20SL'

Crop/situation	Member state or country	Max. No Treatments	Kg a.s./ha max individual dose	max total dose	Treatment interval	Growth stage
Fruiting vegetable (field) crops:						
Cucumber/courgette (F)	EU (S)	2	0.25-0.45	0.5-0.9	14 days	Pre-harvest
tomato/aubergine (F)	EU (S)	2	0.25-0.45	0.5-0.9	14 days	Pre-harvest
Grape (table & wine) (F)	EU (N+S)	2	0.45	0.9	14 days	Pre-harvest

F = field, G = Glasshouse (protected), N= northern Member States, S=southern Member States

Note - following the original submission, the notifier revised the above GAP on grape to reflect that shown in Volume 1, Table 1.1. However, no new risk assessments were submitted by the notifier to reflect this new GAP and therefore no assessment of it has been conducted here. The maximum application rate per treatment in the revised GAP is within the maximum originally cited.

B.9.1 Effects on birds (IIA 8.1, IIIA 10.1)

B.9.1.1 Acute oral toxicity (IIA 8.1.1, IIIA 10.1.1)

Active substance

The results from an acute oral toxicity study with methomyl are summarised in Table B.9.2.

Table B.9.2 Summary of acute oral toxicity data for methomyl

Species	**Purity (%)**	**Acute oral LD50 (mg/kg bw)**	**Test Guideline**	**Reference**
Bobwhite quail *Colinus virginianus*	98.7	24.2[1]	FIFRA 71-2 and not to GLP	Beavers, J.B (1983): HLO 464-83

Five males and five females per dose level. Fourteen day observation period.
[1]95% confidence limits 18.5 to 36.2 mg/kg bw

Plant protection product

The results from an acute oral toxicity study with Methomyl 20SL are summarised in Table B.9.3.

Table B.9.3 Summary of acute oral toxicity data for Methomyl 20SL

Species	Active substance content	Acute oral LD50 (mg/kg bw)	Test Guideline	Reference
Bobwhite quail *Colinus virginianus*	196 g a.s./l	152 mg product/kg 30.4 mg a.s./kg[1, 2]	US EPA 850.2100, GLP	Troup, R. & Barouch, J. (2000) 3394

Five males and five females per dose level. Fourteen day observation period.
[1]Confidence limits 121.5 – 200 mg product/kg (24.3-40.0 mg a.s./kg).
[2]From day-0 to day-3 food consumption in the treatment groups of 30 and 40 mg a.s./kg bw was significantly less than the control. No significant difference subsequently in food consumption was noted.

B.9.1.2 Dietary toxicity (IIA 8.1.2)

Active substance

a) In a study on the short-term dietary toxicity of technical methomyl (purity 98.7%) to young bobwhite quail (13 days old), 7 experimental groups (10 per diet group plus 2 control groups) were fed methomyl in their diet at nominal test concentrations of 178, 316, 562, 1000, 1780, 3160 and 5620 ppm methomyl diet for a 5 day exposure period, followed by a 3 day observation period. During the observation period birds received a toxicant-free diet. The control birds received the basal diet throughout the study. The birds were observed daily for mortality and toxicity. Body weights were recorded at initiation of acclimation, and on days 0, 5 and 8 (test termination day) of the definitive test. Measured concentrations were confirmed by analysis to be within 81.6 –102% of the nominal concentrations.

Toxicological symptoms were noted in the 1780, 3160 and 5620 ppm diet groups, with no mortality in any group. In all of these groups birds displayed slight ataxia and lethargy. In addition, in the 3160 ppm group abnormal behaviours included hyporeactivity, fluffed feathers and wing droop, and in the 5620 ppm group, hyporeactivity, wing droop and laboured breathing were observed. There were statistically significant decreases in percent body weight gains in the 316, 562, 1000, 1780, 3160 and 5620 mg a.s./kg diet groups compared to the control groups on days 0-5. On day 8, significant decreases in percent body weight gains were observed only in the five highest doses when compared with the controls. There was also a decrease in the feed consumption in the 562, 1000, 1780, 3160 and 5620 ppm diet groups during the feed consumption period (days 0-5). No test substance related abnormalities or other indications of toxicity were noted for any of the groups during the gross necropsy examinations.

The 8-day dietary LC50 of methomyl for northern bobwhite quail was >5620 ppm diet the highest concentration tested as no mortality was observed. A No-Observed Effect Concentration (NOEC) for signs of toxicity was determined to be 178 ppm diet, due to the decrease in body weight gains from 316 ppm diet, and the NOEC for mortality was determined to be 5620 ppm diet.

The study was conducted according to OECD 205 and in compliance with GLP.

(Medlicott, B.A and Harris, T (2000): DuPont-4378, No. 00022)

b) In a study on the short-term dietary toxicity of technical methomyl (purity 98.7%) to young mallard ducks (9 days old), 7 experimental groups (10 per diet group plus 2 control groups) were fed methomyl in their diet at nominal test concentrations of 178, 316, 562, 1000, 1780, 3160 and 5620 ppm diet for a 5 day exposure period, followed by a 3 day observation period. During the observation period birds received a toxicant-free diet. The control birds received the basal diet throughout the study. The birds were observed daily for mortality and toxicity. Body weights were recorded at initiation of acclimation and on days 0, 5 and 8 (test termination day) of the definitive test. Measured concentrations were confirmed by analysis to be within 81.6 –102% of the nominal concentrations.

Toxicological symptoms were noted in the 178, 316, 562, 1000, 1780, 3160 and 5620 mg a.s./kg diet groups. A range of symptoms were observed which included head twitching, slight lethargy and ataxia, hyporeactivity, salivation, laboured breathing and emaciation (more severe symptoms observed in the higher concentration treatment groups). Mortality was reported in both the 3160 and 5620 mg a.s./kg diet groups (six birds died per treatment). On day 5 there was a statistically significant decrease in body weights in the 316, 1780, 3160 and 5620 mg a.s./kg diet groups when compared with the control, and on day 8 significant decreases in body weight gains continued to be observed in these groups as well as in the 178 mg a.s./kg diet group. In terms of the percentage change in body weights from days 0-5 and days 0-8, there were statistically significant decreases in weight gain in the three highest concentration groups when compared to the controls. In addition, a decrease in the feed consumption in the 1000, 1780, 3160 and 5620 mg a.s./kg diet groups was reported which was thought to be a dietary concentration response. Birds in the two highest dose groups showed signs of emaciation. Excessive mucous in the mouths of 4 to 5 birds which died during the test were also found on examination. No other test substance related abnormalities or other indications of toxicity were noted for any of the groups during the examinations.

The 8-day dietary LC50 of methomyl for mallard duck was determined to be 3952 mg a.s./kg diet (C.I. 2926-6275 mg a.s./kg diet) due to more than 50% mortality being observed in both the 3160 and 5620 mg a.s./kg diet groups. The LC50 value was determined using probit analysis, for which further information was submitted to justify this approach and subsequent result. A No-Observed Effect Concentration (NOEC) for signs of toxicity was not determined and the NOEC for mortality was 1780 mg a.s./kg diet.

The study was conducted according to OECD 205 and in compliance with GLP.

(Medlicott, B.A and Harris, T (2000): DuPont-4379, No. 00023)

B.9.1.3 Long term/Reproductive toxicity (IIA 8.1.3)

i) Active substance

a) A one-generation mallard duck reproductive study was conducted with technical methomyl (purity 98.35%). The test substance, where possible, was administered *ad libitum* to groups of 16 pairs of mallard ducks (29 weeks old at test initiation) approaching their first breeding season. Nominal food concentrations were 50, 150 and 500 ppm methomyl for 18 weeks. It should be noted that a preparational error caused the birds in the 50 ppm group to receive diet containing approximately 150 ppm methomyl for the first four weeks of the study**.** Analytically confirmed concentrations ranged from an average of 92% to 101.0% of the nominal. Homogeneity of the diet was confirmed by analysis. The food was replaced completely on Friday of each week with additional feed prepared as required. All mallard duck pairs were observed daily for signs of toxicity, abnormal behaviour and mortality. Adult body weights were measured at the initiation of the treatment, at weeks 2, 4, 6 and 8 (unless egg laying had already begun), and at test termination (week 18). Feed consumption was measured weekly. Eggs were collected daily at the onset of egg production and set weekly for incubation.

Results of this reproductive study are shown in the following table:

Table B.9.4 Total Reproductive Performance of mallard duck

Test object	Mallard duck			
Test substance	**Methomyl**			
Conc.: ppm diet	0	50	150	500
No. of Eggs Laid	668	708	539	630
No. of Eggs Laid/Hen	42	44	36	39
Eggs laid per hen per day	0.66	0.70	0.57	0.63
No. of Cracked Eggs	3	8	27*	5
No. of Eggs Set	606	639	461	568
No. of Viable Embryos	573	611	441	507
No. of Live 3-week Embryos	562	602	428	496
No. of Hatchlings	346	431	256	346
No. of 14 d. Survivors/Hen	22	27	17	21
No. of 14 d, Survivors	345	428	255	341
Avg. Eggshell Thickness [mm]	0.378	0.378	0.379	0.370
Avg. Mass of Hatchlings [g]	39	37	39	37
Avg. Mass of 14-Day Survival [g]	270	263	271	259
% of cracked eggs (rel. to eggs laid)	0	1	5*	1
% of viable embryos (rel. to eggs set)	95	96	95	88
% of live 3-week embryos (rel. to viable embryos)	98	98	97	98
% hatched chicks (rel. to live 3-week embryos)	60	68	61	58
% hatched chicks (rel. to eggs set)	57	65	57	58
% of 14 day old survivors (rel. to eggs set)	57	64	57	58

* Statistically significant. ($p=0.05$) adverse deviations from untreated control. Not statistically significant ($p \leq 0.05$) when compared to the control group.

There were no significant effects on the eggshell thickness or egg production. At the 150 ppm test concentration there was a statistically significant increase in the percent of cracked eggs. As this was comparable to the historical control value and was confined to three pens within the 150 ppm group, the increase was not considered to be treatment related, especially as this effect was not seen at the 500 ppm concentration.

It was also observed that at the 150 ppm concentration the total number of eggs laid, and therefore the numbers of eggs set, viable embryos, hatchlings and survivors, were lower than in the other treatment groups. This was not considered to be treatment related as these effects were not seen in the 500 ppm concentration group but rather due to the fact that one of the mallards had to be sacrificed during the study which resulted in the female being sacrificed as well. As a result, the 150 ppm group was not at its full compliment.

No concentration related effects on egg fertility, embryo viability or survivability were reported at levels up to and including 150 ppm diet. At

500 ppm there was a slight decrease in the percentage of viable embryos although this was not significant. No concentration related effects on chick survival or treatment clinical signs were noted in chicks and there were no adverse effects on the body weights of either 1 day old or 14 day old chicks.

There were no statistically significant treatment related effects on parent mortality, overt signs of toxicity or food consumption. No treatment related effects were observed at the 50 ppm or 150 ppm test concentrations, however, at the 500 ppm test concentration there was a significant decrease in body weight gain of hens during the last 10 weeks of the study (i.e. until test termination).

Based on the decrease in the body weight of hens at 500 ppm, the No Observed Effect Concentration (NOEC) was determined to be 150 ppm (the effects observed at this concentration were not considered to be treatment related). On the basis of these data the long term NOEC was considered to be 150 ppm and the reproductive NOEC 500 ppm.

The study was conducted according to USEPA 71-4(b) and in compliance with GLP.
(Beavers, J.B., Hawrot, R., Lynn, S.P., and Jaber, M (1991a) HLO 336-91)

b) Sixteen pairs (male/female) of young adult northern bobwhite (*Colinus virginianus*) received methomyl (purity 98.35%) in the feed at concentrations of 0, 50, 150, and 500 ppm for 20 weeks. Due to an error in the premix preparation birds in the 50 ppm treatment group received diets of 150 ppm methomyl for the first four weeks if the study. All other treatment groups received the correct dose. Analysis showed that levels in the diet were 98-92% of nominals (the 50 ppm treatment level was a weighted average) and methomyl was homogeneously mixed within the diet at 150 and 500 ppm (with a single exception at 500 ppm where the sample was only 77% of the nominal). Reproductive parameters were measured beginning at the onset of egg laying. Adult birds were observed for abnormal behaviour, mortality, signs of toxicity, and changes in body weight and food intake. All birds that died were necropsied after death. Those birds that survived until study termination were also necropsied.

No treatment-related mortalities, overt signs of toxicity or treatment related effects were observed. In the 500-ppm methomyl test group, there was a slight reduction in body weight of the cocks. However, this difference was influenced by one bird, which was noted as feather pecked and penworn. There was no treatment related body weight effects for the hens. No test substance-related gross lesions were observed at necropsy.

Reproductive parameters: There were no apparent treatment related effects on reproductive parameters for 50 or 150 ppm-methomyl groups. At 150 ppm there was a slight but statistically significant decrease in the number of cracked eggs. The difference was slight and not dose related and the values were within the historical control value of 5% ±5. Therefore this was not considered to be treatment related. In the 500 ppm-methomyl concentration group, there was a reduction in the total number of eggs laid per hen that was determined not to be statistically significant. Subsequently, there was a reduction in the number of offspring. No other test substance-related effects were observed on reproductive parameters (Table B.9.5).

Table B.9.5 Summary of reproductive effects, normalised as percentages, of methomyl on northern bobwhite quail

Reproductive parameters (%)	Test group (dietary concentration in ppm)			
	0	50	150	500
Number of replicates[a]	16	16	16	16
Total eggs laid[a]	487	439	543	294
Eggs laid/maximum laid	59	62	58	38
Eggs cracked/eggs laid	6	2	1*	3
Viable embryos/eggs set	87	92	94	86
Live three-week embryos/viable embryos	99	98	99	95
Hatchlings/live 3-week embryos	90	91	94	89
14-Day-old survivors/hatchlings	88	89	87	90
Hatchlings/eggs set	78	83	88	72
14-Day-old survivors/eggs set	68	73	76	65
Hatchlings/maximum set	44	53	51	30
14-Day-old survivors/maximum set	39	47	45	27

[a] Data are expressed as numbers not percentages.
*Significantly different from the control by Dunnett's Multiple comparison procedure at $p < 0.05$.

The overall subchronic and reproductive end points from the study are summarised in Table B.9.6.

Table B.9.6 Summary of subchronic toxicity and reproductive endpoints in northern bobwhite quail exposed to methomyl

Test substance	Methomyl
Test object	Northern bobwhite quail male and female
Lowest observed effect concentration (LOEC)	500 ppm
Highest tested dose without toxic effect (NOEC)	150 ppm
Toxic threshold effect level, TEL (mean LOEC-NOEC)	350 ppm

In conclusion the reproductive NOEC for northern bobwhite quail exposed to methomyl in the diet for 20 weeks was 150 ppm, based on the effect upon egg production (total number of eggs laid per hen) at 500 ppm (the highest level tested). The long term parental NOEC was 500 ppm.

This study was undertaken to US EPA 71-4 and in accordance with GLP.
(Beavers, J.B *et al*. 1991b, HLO 337 91)

B.9.1.4 Supervised cage or field trials (IIIA 10.1.2)

The following residues study was provided and is summarised below.
Test substance: methomyl **Purity:** 20% w:v.
Test System: Grass and broadleaf plants located in centre vegetative strips between grapevines
Crop: Wine Grapes
Materials and methods:
Field information: Four test locations during the 2001 field season: two in the Southern European Region and two in the Northern European Region. In the Southern European Region, two trials were located in southern France. In the Northern European Region, two trials were located in northern France.
Test substance: One formulation of methomyl was used for these trials: Methomyl 20SL, a water soluble concentrate containing 200-g methomyl as/l
Application:
First application timing: 16-Aug – 11-Sep-2001; approximately 28 days before harvest
Last application timing: 14 days before harvest of mature grape berries
Type of application: Foliar broadcast spray
Rates: 430– 474 g methomyl as/ha per application
Number of applications: 2
Interval of Applications: 14 days
Spray volume: 380 – 419 L/ha
Vehicle/solvent: Water only
Sampling:
Sampling interval: -1 hour, + 2 hours, 1, 3, 6, and/or 7 days (harvest) after last application.
Test system portion sampled: individual grass and broadleaf plants of heights approximately 15 ± 5 cm or less cut at the soil line.
Sample storage:
Field storage/shipping temperature: 'frozen' (at least –18°C)/dry ice or freezer truck
Analytical facility storage temperature: approximately -18°C.
Storage stability: Methomyl is stable in a related, predominately water-containing commodity, lettuce/leaf vegetables, for at least 24 months following storage at approximately –20°C [Annex IIA, Section 4, Document M-II (DuPont-5885), Point 6.0.1.4]. Samples were analysed approximately 7 months after sampling.
Analysis method: Multi-Residue Method 2, Submethod 1: N-methylcarbamate Pesticides (Netherlands MRM-2 Method) [Ministry of Public Health, Welfare, and Sport, The Netherlands, 1996 (Annex IIA, Section 2, Document M-II (DuPont-5883), Point 4.2)].
Analysis:
Analyte: Methomyl
Hydration: Plant samples were water-soaked prior to extraction

Extraction Acetone (1st extraction), dichloromethane/petroleum ether (2nd extraction)
Clean-up: Aminopropyl-bonded silica solid-phase extraction cartridge
Chromatography: High performance liquid chromatography (HPLC) using a Zorbax® C8 25 cm × 4.6 mm ID column packed with 5-µm particles
Detection: Hydrolysis, derivatisation, fluorescence

Calculations: Methomyl residues were expressed in mg/kg of plant tissue on a wet weight basis.

Statistics: Recovery data were reported as mean ± S.D.

Findings:

Recovery data: Average recovery data for fortifications run concurrently with treated samples are given in Table B.9.7. Additional method validation data on predominately water-containing matrices can be found in Annex IIA, Section 2, Document M-II (DuPont-5883), see Point 4.2.

Table B.9.7 Recovery data for methomyl in grass and broadleaf plants

Fortification Level (mg/kg)	Number of Samples	Percent Recovery (mean ± S.D.)
0.010	10	88 ± 10
0.10	3	82 ± 5
2.0	2	84
4.0	1	83
20	1	85
Overall	17	86 ± 8

Method limits: Limit of quantification is 0.010 mg/kg in grass and broadleaf plants.

Residue data: Maximum residues of methomyl in grass and broadleaf plants ranged from 5.9 to 18 mg/kg following the last application of formulated product to grapevines. The maximum residues across 3 trials averaged 13 ± 6.1 mg/kg. Methomyl residues did show decline with time. Half-life values were 2, 3, and 2 days for methomyl at Trials 1, 2, and 3, respectively. The overall half-life value for residue decline at all test sites was 2 days.

Table B.9.8 Summary of residue and half-life data for methomyl in grass and broadleaf plants

Country, location, trial number, year	Field plant collected (a)	Methomyl residues in grass and broadleaf plants following treatment of grapevines with two applications of DPX-X1179 20SL (mg/kg) (b)						Half-life (days)
		(-1 hour)	0 DALA	1 DALA	3 DALA	6 DALA	7 DALA	
S. France, Cahuzac-sur-Verè, Tarn, Trial 1, 2001	broadleaf (c)	**0.048**	**5.9**	**3.6**	**1.8**	**0.74**	**0.71**	2
S. France, Villemur, Haute-Garonne, Trial 2, 2001	grass	**1.6**	**14**	**2.6**	**1.6**(d) 1.7, 1.4	**3.0**(d) 3.2, 2.7	**1.4**	3
N. France, Restigné, Indre-et-Loire, Trial 3, 2001	grass & broadleaf (e)	**0.011**	**18**	**11**	**2.8**	**1.3**	**1.5**	2
N. France, Coutures, Maine-et-Loire, Trial 4, 2001	grass (c)	--	--	--	--	--	--	--

(a) Field plant collected reflects the grass and/or broadleaf plants present in the vegetative strips between rows of grapevines.

(b) Individual values are reported to 2 significant figures.

(c) Grass from this site had reached senescence and therefore was not relevant for analysis as it would not be potential wildlife feed.

(d) Calculated average includes duplicate individual values analyzed for verification.

(e) Grass and broadleaf green matter inseparable in the field; combined specimen collected and analyzed.

Conclusion: residues of methomyl ranged from 5.9 to 18 mg/kg in individual grass and/or broadleaf samples harvested following 2 applications of Methomyl 20SL made to grapevines at various locations in Southern and Northern Europe during the 2001 field season. The maximum residues across 3 trials averaged 13 ± 6.1 mg/kg. Methomyl residues declined with an average half-life (first-order linear regression DT_{50}) of 2 days. Quantifiable methomyl residues were not found in the untreated control samples (residues <0.010 mg/kg). Analytical results for analysis of grass and/or broadleaf plants from treated vineyards are summarised above.

This study was undertaken in accordance with Annex IIA, Part A, Section 6, and Annex IIIA, Part A, Section 8, of Directive 91/414/EEC and was to GLP.

(Kennedy, C.M., Dubey, L., Steiner, C., Matni, H. (2002))

B.9.1.5 Acute, short term and long term risk assessment

The studies provided were considered acceptable for use in a risk assessment. The risk assessment has not been based on the methodology outlined in SANCO/4145/2000 as this was not finalised when the dossiers were being compiled. The end points obtained are summarised as follows:

Table B.9.9 Summary of avian toxicity endpoints for methomyl

Test	Measurement endpoint	Bobwhite quail	Mallard duck
Single oral dose	LD_{50}	**24.2 mg a.s./kg body wt.**	Not determined
Short-term dietary (8 day)	LC_{50}	>5620 mg as/kg diet	**3952 mg as/kg diet**
Reproduction (21 week)	NOEC	**150 ppm**	500 ppm
Long term NOEC (parental)	NOEC	500 ppm	**150 ppm**

It should be noted that the acute oral study was undertaken prior to the requirement for studies to be to GLP, however the end point derived (24.2 mg a.s./kg bw) was similar to that from a formulation study done to GLP (30.4 mg a.s./kg bw). This therefore adds support to the end point derived from this non-GLP acute study.

For the avian assessment, the most sensitive toxicity endpoints shown in bold will be used. The reproductive NOEC for the bobwhite quail of 150 ppm is identical to the long term parental NOEC in the mallard duck. The NOEC used in the risk assessment is 150 ppm. It should also be noted that the applicants estimate of a DT50 of 2 days on foliage was considered to be acceptable. In addition, the maximum concentration of methomyl on foliage was 18 mg a.s./kg of grass/broad leaved plants.

In carrying out the bird risk assessment the following procedure has been followed - for the acute toxicity:exposure ratio the LD50 has been compared to the daily food consumption (wet weight) and assuming residue data outlined in EPPO (1992). As regards the short and long-term risk assessment the appropriate endpoint, in terms of ppm diet, has been compared to residues on treated food, where the residue data have been taken from EPPO (1992).

Consideration is required of likely routes of exposure of birds in the field. The foliage of treated crops (e.g. cucumbers, tomatoes, grapes) would not be particularly attractive to birds as a food source. In contrast, aphids (and other insects in the treated crops) are likely to be taken as food, and this route of uptake must be considered. There is also a potential for residues reaching soil to lead to low concentrations in earthworms. However, in comparison to feeding on contaminated insects this route of uptake is considered to be minor. Hence, the following risk assessment is based on intake through consumption of insects.

i) Use on grapevines and vegetables at the maximum proposed rate (2 applications at 450 g a.s./ha).

The scenario considered is use in grape vines which also covers the other proposed uses on short and tall vegetables. According to the EPPO vertebrate risk assessment scheme, the daily food consumption of a small bird (<100 g bw, such as a small insectivorous species) is approximately equal to 30% of its bodyweight. As this is in dry weight a conversion factor of 2.4 is required in order for comparisons with the toxicity value to be made. As a result the daily fresh weight of food required for a small bird is 72%. Using this estimate, together with the predicted residue on small insects (EPPO), and the worst case assumption that the diet consists entirely of contaminated insects, acute and dietary toxicity exposure ratios (TER) have been calculated and are presented in Table 9.10. The estimated theoretical exposure (ETE) level of insects is considered to be 0.45 kg a.s./ha multiplied by the residue conversion factor for small insects of 29 (EPPO) i.e. 13.05 ppm. It is considered unlikely that multiple applications would lead to greater residues on insects than single sprays. For example, individuals of pest species such as aphids are likely to be killed by a single treatment.

It is not considered necessary to address the risk to herbivorous birds as these are not considered to be exposed from these proposed uses. This is in line with 'The Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC' SANCO/4145/2000, 25 September 2002.

Table 9.10 Toxicity exposure ratios for exposure of insectivorous birds to methomyl from use at 450 g a.s./ha

Category	Time scale	Toxicity endpoint	ETE*	TER	Annex VI trigger
Grape (table and vine)[1]					
Small insectivorous bird	Acute	LD50 24.2 mg a.s./kg bw	9.4 ppm a.s. [2]	2.6	10
Small insectivorous bird	Short term dietary	LC50 3952 ppm a.s.	13.05 ppm a.s. [3]	303	10
Small insectivorous bird	Long-term	NOEC 150 ppm a.s.	13.05 ppm a.s. [3]	11.5	5

*ETE= estimated theoretical exposure in the diet based on the EPPO vertebrate risk assessment scheme.
[1] This scenario also covers all other proposed uses i.e. cucumbers, courgettes, tomatoes and aubergines.
[2] Based on an estimated food intake of 72% of bodyweight.
[3] Based on a direct comparison of the study end point and the ETE.

The acute TER is below the Annex VI trigger and requires further consideration.
The short term and long term dietary risk are above the Annex VI trigger value and the risk is therefore acceptable.

Refinement of the acute exposure (Appendix 5)

Additional information has been provided to address the acute risk to birds. This is included in Appendix 5.

a) Considering Section 3.3 Appendix 5 degradation of residues in the diet:

The following parameters are cited by the applicant on page 9 and each of these will be considered in turn:

- Degradation on insects
- Feeding bouts through the day
- Weight and quantity of insects to obtain a lethal dose

Degradation on insects

The degradation studies in insects shows that methomyl was rapidly degraded (Kuhr 1973, Kuhr and Hessney, 1977). The maximum half-life was 60 minutes. However, it should be noted that the insects in these studies were injected with methomyl and that spray application is likely to result in exposure of the external surfaces of insects, therefore the degradation rate could be somewhat different. The data do indicate that residues on insects are likely to decline with time, however the exact rate of this is not fully known. Based on this information the Appendix 5 concludes that it is only necessary to focus on the first 2 hours after application (on the basis that after 2 hours the ETE will be ≤0.25 x 9.4). It is considered that it is not possible to definitively conclude that there is only a risk in the first two hours. However, it can be concluded that the risk assessment should be focused on the first two hours or greater.

Feeding bouts

Appendix 5 concludes that there are likely to be 12 feeding bouts in a 12 hour day and that therefore the ETE can be divided by 12 and multiplied by the number of hours over which a risk is likely to occur (based on the degradation in food above). However, no evidence has been provided to support this statement. It is possible that birds may feed in bouts depending on food availability and that these may not be equally distributed over the day i.e. if a large amount of food is available they will take this when they can. Therefore it is considered that the risk assessment cannot be refined in this way.

Weight and quantity of insects

Calculations have been made of the amount of insects that would need to be consumed per unit time to obtain a lethal dose of methomyl. However, it should be noted that these calculations do not take account of any uncertainty factor e.g. to account for variation between birds etc. For birds the uncertainty factor is 10 according to Annex VI. Therefore the values calculated should be divided by 10. The resulting values are 1.3 aphids/second and 1.3 caterpillars per minute. Without evidence to the contrary it is considered that such values could be theoretically possible and that therefore it is not possible to discount the risk on this basis.

The weight of food that would be required to deliver a lethal dose can be calculated based on the approach given in Appendix 5. Using the approach given the LD50 is divided by 2 (based on the initial dose after the first feeding being D_0 then the cumulative dose after n feedings is D_0 + 1/2 D_0 + 1/4D_0 (see Paragraphs 5 and 6 page 9, Appendix 5)). It should be noted that this is a very worst case approach since the LD50 is divided by 2 to take account of potential cumulative accumulation. However, since this is the approach taken by the applicant this is what has been considered.

The quantity of food estimated to deliver an LD50 of 12.1 mg a.s./l can be calculated for a 10 g bird. This is done by calculating the LD50 for a 10 g bird. i.e. 0.121 mg and then dividing it by the ETE. The ETE is 13.05 (based on a Residues per Unit Dose (or EPPO factor) of 29 and an application rate of 0.45 kg a.s./ha). Therefore the resulting calculation is 0.121/13.05. This means that 9.27 x 10^{-3} kg i.e. 9.27 g of food is required. However, it should be noted that this does not include any uncertainty value (see above). When an uncertainty factor is included the resulting value is 0.927 g of food. This indicates that a relatively large amount of food is required to obtain an acute dose. However, without detailed information to the contrary it is considered that this is theoretically possible.

Therefore it is considered that this information alone does not allow refinement of the acute risk to birds.

b) Considering Section 3.4, Appendix 5 - degradation of methomyl in the bird

The acute study is based on administration of the dose of the active substance by gavage. In the field it is likely that consumption will be occurring over the day rather than the methomyl all being obtained in a single dose. Information has been provided in Appendix 5 Section 3.4 indicating that metabolism and degradation of methomyl is likely to occur in the bird. The half life is stated to be 2.4 hours although it is unclear exactly how this has been derived. Therefore these data cannot be used in the proposed manner. However the data do indicate that the metabolism of methomyl is likely to be rapid.

Conclusion:

The information provided does indicate that there is likely to be degradation on the insects, that methomyl is rapidly metabolised and that it will be difficult for small birds feeding to obtain an acute lethal dose in a single day. The acute oral LD50 may not be the most appropriate end point for the risk assessment, since it is unlikely that birds will be able to consume sufficient treated insects in a single day to consume a lethal dose. This is in line with the 'time quotient>1' scenario in the *Report of the SETAC/OECD workshop on Avian Toxicity Testing* (OECD 1996). Since the acute TER is >1 then the time quotient is also >1 for methomyl. Therefore it is considered that the dietary route of exposure is the most appropriate scenario.

The TER for the dietary route of exposure is above the trigger value of 10. However, it should be noted that this has been calculated via the EPPO approach comparing a toxicity end point in terms of food concentration with environmental concentrations. Where the dietary approach is being used to cover the acute exposure it is necessary for the LC50 to be calculated in terms of mg a.s./kg bw/day i.e. account needs to be taken of both food consumption and body weight in the dietary study. In addition, the situation is more complex where the LC50 value is below the top concentration and there is a decrease in food consumption. This is the case for methomyl where there was a decrease in consumption at 1000 ppm and concentrations above this (Medlicott, B.A and Harris, T (2000)). Therefore further detailed consideration of the appropriate dietary end points to be derived from this study is necessary before an acceptable dietary risk can be identified.

ii) Use on fruiting vegetables (cucumber, courgette, tomato, aubergine) at the lower rate (2 applications at 250 g a.s./ha)

Using the same assumptions as above at (i) use at the lower rate of 2 applications of 250 g a.s./ha is also assessed. The estimated theoretical exposure (ETE) level of insects is considered to be 0.25 kg a.s./ha multiplied by the residue conversion factor for small insects of 29 (EPPO) i.e. 13.05 ppm. The resulting TERs are shown in the table below.

Table 9.11 Toxicity exposure ratios for exposure of insectivorous birds to methomyl from use at 250 g a.s./ha

Category	Time scale	Toxicity endpoint	ETE*	TER	Annex VI trigger
Listed vegetables					
Small insectivorous bird	Acute	LD50 24.2 mg a.s./kg bw	5.22 ppm a.s.[2]	4.6	10
Small insectivorous bird	Short term dietary	LC50 3952 ppm a.s.	7.25 ppm a.s.[3]	545	10
Small insectivorous bird	Long-term	NOEC 150 ppm a.s.	7.25 ppm a.s.[3]	21	5

*ETE= estimated theoretical exposure in the diet based on the EPPO vertebrate risk assessment scheme.
[1] This scenario also covers all other proposed uses i.e. cucumbers, courgettes, tomatoes and aubergines.
[2] Based on an estimated food intake of 72% of bodyweight.
[3] Based on a direct comparison of the study end point and the ETE.

The acute TER is below the Annex VI trigger and requires further consideration. Again as argued at (i) above it is considered likely that the dietary route of exposure is more appropriate. However, as at (i) further information is required. Therefore further detailed consideration of the appropriate dietary end points are necessary before an acceptable dietary risk can be identified. The short term and long term dietary risk are above the Annex VI trigger value and the risk is therefore acceptable.

Metabolites

It is considered that the metabolite, methomyl oxime was intrinsically evaluated in the toxicological studies with the active substance. In addition, methomyl oxime does not pose a risk of inducing AChE inhibition, which is the primary and most sensitive parameter for assessing methomyl-induced toxicity (Section B.6.8.1). Therefore it is considered that the risk assessment for methomyl also covers the metabolite methomyl oxime.

Overall conclusion for the risk to birds

Conclusion

An acute risk from methomyl was identified for both representative uses. Extra information was provided that showed that there was degradation on insects, that methomyl was rapidly metabolised and that it will be difficult for a bird to obtain an acute lethal dose. On the basis of this information it is considered that the dietary route of exposure is more appropriate than the acute risk. However, to undertake a satisfactory risk assessment to address the acute risk it is necessary for the dietary end points from the LC50 study to be converted to mg a.s./kg bw /day. Food avoidance occurred in the dietary study and therefore this needs to be considered appropriately in deriving the end points. The expectation is that with appropriate additional information it should be possible to identify an acceptable use for methomyl.

The dietary and long term risk were considered acceptable. It should be noted that use of the EPPO approach is considered acceptable for the dietary risk. The issues discussed above relate to the appropriate approach to use when the dietary risk is also effectively being used to cover the acute risk.

Data required before inclusion in Annex I can be considered – use on fruiting vegetables and grape vine

An acute risk to small birds has been identified, however it is considered that the dietary route of exposure is the most appropriate for the risk assessment. To address the dietary risk, further information is required to allow a proper calculation of the LC50 value in terms of mg a.s./kg bw/day together with a consideration of the risk. It should be noted that alternative approaches may be possible to address this issue.

B.9.2 Effects on aquatic organisms (IIA 8.2, IIIA 10.2)

B.9.2.1 Acute toxicity (IIA 8.2)

Acute toxicity studies with technical methomyl are summarised in Table B.9.12.

Active substance

Table B.9.12 Summary of acute toxicity of technical methomyl to aquatic organisms

Species	Test type and duration (% purity of test substance)	Actual conc'n (as % of nominal)	LC/EC_{50} mg a.s. /l (95% CL)	NOEC mg a.s. /l	Test Guideline and GLP status	Ref.
Fish (IIIA 8.2.1)						
Lepomis macrochirus	Static renewal 96h (100)	85-115% except at 24 hr for 1.0 and 1.8 mg a.s./l at 122 & 121%	0.63[1, 2] (0.51-0.76)	0.30[1]	OECD 203, GLP	Wetton, P. and Mullee, D.M. (1999) SPL 282/571
Oncoryhnchus mykiss	Static 96h (98.6)	100-105%	2.49[3] (1.98->3.06)	0.408[3]	OECD 203, GLP	Boeri, R.L. *et al.* (2000)
Invertebrates (IIIA 8.2.4)						
Daphnia magna	Static 48h (100)	82-120%	0.017[3]	0.0104[3]	OECD 202, GLP	Wetton, P.M. and Mullee, D.M. (1999) SPL 282/572
Algae (IIIA 8.2.6)						
Pseudokirchneriella subcapitata (formerly called *Selanastrum capricornutum*) (green alga)	Static 72hr (100)	91-96%	72h values Cell density EC50: >100[4] Area under curve EC50:>100[4] Growth rate EC50: >100[4]	NOECs: all 100[4]	OECD 201, GLP	Mead, C. & Mullee, D.M. (1999) SPL 282/573
Scenedesmus subspicatus (green alga)[3]	Static 72hr (100)	90-101%	72h values Cell density EC50: >100[4] Area under curve EC50:>100[4] Growth rate EC50: >100[4]	NOECs: all 100[4]	OECD 201, GLP	Mead, C. & Mullee, D.M. (1999) SPL 282/594

[1]Based on nominal concentrations.
[2]Moribund fish with arched bodies were observed at 0.56, 1.0 , 1.8 and 3.2 mg a.s./l between 6 and 48 hr, all moribund fish were euthanised and classified as mortalities.
[3]Based on mean measured concentrations.
[4]Based on nominal concentrations.

Plant protection products (IIIA 10.2.1)

Studies with the product Methomyl 20 SL are summarised in Table B.9.13.

Table B.9.13 The acute toxicity of the formulated product 'Methomyl 20 SL'

Species	Test type and duration (% purity of test substance)	Actual conc'n (as % of nominal)	LC/EC_{50} mg formulation l (95% CL) (a.s. /l)	NOEC mg a.s. /l	Test Guideline and GLP status	Ref.
Fish (IIIA 8.2.1)						
Oncoryhnchus mykiss	96hr static Methomyl 20 SL* (21.5)	79-116%	18 mg product/l (CL 14-25 mg product/l) (3.9 mg a.s./l)[1]	5 mg product /l[1, 2]	OECD 203, GLP	Baer, K (1991) HLR 29-91
Lepomis macrochirus	96hr static Methomyl 20 SL* (21.5)	55-102%	5.1 mg product/l (FL 3.8-6.8) (1.1 mg a.s./l) [1]	2.5 mg product /l[1, 3]	OECD 203, GLP	Baer, K (1991) HLR 30-91
Invertebrates (IIIA 8.2.4)						
Daphnia magna	Static, 48h Methomyl 20 SL (200 g a.s./l)	i) <24 hr daphnia 110-114% ii) 12 day old daphnia 110-114%	i) <24 hr daphnia 48 hr EC50: 0.096 (CL 0.053-0.15) (EC50:0.0193 mg a.s./l) [1,] ii) 12 day old daphnia 48 hr 48 hr EC50: 0.180 (CL 0.15-0.23) (EC50:0.0362 mg a.s./l) [1,]	i) <24 hr daphnia: 0.053[1, 4] ii) 12 day old daphnia: 0.0.090[1, 4]	OECD 202, GLP	Ward, T.J et al. (2001) 3726
Daphnia magna –28 day old	Static, 48h Methomyl 20 SL (200 g a.s./l)	118-141%	28 day old *D. magna* 48 hr EC50: >0.5 mg product/l (>0.123 mg a.s./l) [5]	0.063 mg product/l [4,5]	OECD 202, GLP	Hoke, R.A. (2002a) 10461

[1] Based on nominal concentrations.
[2]NOEC was not presented in the study but this is the value based on the tabulated results in the report and the observation of a dark colouration and also of a fish lying at the bottom of the tank at 10 mg product/l.

continued//

continued//

[3]NOEC was not presented in the study but this is the value based on the tabulated results in the report and the observation of some fish showing loss of equilibrium, being hemorrhagic, lying at the bottom of the tank and some mortality at 5.0 mg product/l.
[4]NOEC was not presented but these are the values based on the tabulated results and some immobility being observed at greater concentrations.
[5]Based on mean measured concentrations
*The formulation used in these studies contained 51% methanol solvent rather than 28%.

a) A study was undertaken to determine the effects on adult *Daphnia magna* and their neonates under time varied exposure. The acute toxicity of 'Methomyl 20SL' (200 g a.s./l) to unfed *Daphnia magna* adults (27-days old) was determined in an unaerated, 96-hour test. Treatments consisted of a dilution water control, and nominal concentrations of 0.063, 0.125, 0.250, 0.500 and 1.0 mg Methomyl 20SL/l. The test substance concentrations at test initiation were varied over time by the continuous addition of dilution water via peristaltic pump at a rate of approximately 3 ml per hour. The dilution of the initial test substance concentrations was designed to mimic the observed DT_{50} of approximately 33.5 hours from a simulated pond dissipation study (Section B.8.4.4). Three replicates with 5 daphnids per replicate were used per test substance concentration and control.

A summary of the findings is presented in Table B.9.14. Mean, measured concentrations of methomyl were 0.0129, 0.0269, 0.0523, 0.105, and 0.211 mg a.s./l and ranged from 99 to 103% of nominal concentrations at test initiation. Exposure of 27-day old daphnids to nominal, Methomyl 20SL total formulation concentrations 0.063, 0.125, 0.250, 0.500 and 1.0 mg Methomyl 20SL/l resulted in 0, 0, 0, 40, and 80% immobility, respectively, at the end of 48 hours and 0, 0, 0, 60, and 100% immobility, respectively, at the end of 96 hours. Pale, lethargic adult daphnids were observed throughout the study at nominal total formulation concentrations of 0.500 and 1.0 mg product/l. At test end, 1 of the 6 surviving adult daphnids at the nominal total formulation concentration of 0.500 mg/l was lethargic. Immobile neonates were observed at nominal total formulation concentrations of 0.063, 0.125, 0.250, and 0.500 mg/l at test end (Table B.9.15).

No immobility was observed in the water control daphnids during the study. The highest nominal, total formulation concentration causing no immobility in adult daphnids at test end was 0.250 mg/l. The lowest nominal, total formulation concentration causing 100% immobility of adult daphnids at test end was 1.0 mg/l. Nominal total formulation concentrations of Methomyl 20SL concentrations were used for calculation of EC_{50} values. The 96-hour EC_{50} and NOEC for neonates produced by 27-day old adults used to start the test were 0.406 mg/l (0.084-mg/l methomyl a.s.) and 0.125 mg/l (0.026-mg/l methomyl a.s.), respectively, based on nominal total formulation concentration of Methomyl 20SL. The adult *Daphnia magna* 96-hour EC_{50}, based on nominal total formulation concentrations of Methomyl 20SL and immobility, was 0.474 mg/l.

Table B.9.14
Summary of observed immobility and sublethal effects on unfed *Daphnia magna* exposed to Methomyl 20SL in unaerated, 96-hour test with time-varied exposure

Nominal, concentration Methomyl 20SL Total formulation (mg/l)	Immobility (No. immobile/No. at test start)											
	24 Hours			48 Hours			72 Hours			96 Hours		
	A†	B†	C†	A†	B†	C†	A†	B†	C†	A†	B†	C†
Dilution Water Control	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.063	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.125	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.250	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.500	$0^{1a,c}/5$	$0^{3a,c}/5$	$0^{2a,c}/5$	$2^{1a,c}/5$	$3^{1a,c}/5$	$1^{2a,c}/5$	3/5	$3^{1a,c}/5$	$2^{1a,c}/5$	3/5	4/5	$2^{1a}/5$
1.0	$1^{3a,c}/5$	$2^{2a,c}/5$	$2^{3a,c}/5$	$4^{1a,c}/5$	$3^{2a,c}/5$	5/5	5/5	5/5	5/5	5/5	5/5	5/5

† A – C represent replicate test vessels containing 5 daphnids.

A Daphnids lethargic, superscript numbers indicate the number of daphnids with this sublethal effect.

C Daphnids pale in colour.

N.B. Note concentrations in table are expressed in µg/l rather than mg/l.

Table B.9.15
Immobility of adult and neonate *Daphnia magna* in an unaerated, 96-hour acute test with time-varied exposure to Methomyl 20SL

Nominal, Methomyl 20SL total formulation concentration (µg/l)	Surviving adults at 96 Hours	Surviving neonates at 96 Hours	Immobile Neonates at 96 Hours
Water Control A	5	134	0
Water Control B	5	167	0
Water Control C	5	147	0
63 A	5	118	1
63 B	5	169	0
63 C	5	109	2
125 A	5	111	0
125 B	5	121	11
125 C	5	141	6
250 A	5	107	5
250 B	5	38	27
250 C	5	81	6
500 A	2	12	84
500 B	1	45	37
500 C	3	0	34
1000 A	0	-[a]	-
1000 B	0	-	-
1000 C	0	-	-

a No neonates were produced at this concentration.

N.B. Note concentrations in table are expressed in µg/l rather than mg/l.

In conclusion the 96 hour EC50 for 27-day old *Daphnia magna* based on nominal total formulation concentrations and immobility was 0.474 mg Methomyl 20SL/l (95% confidence limits 0.384-0.615 mg/l) (0.098 mg a.s./l). The 96 hr EC50 and NOEC for neonates produced by 27-day old adults used to start the test was 0.406 mg Methomyl 20SL/l (95% CL 0.387-0.427 mg/l) (0.084 mg a.s./l) and 0.125 mg Methomyl 20 SL/l (0.026 mg a.s./l) respectively based on nominal total formulation concentration of Methomyl 20 SL.

This study was undertaken in accordance with OECD 202 and GLP.

(Hoke, R.A. (2002b) 11049)

b) The acute toxicity of methomyl (purity 99%) to unfed mature adult individuals of *Gammarus italicus* Goedm and *Echinogammarus tibaldii* Pink (both Amphipoda), was determined in an unaerated, static, 96-hour test. Treatments consisted of a dilution water control, and six concentrations of methomyl in logarithmic intervals to determine the LC_{50} for methomyl. Reconstituted water (OECD 1981), hardness and alkalinity were 240 mg/l and 55 mg/l as $CaCO_3$, respectively, and pH was 7.9 ± 0.5. Each treatment and the control contained 20 individuals. Test solutions were maintained at 8 ± 0.5°C. Mortality was determined by gentle prodding of the organism with a spatula. . The organism was considered dead if no movement of the pleopodes was observed. Experimental data were analysed through probit analysis (Finney, 1971) and the LC_{50} values were expressed as nominal concentration of methomyl technical.

In conclusion the 96-hour LC_{50} for *Gammarus italicus* was 0.047 mg methomyl/l and 0.250 mg methomyl/l for *Echinogammarus tibaldii*

No guidelines are available for this study, but OECD methods were used where appropriate. This study was not undertaken to GLP.

Pantani, C., Pannunzio, G., De Cristofaro, M., Novelli, A.A., Salvatori, M. (1997) Published.

c) A study was undertaken with 'Lannate' (90% methomyl). Five invertebrate, freshwater species (2 planktonic and 3 benthic) representing different taxonomic groups were used for the acute toxicity tests. These are the cladoceron *Daphnia longispina* (average length 1.3 mm), the copepod *Cyclops strennus* (average length 1.1 mm), the amphipod *Gammarus pulex* (average length 0.90 cm) and the snails (gastropods), *Biomphalaria alexandrina* (average mean shell diameter was 11.5 ± 0.33 mm) and *Bulinus truncatus* (average shell length 10.8 ± 0.4 mm). All organisms were collected from the field, either from Wadi El Rayan Lake or from El Wadi drain in Egypt. Acute 96-hour tests were performed under unaerated, static conditions. Treatments consisted of a dilution water control, and ten concentrations of methomyl to allow determination of the EC/lC_{50}, depending upon species. Each concentration was replicated twice. Holding containers of 0.25 L were used for all species except for the snails for which 1.5 L glass aquaria were used. Dilution water used was filtered lake water. Each treatment and the control contained between 10 and 20 individuals, depending upon the test species. Test solutions were maintained at 27 ± 2°C. The number of organisms surviving at each concentration was recorded over the length of the test, at intervals of 15 min, 30 min and 45 min, 1, 6, 12, 18, 24, 48, 72, and 96 hours. Mortality was determined by a lack of response to mechanical stimulation. The exception was for the snails, where adherence to the side of the aquarium was determined as an effect and therefore an EC_{50}, rather than LC_{50} is reported. Dead and affected organisms were removed after each monitoring period. The LC_{50} was estimated graphically by plotting the experimental data on a semi-logarithmic graph, with the test concentrations laid on the log-scale and the mortality (or effect) percent on the arithmetic scale. The best fit straight line was drawn from the observed points as the dose-response line and the concentrations corresponding to 50% cumulative mortality up to 96 hours was noted as the 96-hr LC_{50}.

The behavioural responses of the organisms varied according to the test concentrations. After introducing the planktonic organisms, definite symptoms of restlessness were shown by making frequent visits to the surface of the water. The results are shown in Table B.9.16.

Table B.9.16 The toxicity of methomyl to the following species

Test organism	96-hr LC_{50}/EC_{50} (mg methomyl/l)
Daphnia longispina	0.220
Cyclops strenuous	0.190
Gammarus pulex	0.760
Biomphalaria alexandrina	1.100
Bulinus truncatus	0.870

No guidelines are available for this study, but OECD methods were used where appropriate. This study was not undertaken to GLP.

(Aboul-Ela, I.A., Khalil, M.T. (1987) Published)

d) The acute toxicity of methomyl (95-98%) to unfed mature adult individuals of *Gammarus pseudolimnaeus* (a benthic organism (Amphipoda), common name scud), and two stonefly species (Plecoptera) (*Pteronarcella badia* and *Schwala* sp.), was determined in an unaerated, static, 96-hour test. In addition a species of Chironomus was also tested. Treatments consisted of a dilution water control, and several concentrations of methomyl in logarithmic intervals to determine the LC_{50} for methomyl. Reconstituted water was used containing an alkalinity of between 30 and 35 mg/l, and hardness of between 40 and 50 mg/l as $CaCO_3$. The scud test was conducted at a water hardness of 272-ppm $CaCO_3$. The pH was 7.2 to 7.5. Each treatment and the control contained the same number of individuals of each tested species. The mean test temperature for the stoneflies was 7°C and for the scud 12°C ± 1°C. Mortality was determined by gentle prodding of the organism with a spatula. The organism was considered dead if no movement was observed. Experimental data were analysed by the method of Litchfield and Wilcoxon (1949) and the LC_{50} values were expressed as nominal concentration of the test substance based on the purity of the test substance (95-98% purity) with 95% confidence intervals.

Table B.9.17 The 96-hour LC_{50}s to methomyl and the confidence interval for each species

Test Organism	96-hr LC50 (mg methomyl/l) (95% CI)
Pteronarcella badia	0.069 (0.034-0.143)[1] 0.060 (0.050-0.080)[2]
Skwala sp.	0.034 (0.027-0.044)[1] 0.029 (0.021-0.041)[2]
Chironomus sp.	0.032 (0.013-0.080)[2]
Gammarus pseudolimnaeus	1.050 (0.424-2.600)[2]

1 Using technical material (95-98%) ; 2 Using liquid concentrate (24% active substance).

Testing was undertaken in accordance with EPA-660/3-75-009 but was not in accordance with GLP.

Johnson, W. W., Finley, M.T. (1980); Published.

e) The acute toxicity of methomyl to unfed individuals of *Isogenus* sp. (Pletoptera, stone fly) (1st year class), and *Chironomus plumosus* (Diptera) (3rd instar) (midge) was determined in an unaerated, static, 96-hour test and 48-hour test, respectively. Treatments consisted of a dilution water control, and several concentrations of methomyl (95% purity) in logarithmic intervals to determine the LC_{50} for methomyl. Reconstituted water hardness was set at 42 mg/l as $CaCO_3$ for *Isogenus* and 40-mg/l CaCO3 for *C. plumosus*. The pH was 7.4 ± 0.1 for both tests. Test solutions were maintained at 7°C for *Isogenus*, and at 22°C for *C. plumosus*. Mortality was determined by gentle mechanical prodding of the organism. The organism was considered dead if no movement was observed. Experimental data were analysed by the method of Litchfield and Wilcoxon (1949) and the LC_{50}/EC_{50} values were expressed as nominal concentration of the test substance based on the purity of the test substance (95% purity) with 95% confidence intervals.

LC_{50}s were determined at 24- and 96-hours in the *Isogenus* sp. test. These values were 0.490 mg/l (95% confidence interval, 0.368-0.653 mg/l) and 0.343 mg/l (95% confidence interval, 0.268-0.440 mg/l), respectively. For *C. plumosus*, the 48-hour EC_{50} was 0.088 mg/l (0.060-0.129 mg/l).

In conclusion the 96-hour LC_{50} for *Isogenus* sp. was 0.343-mg methomyl/l and for *Chironomus plumosus* the 48-hour EC_{50} was 0.088-mg methomyl/l.

Testing was undertaken in accordance with EPA-660/3-75-009 but was not in accordance with GLP.

(Mayer, F.L., Ellersieck, M.R. (1986) Published)

Hazard Classification/Labelling

Classification of the active substance for environmental effects according to 67/548/EEC

The most acutely sensitive aquatic species to methomyl from fish, daphnia and algae was *Daphnia magna* with a 48 hour EC50 of 0.017 mg a.s./l (Table B.9.12). This is <1 mg a.s./l and therefore the active substance should be categorised as 'Very toxic to aquatic organisms' (R50). It was concluded that methomyl was not readily biodegradable (Section B.8.4.3) and so it should be categorised as 'May cause long term adverse effects in the aquatic environment' (R53). On the basis of receiving this classification, methomyl is considered 'Dangerous for the environment' and should carry the 'N' symbol and also be labelled as follows:

S60 This material and its container must be disposed of as hazardous waste.
S61 Avoid release to the environment. Refer to special instructions/Safety data sheet.'

B.9.2.2 Chronic toxicity

Active substance

Fish (IIA 8.2.2)

a) The chronic toxicity of Methomyl 20SL* (purity 21.5% active substance) to unfed fingerling rainbow trout, *Oncorhynchus mykiss,* was determined in a flow-through, 21-day toxicity test. Treatments consisted of a dilution water control, and nominal concentrations of 0.63, 1.3, 2.5, 5.0, 10, and 20 mg/l Methomyl 20SL. Two replicates, containing 5 fish, were exposed to each treatment concentration and control.

Summaries of cumulative mortality and sublethal effects are presented in Table B.9.18 and Table B.9.19 respectively. Mean, measured concentrations of methomyl were 0.15, 0.32, 0.56, 1.1, 2.3, and 4.5-mg a.s./l. There were no mortality or sublethal effects below 2.5-mg/l Methomyl 20SL. The following parameters were calculated using nominal, total formulation concentrations of Methomyl 20SL. The lowest observable effect concentration at 21-day was 5.0-mg a.s./l Methomyl 20SL. The highest concentration causing no mortality was 1.3-mg/l Methomyl 20SL. No concentration of Methomyl 20SL caused 100% mortality. Surviving fish exhibited either no sublethal effects or effects such as, lying on the bottom of the test vessel, gasping for air, partial loss of equilibrium, discoloration, or bloating of the stomach area. Time to first observed mortality was approximately 12 hours at 20-mg methomyl/l. The 21-day LC_{50} was 6.1-mg Methomyl 20SL/l, calculated on total nominal formulation concentrations. The NOEC was 2.5 mg Methomyl 20SL/l based on mortality and sublethal effects at 5.0 mg Methomyl 20SL/l (see Table B.9.18* and Table B.9.19).

Table B.9.18 Observed mortality of rainbow trout, *Oncorhynchus mykiss*, exposed to Methomyl 20SL in a flow-through 21-day toxicity test

Day	Cumulative mortality (No. dead/No. at test start) Nominal total Formulation concentrations of Methomyl 20SL(mg/l)													
	Water Control		0.63		1.3		2.5		5.0		10		20	
	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]
0	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
1	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5
2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5
3	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
4	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
6	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
8	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
9	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	2/5	3/5
10	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	2/5	0/5	2/5	3/5
11	0/5	1/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	2/5	0/5	3/5	3/5
12	0/5	1/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5	2/5	0/5	3/5	3/5
13	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	2/5	2/5	0/5	4/5	3/5
14	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	2/5	3/5	0/5	4/5	3/5
15	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	2/5	3/5	0/5	4/5	3/5
16	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5	2/5	3/5	1/5	4/5	3/5
17	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5	2/5	3/5	1/5	4/5	4/5
18	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	4/5	2/5	3/5	1/5	4/5	4/5
19	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	4/5	2/5	4/5	2/5	4/5	4/5
20	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	4/5	2/5	5/5	2/5	4/5	4/5
21	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/5	4/5	3/5	5/5	2/5	4/5	4/5

[a] A and B represent replicates; each replicate contained 5 fish (total 10 fish per test concentration) at test start.

Table B.9.19 Observed sublethal effects of rainbow trout, *Oncorhynchus mykiss*, exposed to Methomyl 20SL in a flow-through 21-day toxicity test

Day	Sublethal effects[b] (No. affected/No. Surviving) Nominal, Total Formulation Concentrations (mg/l)													
	Water Control		0.63		1.3		2.5		5.0		10		20	
	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]	A[a]	B[a]
0	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	0/5	0/5	1/5	0/5	1/5
1	0/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	3/5	3/5	5/5	5/5	4/4	3/3
2	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	5/5	5/5	5/5	5/5	4/4	3/3
3	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	4/5	4/5	5/5	5/5	3/3	2/2
4	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	2/5	3/4	5/5	3/3	2/2
5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	3/5	3/5	3/4	5/5	3/3	2/2
6	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	2/5	4/5	2/4	5/5	3/3	2/2
7	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	2/5	2/4	5/5	3/3	2/2
8	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	1/4	5/5	3/3	2/2
9	0/5	0/5	0/5	0/5	1/5	0/5	0/5	0/5	1/5	1/5	4/4	3/5	2/3	2/2
10	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/3	3/5	3/3	2/2
11	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/5	0/5	0/5	1/3	3/5	2/2	2/2
12	0/5	0/4	0/5	0/5	1/5	0/5	0/5	1/5	1/4	1/4	1/3	3/5	1/2	2/2
13	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	1/4	0/3	2/3	3/5	1/1	2/2
14	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/4	0/3	1/3	1/5	1/1	2/2
15	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	1/4	0/3	0/3	1/5	1/1	2/2
16	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/3	0/3	0/3	1/4	1/1	2/2
17	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/3	0/3	0/3	1/4	1/1	1/1
18	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/1	0/3	0/3	1/4	1/1	1/1
19	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/1	0/3	1/1	1/3	1/1	1/1
20	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/1	0/3	D[c]	2/3	1/1	1/1
21	0/5	0/4	0/5	0/5	1/5	0/5	0/5	0/4	0/1	1/3	D[c]	2/3	1/1	1/1

[a] A and B represent replicates; each replicate initially contained 5 fish (total 10 fish per test concentration) at test start

[b] Sublethal effects mean the number affected per total surviving fish. Fish were affected if they exhibited any one or a combination of the following: lying on the bottom of the test vessel, gasping, partial loss of equilibrium, discoloration, or bloating of the stomach area.

[c] D means all fish were dead.

In conclusion the 21-day LC_{50} for the rainbow trout was 6.1-mg Methomyl 20SL/l (1.2 mg a.s./l) based on the total nominal formulation concentrations. The NOEC was 2.5 mg Methomyl 20SL/l (0.49 mg a.s./l) based on mortality and sublethal effects at 5.0 mg Methomyl 20SL/l.

* It should be noted that the formulation used in this study contained more 51% methanol solvent rather than 28%. Full formulation details are given in Volume 4i, Section C.1.3.

The study was undertaken in accordance with OECD 204 and GLP.

(Baer, K.N. (1991) HLR 34-91)

b) The effects of methomyl (purity 98.4%) to eggs and fry of the fathead minnow, *Pimephales promelas,* was determined in a flow-through, early life-stage 35-day toxicity test. Treatments consisted of a dilution water control and nominal concentrations of 19, 38, 75, 150, and

300µg/l methomyl. Two replicates containing 25 eggs each were exposed to each treatment concentration and control in incubation cups. All incubation cups were observed daily. Dead eggs and fungal-infected eggs were removed. The 29-day post-hatch growth period began on study Day 6, when 95% hatch was attained. Observations of abnormal behaviour, physical changes, and mortality were recorded daily. At the end of the study, standard length and blotted wet weight were measured.

Mean measured concentrations of methomyl were 18.0, 39.3, 73.0, 145, and 261 µg a.s./l and ranged from 87 to 103% of nominal concentrations. Egg hatchability and fry survival were not significantly reduced at any test concentration. The no observed effect concentration (NOEC) was 73.0 µg a.s./l based on significant effects on fry growth, as measured by standard length and wet weight, after 35 days of exposure at 145, and 261µg a.s./l. Mean standard lengths were 21.15, 21.71, 20.648, 21.080, 19.286 and 18.563 mm in the control and at the concentrations of 18.0, 39.3, 73.0, 145, and 261-µg a.s./l respectively. Mean blotted wet weights were 0.146, 0.148, 0.135, 0.147, 0.118 and 0.112 g in the control and at the concentrations of 18.0, 39.3, 73.0, 145, and 261 µg a.s./l respectively. The lowest observed effect concentration (LOEC) was 145 µg a.s./l, and the maximum acceptable toxicant concentration (MATC) was 104µg a.s./l. All chemical and physical parameters for the 35-day study were within acceptable ranges.

A summary of percent fry survival, percent egg hatch, fry standard length for all fry and blotted wet weight of surviving fry is presented in Table B.9.20.

Table B.9.20 Summary of test endpoints following exposure of *Pimephales promelas* to methomyl for 35 days

Mean, measured concentrations of methomyl (µg/l)	Mean % Survival[a]	Mean % Egg Hatch	Mean Standard Length[b] (mm)	Mean Blotted Wet Weight[b] (g)
Water Control	92.00	94.00	21.15	0.146
18.0	86.00	92.00	21.17	0.148
39.3	86.00	90.00	20.68	0.135
73.0	86.00	88.00	21.08	0.147
145	94.00	96.00	19.29*	0.118*
261	92.00	96.00	18.56*	0.112*

a Percent of fathead minnow fry alive at the end of the test
b Standard length (all fry) and blotted wet weight (surviving fry) were measured at the end of the study
* Denotes statistically significant (Dunnett's, single-tailed, test, P≤ 0.05) reduction when compared to the control.

In conclusion the 35-day NOEC for the fathead minnow (*Pimephales promelas*) was 73.0 µg a.s./l (0.073 mg a.s./l) the LOEC was 145-µg a.s./l, based on mean, measured concentrations of methomyl. The MATC was 104-µg a.s./l.

The study was broadly in line with OECD 210 although this guideline was only adopted in 1992. Testing was in accordance with GLP.

Rhodes, J.E. (1991) HLO 702-91.

c) The toxicity of methomyl (purity 98.35%) to the fathead minnow (*Pimephales promelas*), was determined in a flow-through full life-cycle toxicity study. The study was conducted to determine the estimated maximum acceptable toxicant concentration (MATC). Newly fertilised eggs were used for the study with exposure continuing for 193 days. Treatments consisted of a dilution water control, and nominal concentrations of 19.0, 38.0, 75.0, 150, and 300 µg a.s./l. Four replicates with 50 eggs each, were randomly set-up for the control and the five test concentrations. Eggs were placed in incubation cups and allowed to hatch. At Day 7, the fry were thinned to 25 per replicate and released into their respective chambers. Measurements for length and blotted wet weights were recorded. Observations of abnormal behaviour, abnormal physical change, and mortality were recorded daily for both the parental group and first generation offspring exposures.

Mean measured exposure concentrations of methomyl were 18.0, 40.7, 76.0, 142, and 280-µg a.s./l. These values ranged from 93.3 to 107% of the target nominal test concentrations. Parental generation egg hatchability and survival were significantly reduced at the 142 and 280-µg a.s./l. At 28, 56, and 84 days post-hatch, parental generation growth, in terms of length, was significantly reduced after exposure to 142 and 280-µg a.s./l. Parental generation growth, in terms of wet weight, showed a significant reduction after 84 days of exposure to 280-µg a.s./l. Reproductive activity, measured by days to first spawn, number of spawning days, number of spawns, and number of eggs per spawn, was not significantly affected at any test concentration. F_1 generation egg hatchability and survival after 56 days of growth were not significantly reduced at any test. F_1 generation growth measured by length and by blotted wet weight at 56 days post-hatch resulted in significant reductions after exposure to 142 and 280-µg a.s./l, respectively. Treatment related physical abnormalities included distended abdomens and a bloated appearance in the 280-µg/l a.s. test concentration.

Based on the growth endpoints evaluated in this fathead minnow (*Pimephales promelas*), full life-cycle toxicity study, the MATC for methomyl is 104 µg/l. The no observed effect concentration is 76.0 µg/l (0.076 mg a.s./l) and the lowest observed effect concentration is 142-µg/l methomyl.

Table B.9.21 Mean percent hatch of embryos and percent survival for parental and F1 generation fathead minnow (*Pimephales promelas*) exposed to methomyl

Mean measured concentration µg/l	Overall percent hatch of parental generation embryos		Overall percent hatch of F1 generation embryos		Overall Percent survival of parental generation			Overall percent survival of F1 generation
	Day 0	Day 2	Day 0	Day 2	Day 28	Day 56	Day 84	Day 56
Water Control	93.5	100	94	96	100	100	99	95
18.0	92	100	91[x]	91[x]	96	95*	95	96[x]
40.7	89	100	82*	91	100	99	99	96
76.0	90.5	99.5	92	96	99	99	99	94
142	85*	100	90	95	97	97	97	90
280	90	100	86*	98	94*	93*	93*	86

* Statistically significant (Dunnett's, single-tailed, test, $p \leq 0.05$) reduction from the control.
[x] Value from one replicate and does not represent a mean.

Table B.9.22 Mean percent hatch of embryos and percent survival for parental and F1 generation fathead minnow (*Pimephales promelas*) exposed to methomyl

Mean measured concentration µg/l	Mean standard lengths of parental generation (mm)			Mean standard length of F1 generation (mm)	Mean blotted wet weight of parental generation (g)	Mean blotted wet weight of F1 generation (g)
	Day 28	Day 56	Day 84	Day 56	Day 84	Day 56
Water Control	21.90	35.50	42.60	37.70	1.574	0.945
18.0	21.70	35.50	42.50	38.10	1.591	1.048
40.7	21.10	34.30	42.10	37.20	1.494	0.915
76.0	21.80	35.00	42.20	36.50	1.522	0.932
142	20.70*	33.30*	40.30*	35.40*	1.434	0.815
280	18.10*	30.50*	37.30*	30.60*	1.294*	0.677*

* Statistically significant (Dunnett's, single-tailed, test, $P \leq 0.05$) reduction from control

In conclusion the no-observed effect concentration is 76.0-µg a.s./l (0.076 mg a.s./l) (based on the most sensitive endpoint, growth, evaluated in this fathead minnow (*Pimephales promelas*) full life-cycle toxicity study. In addition, it should be noted that effects on egg hatchability and survival were noted at 142 and /or 280 -µg a.s./l. The MATC is 104-µg a.s./l and the lowest observed effect concentration (LOEC) is 142-µg a.s./l based on mean measured concentrations.

This study was undertaken in accordance with U.S. EPA 72-5 and to GLP.
(Strawn, T., Rhodes, J.E., Leak, T. (1993 HLO 47-93)

Aquatic invertebrates (IIA 8.2.5)

A static renewal chronic toxicity test was conducted by exposing groups of cladocerans (*Daphnia magna*), less than 24 hours old, to six nominal concentrations of methomyl (purity 99.0%) for 21 days. Test solutions were renewed 3 times a week. Nominal test concentrations used in the study were 0.4, 0.8, 1.6, 3.2, 6.2, and 12.5 µg a.s./l. There was also a dilution water control. During the study, concentrations were measured at 0, 24, 48 or 72 hours. The stability of methomyl over a 72 h period was also established. Analytical verification of methomyl concentrations was made on day 0 and at regular intervals throughout the study. The mean measured concentrations of methomyl were 0.7, 1.0, 1.6, 3.5, 7.5, and 13.8 µg/l and ranged from 100 to 175% of the nominal concentrations. It was noted that at the lower concentration rates the measured versus the nominal did not correlate well which was attributed to detection limitations and the technology available at the time. Survival, growth (adult body length), reproduction (young produced/adult reproductive day) were measured.

No dead adults were observed in any of the concentrations above the allowed 10% level at any time during the study. Mean body lengths of adults were 3.7 mm in the control and 3.8 mm in all the test groups. Mean numbers of offspring/adult were 149, 159, 143, 162, 105, 95 and 114 in the control, 0.4, 0.8, 1.6, 3.1, 6.3, and 12.5 µg a.s./l groups, respectively. This shows that the reproduction was significantly reduced at 3.1, 6.3 µg a.s./l and 12.5 µg a.s. /l. The first day of reproduction was significantly delayed at 0.8, 1.6, 3.1, 6.3 and 12.5 µg a.s./l, being day 8.5, 8.5, 8.4, 9.6 and 8.7 compared with day 7.4 in the control. It was concluded that this delay of approximately 1 day was not biologically relevant. At 3.1, 6.3 and 12.5 µg/l this delay was also accompanied by a significant reduction in the number of young produced which was considered to be biologically relevant. Results for the number of offspring and the day of reproduction are shown in Table B.9.23. Based on the statistical analyses of these data, the reproductive NOEC for *Daphnia magna* is considered to be 1.6 µg a.s./l (0.0016 mg a.s./l) (based on the reduction in offspring at concentrations of 3.1 µg/l and above). It was concluded that the Maximum Acceptable Toxicant Concentration is between 1.6 and 3.1 µg a.s./l.

Table B.9.23 Number of offspring and day of reproduction for *D. magna* at different concentrations of methomyl

Concentrations (µg a.s./l)	No of offspring	Day of reproduction
0	149	7.4
0.4	159	7.6
0.8	143	8.5*
1.6	162	8.5*
3.1	105*	8.4*
6.3	95*	9.6*
12.5	114*	8.7*

* P<0.05

The study was not conducted to GLP and used ASTM (1981) draft method.
(Brittelli, M.R (1982): HLR 46-82)

Effects on sediment-dwelling organisms (IIA 8.2.7)

Studies summarised in Sections B.9.2.1 above contained information on benthic organisms including *Chironomus sp.*. The end points for these species are summarised below.

Table B.9.24 Summary of acute toxicity studies with methomyl for sediment dwelling species

Test Organism	End-Point mg /l
Gammarus italicus Goedm.	96-hr LC_{50} = 0.047
Echinogammarus tibaldii Pink	96-hr LC_{50} = 0.250
Gammarus pulex	96-hr LC_{50} = 0.760
Gammarus pseudolimnaeus	96-hr LC50 = 1.050
Chironomus plumosus	48-hr EC_{50} = 0.088
Chironomus sp.	96hr EC_{50} = 0.032

Mesocosm study (IIIA 10.2.2)

A microcosm study with the formulation Lannate has been made available. It is important to note that the applicant did not consider that this study was of use in support of this application. The study design applied methomyl at daily, every three days and seven day intervals. This is out of line with the proposed EU application interval of 14 days. In addition, total load into the system were greater than those proposed in Europe. Water temperatures in the study were approximately 28.5 – 33.8 ^{o}C. The study also contained fish which can also have the potential to adversely effect the results obtained. In addition results were expressed in terms of the total amount of active substance per microcosm rather than as a water concentration thus making the results difficult to interpret. For this reason this study is not considered to be appropriate for use in the risk assessment for methomyl.

Bioaccumulation (IIA 8.2.3)

The logKow of methomyl is 0.09and therefore a fish bioaccumulation study is not required.

B.9.2.3 Risk assessment

The overall results for both methomyl and the formulation Methomyl 20SL are summarised in Table B.9.25. It should be noted that some of the testing with additional non-standard species were from studies not undertaken to GLP and that there was not always analytical confirmation of study concentrations. The majority of these studies were done at a time prior to their being an actual requirement for GLP testing, but were nonetheless undertaken in line with standards then prevailing. In addition, some of the results were undertaken by recognised organisations e.g. United States Department of the Interior Fish and Wildlife Service. Therefore it is considered that these data can be used as supporting information and provide an overview of the general toxicity of methomyl to aquatic species.

The fish acute formulation studies used a formulation with an increased methanol solvent content than the proposed formulation. However, it is considered that the results can still be used for risk assessment purposes as potentially they may be more worse case than with the formulation proposed. The end points for the standard species to be used in the risk assessment are highlighted in bold.

Table B.9.25 Summary of aquatic end points for methomyl and Methomyl 20SL

Test substance	Test organism	Exposure period	EC_{50} or LC_{50} (mg as/l)	NOEC (mg as/l)
Methomyl (DPX-X1179 Technical)	*Oncorhynchus mykiss* (rainbow trout)	96 h	2.49	NA
Methomyl (DPX-X1179 Technical)	*Lepomis macrochirus* (bluegill sunfish)	96 h	**0.63**	NA
Methomyl (DPX-X1179 Technical)	*Pimephales promelas* (fathead minnow)	35 d	NA	**0.073**
Methomyl (DPX-X1179 Technical)	*Pimephales promelas* (fathead minnow)	84 d	NA	0.076
Methomyl 20SL	*Oncorhynchus mykiss* (rainbow trout)	96 h	3.9	NA
Methomyl 20SL	*Lepomis macrochirus* (bluegill sunfish)	96 h	1.1	NA
Methomyl 20SL	*Oncorhynchus mykiss* (rainbow trout)	21 d	1.2	0.49
Methomyl (16RLMX99 Technical)	*Daphnia magna* (waterflea)	48 h	**0.017**	0.0104
Methomyl 20SL	*Daphnia magna* (waterflea)	48 h	Neonates = 0.0193 12-day old adults = 0.0362	NA
Methomyl 20SL	*Daphnia magna* (waterflea)	48 h	28-day old adults > 0.123	NA
Methomyl 20SL	*Daphnia magna* (waterflea)	96 h	27-day old adult = 0.098 neonate = 0.084 acute NOEC = 0.026	NA
Methomyl (DPX-X1179 Technical)	*Daphnia magna* (waterflea)	21 d	NA	**0.0016**
Methomyl technical	*Gammarus italicus* (scud)	96 h	0.047	NA
Methomyl technical	*Echinogammarus tibaldii* (scud)	96 h	0.250	NA
Methomyl technical	*Daphnia longispina* (cladoceran, water flea)	96 h	0.220	NA

Test substance	Test organism	Exposure period	EC_{50} or LC_{50} (mg as/l)	NOEC (mg as/l)
Methomyl technical	*Cyclops strenuous* (copepod)	96 h	0.190	NA
Methomyl technical	*Gammarus pulex* (scud)	96 h	0.760	NA
Methomyl technical	*Biomphalaria alexandrina* (snail)	96 h	1.10	NA
Methomyl technical	*Bulinus truncatus* (snail)	96 h	0.870	NA
Methomyl technical	*Pteronarcella bahia* (stonefly)	96 h	0.060	NA
Methomyl technical	*Skwala* sp. (stonefly)	96 h	0.029	NA
Methomyl technical	*Gammarus pseudolimnaeus* (scud)	96 h	1.050	NA
Methomyl technical	*Chironomus sp.*	96 h	0.032	NA
Methomyl technical	*Isogenus* sp. (stonefly)	96 h	0.343	NA
Methomyl technical	*Chironomus plumosus* (midge)	48 h	0.088	NA
Methomyl (16RLMX99 Technical)	*Pseudokirchneriella subcapitata* (green algae)	72 h	> **100**	100
Methomyl (16RLMX99 Technical)	*Scenedesmus subspicata* (green algae)	72 h	> **100**	100

NA = Not applicable to risk assessment.

To undertake the risk assessment for methomyl it is necessary to consider three different exposure scenarios. These are use on (i) taller growing crops i.e. tomatoes and grapes post-flowering (ii) use on grapes early pre-flowering and (iii) use on low-growing vegetables i.e. courgettes and aubergines (Section B.8.6). For cucumbers it is necessary for Member States to consider which category cucumbers fit into under their growing regimes. In addition, the risk assessment focuses on the maximum individual dose of 0.45 kg a.s./ha with two applications at a 14 day interval. For tomatoes, aubergines, cucumbers and courgettes two applications at a lower individual dose of 0.25 kg a.s./ha are also recommended. The risk assessment for these lower rates should be considered on a Member State basis where these uses are recommended.

Acute risk and chronic risk assessment

Test with the formulation Methomyl 20SL were provided for *Lepomis macrochirus* and *Daphnia magna.* The results in terms of active substance are shown in Table B.9.25. These results show that the formulation is of similar or slightly lower toxicity than the active substance. Therefore the acute risk assessment will be based on the active substance.

Several chronic studies were provided for fish, these included a 21-day study, a fish early life cycle study and a full life cycle study. The end points are shown in Table B.9.25. The end points from the early life cycle study and the full life cycle study were closely comparable being 0.073 and 0.076 mg a.s./l respectively. The slightly lower value of 0.073 has been used in the chronic risk assessment.

i) Taller growing crops i.e. tomatoes and grapes post-flowering (i.e. late grapes); 2 applications at 450 g a.s./ha

Acute risk

The resulting Toxicity Exposure Ratios (TERs) using the acute end points for the active substance and are show in Table B.9.26.

Table 9.26 Acute and chronic toxicity exposure ratios for methomyl from spray drift at 3 m (tall vegetables and late grapes)

Species	LC/EC50 mg a.s./l	PEC at 3 m (mg a.s./l)	TER for a.s.	Annex VI trigger
Acute risk				
Fish *Lepomis macrochirus*	0.63	0.0124	50.8	100
Aquatic invert. *Daphnia magna*	0.017	0.0124	1.37	100
Algae *Scenedesmus subspicatus and Pseudokirchneriella subcapitata*	>100	0.0124	8064	10
Chronic risk				
Fish *Pimephales promelas*	0.073	0.0124	5.9	10
Aquatic invert. *Daphnia magna*	0.0016	0.0124	0.129	10

Both the acute TER for aquatic invertebrates and fish is below the Annex VI trigger value and therefore require further consideration. The TER for algae is above the trigger value and the risk is therefore considered to be acceptable.

In order to assess the interspecies sensitivity of aquatic invertebrates a literature search was undertaken. These data are summarised in Table B.9.27. They include species representative of another water flea (Cladoceran species), *Daphnia longispina*, a copepod (*Cyclops strenuous*), stone flies (Plecoptera) (*Pteronarcella bahia, Skwala sp. Isogenus sp.*), several benthic organisms (*Chironomus plumosus, Gammarus pulex, G. pseudolimnaeus, G. italicus, Echinogammarus tibadii*) and in addition some snail species (gastropod molluscs, *Bulinus truncates* and *Biomphalaria alexandrina*).

Table B.9.27 Summary of acute aquatic fresh-water invertebrate end points for methomyl

Test Substance	Test organism	Exposure Period	EC_{50} or LC_{50} (mg a.s./l)	NOEC (mg a.s./l)
Amphipoda				
Methomyl technical	*Echinogammarus tibaldii* (scud)	96 h	0.250	NA
Methomyl technical	*Gammarus italicus* (scud)	96 h	0.047	NA
Methomyl technical	*Gammarus pulex* (scud)	96 h	0.760	NA
Methomyl technical	*Gammarus pseudolimnaeus* (scud)	96 h	1.050	NA
Cladocera				
Methomyl (16RLMX99 Technical)	*Daphnia magna* (water flea)	48 h	0.017[1]	0.0104
Methomyl technical	*Daphnia longispina* (water flea)	96 h	0.220	NA
Copepoda				
Methomyl technical	*Cyclops strenuous* (copepod)	96 h	0.190	NA
Diptera				
Methomyl technical	*Chironomus plumosus* (midge)	48 h	0.088	NA
Gastropoda				
Methomyl technical	*Biomphalaria alexandrina* (snail)	96 h	1.10	NA
Methomyl technical	*Bulinus truncatus* (snail)	96 h	0.870	NA
Plecoptera				
Methomyl technical	*Pteronarcella bahia* (stonefly)	96 h	0.069	NA
Methomyl technical	*Skwala* sp. (stonefly)	96 h	0.032	NA
Methomyl technical	*Isogenus* sp. (stonefly)	96 h	0.343	NA

The 'Guidance Document on Higher Tier Aquatic Risk Assessment for Pesticides' (HARAP), Ed. P.J Campbell et al. (1998) indicates that uncertainty factors can potentially be reduced by an order of magnitude if additional species testing is undertaken. It is proposed that for aquatic invertebrates it would be appropriate to test eight species in order to be able to consider a reduction in the uncertainty factor.

In this instance the results from in excess of eight additional aquatic invertebrate species are presented. *Daphnia magna* is the most sensitive species amongst these additional species tested. On the basis of this information it is considered that the uncertainty about variation between species is reduced and that it is therefore acceptable to reduce the uncertainty trigger value to below the normal value of 100. HARAP proposes that an order of magnitude reduction is appropriate.

In addition, separate studies were performed on *D. magna* of different age groups (Table B.9.28). These included standard tests on <24-hour old neonates, 12-day old daphnids and 28-day old adult daphnids. In all cases the time to event increased with age as a function of concentration and the sensitivity of daphnid to methomyl decreased with increasing age. Adults (28-day old) were approximately 7-fold less sensitive than neonates and 3.4-fold less sensitive than the 12-day old daphnids. Again 12-day old daphnids were approximately 2-fold less sensitive than the neonates. The toxicity end points for *Daphnia magna* are summarised in the table below.

Table B.9.28 EC50 values for different ages of *D. magna* to methomyl

Age of *Daphnids*	Test Duration	EC50 (mg a.s./l)	Ref.
24 hours	48 hours	0.017	Wetton, P.M. & Mullee, D.M. (1999) SPL 282/572
24 hours	48 hours	0.019	Ward, T.J. et al (2001) 3726
12 days	48 hours	0.036	Ward, T.J. et al (2001) 3726
27 days	96 hours	0.098	Hoke, R.A. (2002b) 11049
neonates from 27 day old adults	96 hours	0.084	Hoke, R.A. (2002b) 11049
28 days	48 hours	>0.123	Hoke, R.A. (2002a) 10461

The study by Hoke, R.A 2000b, 11049 was undertaken to examine the effects on adult *D.* magna and neonates under time-varied exposure to methomyl. This study was undertaken to match the breakdown of methomyl in a natural pond system of 33.5 hours (B.8.4.4, Koch Singles,S and Theilaker, W 2002). However it should be noted that it was considered that this study did not provide an appropriate representation of the DT50 of methomyl due to the high temperatures occurring in the study and the fact that plants in the study accounted for sorption of 38% of applied radioactivity (B.8.4.6). Instead it was considered that the DT50 in water is 5 days (B.8.4.6) i.e. significantly in excess of that used in the study. Therefore this study does not reflect the DT50 of methomyl which is considered to be 5 days. However, it does provide a further indication that different ages of daphnids have differing sensitivity.

In conclusion at 3m the TERs for *Daphnia* even taking account of an order of magnitude reduction in uncertainty is still below the required trigger value of 10 (Table B.9.26). Therefore it is necessary to consider an increased buffer distance which will result in the TER for aquatic invertebrates, represented by *Daphnia*, being in excess of 10. However, it should be noted that it is also necessary to consider the chronic TERs for both fish and aquatic invertebrates (see below). It should be noted that it is only with a buffer zone of 50 m that the chronic TER for aquatic invertebrates is above the trigger value of 10. In this particular instance it is therefore the chronic risk assessment rather than the acute risk assessment that is pivotal in determining the necessary buffer distance. Due to this reason, at a distance of 50m the acute TERs are above the Annex VI trigger value. In reality therefore no use has been made of the HARAP approach for the acute risk assessment. At 50 m the PEC is 0.00015 mg a.s./l and the acute TERs for aquatic organisms are shown in Table B.9.29.

Table 9.29 Acute and chronic toxicity exposure ratios for methomyl from spray drift at 50 m (tall vegetables and late grapes)

Species	LC/EC 50 mg a.s./l	PEC at 50 m (mg a.s./l)	TER for a.s.	Annex VI trigger
Acute risk				
Fish *Lepomis macrochirus*	0.63	0.00015	4200	100
Aquatic invert. *Daphnia magna*	0.017	0.00015	113	100
Algae *Scenedesmus subspicatus and Pseudokirchneriella subcapitata*	>100	0.00015	>666667	10
Chronic risk				
Fish *Pimephales promelas*	0.073	0.00015	487	10
Aquatic invert. *Daphnia magna*	0.0016	0.00015	10.7	10

Chronic risk

The chronic TERs for fish and aquatic invertebrates at 3m are shown in Table B.9.26. At this distance both the TERs are below the Annex VI trigger value, however with a 50 m buffer zone the TERs are all acceptable

(Table B.9.29). A case was made by the notifier for the use of time-weighted averages in the risk assessment. It is considered that the use of time weighted averages could potentially underestimate the risk resulting from initial period of exposure. Therefore this approach has not been used.

ii) Grapes – pre-flowering

In certain Member States it is potentially possible that application may be made to grapes prior to flowering. The PECs for this use are lower than those examined at (i) above. Where this use is required this should be considered on a Member State basis.

iii) Low-growing vegetables e.g. courgettes and aubergines; 2 applications at 450 g a.s./ha

Acute and chronic risk

The PECs for low-growing vegetables are lower than those for tall growing vegetables. It should be noted that the maximum PEC results from considering a single spray rather than from two sprays (Section B.8.6) and therefore this is the value that has been used in the risk assessment. For details of the full approach see (i) above. The resulting TERs using the PECs at 1m are shown in Table B.9.30.

Table 9.30 Acute and chronic toxicity exposure ratios for methomyl from spray drift at 1 m (low-growing vegetables)

Species	LC/EC50 mg a.s./l	PEC at 1 m (mg a.s./l)	TER for a.s.	Annex VI trigger
Acute risk				
Fish *Lepomis macrochirus*	0.63	0.00415	151	100
Aquatic invert. *Daphnia magna*	0.017	0.00415	4.1	100
Algae *Scenedesmus subspicatus and Pseudokirchneriella subcapitata*	>100	0.00415	24096	10
Chronic risk				
Fish *Pimephales promelas*	0.073	0.00415	17.5	10
Aquatic invert. *Daphnia magna*	0.0016	0.00415	0.38	10

As shown in Table B.9.30 the acute and chronic TERs for aquatic invertebrates are below the appropriate trigger values at 1m. However with a buffer zone of 30 m the TERs are all above the relevant trigger values (Table B.9.31).

Table 9.31 Acute and chronic toxicity exposure ratios for methomyl from spray drift at 30 m (low-growing vegetables)

Species	LC/EC50 mg a.s./l	PEC at 30 m (mg a.s./l)	TER for a.s.	Annex VI trigger
Acute risk				
Fish *Lepomis macrochirus*	0.63	0.00015	4200	100
Aquatic invert. *Daphnia magna*	0.017	0.00015	113	100
Algae *Scenedesmus subspicatus and Pseudokirchneriella subcapitata*	>100	0.00015	>666667	10
Chronic risk				
Fish *Pimephales promelas*	0.073	0.00015	487	10
Aquatic invert. *Daphnia magna*	0.0016	0.00015	10.7	10

For cucumbers, it is highlighted that Member States should consider whether they fit into the tall or low-growing vegetable category under their growing regimes.

iv) Use on the listed vegetables at the lower rate; 2 applications of 250 g a.s./ha

In certain Member States it is possible that application may be required at the lower rate of 250 g a.s./ha. The PECs for this use are lower than those examined above. Where this use is required this should be considered on a Member State basis.

Risk to sediment-dwelling invertebrates

Testing on sediment dwellers is required when >10% of applied radioactivity represented by the parent compound is present in sediment at or after 14 days. This was not the case for methomyl (Section B.8.4.6) and hence a risk assessment for sediment dwelling organisms is not required. In addition, it should be noted that acute studies were provided for a number of sediment dwelling organisms. These studies showed *Daphnia magna* to be the most sensitive aquatic invertebrate and a chronic risk assessment has been undertaken for this species.

Drainflow/runoff

It is considered that methomyl is unlikely to enter drains from the proposed uses and therefore a risk assessment is not required. However, if this is not considered to be the case then it should be assessed at Member State level. Similarly runoff should also be considered at a Member State level.

Groundwater

No metabolites or breakdown products are expected to occur in groundwater at >0.1 µg/l (Section B.8.2.4).

Bioaccumulation

The log Kow for methomyl is 0.09 at 25 °C i.e. <3 and in addition the DT50 in water is only 5 days (Section B.8.4.6). Therefore a bioconcentration study is not required.

Metabolites/Degradation products

No significant environmental metabolites have been identified.

Overall conclusion for the aquatic risk

An acceptable acute and chronic risk to aquatic invertebrates in surface water was identified at the maximum proposed application rate (for taller growing crops and grapes post-flowering) with appropriate risk mitigation measures. A 50 m buffer zone is necessary to manage the chronic risk to *Daphnia magna* the most sensitive aquatic organism. For low-growing crops the buffer zone required is reduced to 30 m. For other uses e.g. lower rates in vegetables and pre-flowering grapes risk management measures need to be considered as appropriate at Member State level.

Modelling showed that levels of methomyl in groundwater were below 0.1 µg a.s./l.. Data on degradation in the saturated zone indicated that groundwater contamination will not occur.

Methomyl was not considered to bioconcentrate and no aquatic metabolites were identified.

B.9.3 Effects on other terrestrial vertebrates (IIIA 10.3)

B.9.3.1 Toxicity

Data on the mammalian toxicity of methomyl have been assessed in Section B.6. The end points obtained are summarised as follows:

Table B.9.32 Summary of toxicity endpoints for methomyl

Test type	Measurement endpoint	End point and species
Acute LD50 Multigeneration	LD_{50} NOAEL	30 mg a.s./kg bw for female rat 75 ppm rat (NOAEL for pup growth and development) Pup survival was reduced at 1200 ppm however there were no observable adverse effects at 600 ppm. No effects on reproduction or fertility at the highest dose (1200ppm). Section B.6.6.1 (Lu, 1983).

The long-term risk assessment has been undertaken using end point of 75 ppm as proposed by the notifier. However, it should be noted that there were no observable adverse effects on reproduction or fertility at 1200 ppm. The NOAEL for pup survival was considered to be 600 ppm. This is further discussed below.

The risk assessment has not been based on the methodology outlined in SANCO/4145/2000 as this was not finalised when the dossiers were being compiled. However, reference has been made to the principles in this guidance where this is appropriate in the risk assessment approach.

It should be noted that in carrying out the (bird and) mammal risk assessment the following procedure has been followed - for the acute toxicity:exposure ratio the LD50 has been compared to the daily food consumption (wet weight) and assuming residue data outlined in EPPO (1992). As regards the short and long-term risk assessment the appropriate endpoint, in terms of ppm diet, has been compared to residues on treated food, where the residue data have been taken from EPPO (1992).

Acute and long term risk

Use is recommended on grape vines and on tomatoes, cucumbers, courgettes and aubergines. It is considered that there are therefore two exposure scenarios that need to be addressed i.e. grapes and fruiting vegetables.

i) Grapes – herbivorous mammal; 2 applications at 450 g a.s./ha

It is considered that the most appropriate scenario for use in grape vines is a small herbivorous mammals potentially grazing grass strips between the vines. The risk assessment approach is as detailed in Section B.9.1.5. According to the EPPO vertebrate risk assessment scheme, the daily food consumption of a small mammal (<100 g bw, such as a small herbivorous species) is approximately equal to 30% of its bodyweight. As this is in dry weight a conversion factor of 2.4 is required in order for comparisons with the toxicity value to be made. As a result the daily fresh weight of food required for a small mammal is 72%. The ETE is considered to be 0.45 kg a.s./ha x 112 (EPPO factor for short grass) x 0.4 interception value for short grass x 1.2 acute multiple application factor these last two values are derived from the proposed *Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC*, SANCO/4145/2000, 25 September 2002, resulting in a value of 24.19. The use of these values would result in acute and long term TER values below the Annex VI trigger values. However, actual residue trials have been provided and the maximum value derived from grass strips in these is a concentration of 18 mg a.s./kg on grass and broadleaf vegetation (Section B.9.1.4). These values have therefore been used in the risk assessment and the resulting TERs are shown in Table B.9.33.

Table 9.33 Toxicity exposure ratios for exposure of small herbivorous mammals in grapevines to methomyl

Category	Time scale	Toxicity endpoint	ETE*	TER	Annex VI trigger
Grape (table and vine)[1]					
Small herbivorous mammal	Acute	30 mg a.s./kg bw	12.96	2.3[1]	10
Small herbivorous mammal	Long-term	75 ppm feed	18 ppm	4.2[2]	5

*ETE= Based on the maximum value from field trials (Section B.1.9.4)
[1] Based on an estimated food intake of 72% of bodyweight.
[2] Based on a direct comparison of the study end point and the ETE.

Both the acute and long term TERs are below the Annex VI trigger value. The applicant has made the following observations with regard to the risk assessment for herbivorous mammals:

- Herbivorous mammals e.g. voles are unlikely to use the vineyard as their permanent habitat since their grass tunnels would be continually disturbed by mowing to keep the grass short.
- Their diet is also likely to consist of plant roots and not solely aerial foliage.
- Vineyards will not always contain grass strips between the rows (grass may be removed).
- Where grass strips exist it is possible that they may be senesced or dormant at the time of application of methomyl.

Although it is possible that some of these points may be pertinent, it is also the case that they may not apply in all circumstances. In addition, no information has been provided to verify or support the statements made. Therefore it is considered that they cannot be used to refine the risk assessment.

Refinement of the acute exposure (see Appendix 5)

Additional information has been provided to address the acute risk to mammals. This is included in Appendix 5.

a) Considering Section 4.1 of Appendix 5:

It should be noted that it is considered that slightly different (lower) figures should be used in the risk assessment. These are that the LD50 value should be 30 based on the end point for females. In addition, it is considered that it is inappropriate to use an average value for residues on grass. Instead the worse case value from the residue trials of 18 ppm should be used (Section B.9.1.4). See Table B.9.33 for TERs and ETE values.

b) Considering Section 4.2 of Appendix 5 – continuous feeding and degradation within the animal

It is considered that the acute oral study where methomyl is administered by gavage as a single dose represents a worse case situation. In the field metabolism and degradation will be occurring within the animal as the intake of methomyl will occur over a period of time. . This is supported by the information presented in Appendix 5 where rapid elimination was demonstrated in the rat. In the TER approach produced in Table 6 Section 4.2 Appendix 5, use has been made of both degradation on vegetation and within the animal. It is considered that such an approach is potentially feasible to address this issue however further explanation is required of exactly how the values are being used in the calculation. In addition, further consideration of the scientific concepts behind this type of approach is also required.

In addition, calculations have been undertaken to quantify the amount of treated food that would be required to obtain a LD50 for a 30 g mammal. As noted at (a) above some of the values used in this assessment are slightly below the worst case values, however they are adequate here to give a rough indication of the quantity of food. It is estimated that 74 g of food would be required but again as noted in the bird section (B.9.1.5 (i)) this does not include any uncertainty factor. When an uncertainty value of 10 is included this value is reduced to 7.4 g food. It is considered that there is insufficient information available to show whether or not this is likely in practice.

At this stage it is considered that there is insufficient information available to identify an acceptable use on grapes for mammals. However, it should be noted that the TER is >1 (being 2.3) and the expectation is that it will be possible to address this issue with further appropriate information and clarification.

For the long term risk it is important to note that the residues declined very rapidly on vegetation and the DT50 value on foliage was considered to be

2 days (Section B.9.1.4). The residue field trials showed that the maximum residue recorded three days after the second application was only 11 mg a.s./kg. If this value is used in the risk assessment the resulting long term TER is 6.8 i.e. greater than the Annex VI trigger value. It should be noted that this risk assessment has been based on the worst case scenario that herbivorous mammals obtained 100% of their diet from the treated area. This is unlikely to be the case. Therefore taking these factors into consideration it is considered that in reality the long term risk to herbivorous mammals is acceptable.

In addition, it should be noted that it could be argued that the NOAEL of 600 ppm for pup survival could be used for the long term risk assessment rather than considering effects on pup growth and development. If this value was used then the long term TER is 600/18 i.e. 33.

It is considered that the long term risk to herbivorous mammals is acceptable and that this does not need to be considered further.

ii) Vegetables – insectivorous mammal; 2 applications at 450 g a.s./ha

It is considered that for courgettes, aubergines, tomatoes and cucumbers that it is unlikely that the foliage will be attractive to mammals and directly consumed. Therefore exposure via the consumption of contaminated insects on foliage will be considered instead. The risk assessment approach is as detailed in Section B.9.1.5 and as above i.e. 72% consumption for a small mammal. It is considered unlikely that multiple applications would lead to greater residues on insects than single sprays. For example, individuals of pest species such as aphids are likely to be killed by a single treatment. The ETE is therefore 0.45 kg a.s./ha x 2.7 (EPPO based factor for large insects) i.e. 1.22 mg a.s. /kg. The resulting TERs using this value are shown in Table B.9.34.

Table B.9.34 Acute and long term toxicity exposure ratios for insectivorous mammals to methomyl

Category	Time scale	Toxicity endpoint	ETE*	TER	Annex VI trigger
Vegetables					
Insectivorous mammal	Acute	30 mg a.s./kg bw	0.88	341	10
Insectivorous mammal	Long-term	75 ppm feed	1.22 ppm	61[2]	5

*ETE= estimated theoretical exposure in the diet based on the EPPO vertebrate risk assessment scheme.
[1] Based on an estimated food intake of 72% of bodyweight.
[2] Based on a direct comparison of the study end point and the ETE.

The acute and long term TERs are above the trigger value and the risk is acceptable.

iii) Use on fruiting vegetables (cucumber, courgette, tomato, aubergine) at the lower rate (2 applications at 250 g a.s./ha)

The risk from this use is covered by the risk assessment undertaken at (ii) above and the risk is acceptable.

Metabolites

It is considered that the metabolite, methomyl oxime was intrinsically evaluated in the toxicological studies with the active substance. In addition, methomyl oxime does not pose a risk of inducing AchE inhibition, which is the primary and most sensitive parameter for assessing methomyl-induced toxicity (Section B.6.8.1). Therefore it is considered that the risk assessment for methomyl also covers the metabolite methomyl oxime.

Overall conclusion on the risk to mammals

There are two routes of exposure that require consideration for the proposed uses i.e. herbivorous mammals (grapes) and insectivorous mammals (fruiting vegetable use). For herbivorous mammals the acute risk was below the trigger value. Further refinement of this was then undertaken. However further consideration is required of the proposed approach and of the principles underlying the concept. The expectation is that it should be possible to address this issue with appropriate additional information. The long term risk to herbivorous mammals was considered acceptable. For insectivorous mammals both the acute and long term risk was acceptable. Therefore an acceptable use has been identified on the representative vegetable crops.

Data required before inclusion in Annex I can be considered

An acute risk to herbivorous mammals from grapes (not insectivorous mammals; therefore use on fruting vegetables is acceptable) has been identified. To address this risk additional information was provided. Further clarification of the information provided is required together with a consideration of the scientific concept behind this type of approach.

B.9.4 Effects on bees (IIA 8.3.1, IIIA 10.4)

B.9.4.1 Toxicity

Active substance

Studies on the acute oral and contact toxicity of technical methomyl to honeybees are summarised in Table B.9.35. Tests were carried out in accordance with GLP.

Table 9.35 The acute toxicity of technical YRC 2894 (purity 97.3%) to honeybees.

Test type	LD50(µg as/bee)	Test guideline	Reference
acute oral, 48 h	0.28	EPPO 170	Schur, A (2000) 2738
acute contact	0.16	EPPO 170	Schur, A (2000) 2738

* 95% confidence limits not reported.

Plant protection products

Data on the acute toxicity of Methomyl 20SL to honeybees are summarised in Table 9.36. Tests were carried out in accordance with GLP.

Table 9.36 The acute toxicity of formulation Methomyl 20SL to honeybees.

Test type	LD50 in µg form./bee (a.s. µg/bee)	Test guideline	Ref
acute oral, 48 h	1.06 (0.20 µg a.s./bee)	EPPO 170	Schur, A (2000) 2739
acute contact, 48 h	0.90 (0.17 µg a.s./bee)	EPPO 170	Schur, A (2000) 2739

Cage tests (AIII 10.4.3)

a) The effects of spray deposits of Methomyl 20SL (196 g a.s./l) aged for 1, 5, and 10 days on honey bees were evaluated in a semi-field study. Methomyl 20SL was applied once at a rate of 2.250 l/ha (i.e., 450-g methomyl/ha) to plots of apple trees enclosed in field cages. A toxic standard Hostathion 40 EC (Triazofos, 420 g/l) was applied at a rate of 0.6 L/ha. The control plots were treated with tap water. The water volume used at all applications was 600 L/ha. Small colonies of bees were inserted into the tunnels 1, 5, and 10 days post-application of Methomyl 20SL and the bees were allowed to forage on the flowers. Colonies contained 6 combs. Nuclei met the following criteria: at least 2 brood combs, at least 1 honey and pollen comb and bees were free of Nosema disease. In the control and the toxic reference plots bees were inserted into the tunnels 1 day after, or on the day of application, respectively. Evaluation of mortality and foraging activity started one day after exposure of bees. All treatments were tested in 3 replicates. Observations were made on mortality, foraging activities, behaviour and development of the brood for 5 subsequent days after inserting the hives into the tunnels.

The total mortality of *Apis mellifera* caused by Methomyl 20SL applied at 450-g methomyl/ha 1, 5, and 10 days prior to exposure was 141.0, 92.6, and 144.9 bees/hive/day, respectively. The total mortality observed in the control group was 63.5 bees/hive/day. In the toxic standard group the total mortality was 199.0 bees/hive/day.

The mean numbers of dead bees at the edges of the plots in the Methomyl 20SL groups exposed 1, 5, and 10 days post-application were 122.3, 86.7, and 137.7 bees/hive/day, respectively. The mean mortality in the control group was 62.7 bees/hive/day. The mean number of dead bees in the toxic standard group was 163.3 bees/hive/day. The maximum daily mortality was observed on day 1 or 2 of exposure in all treatment groups.
The mean number of dead bees in the dead bee traps in the Methomyl 20SL groups exposed 1, 5, and 10 days post-application were 18.7, 5.9, and 7.2 bees/hive/day, respectively. The mean mortality in the control group was 0.8 bees/hive/day. The mean number of dead bees in the toxic standard

group was considerably higher with 35.7 bees/hive/day, indicating the validity of the test system. Results are summarised in the tables below and significant differences are indicated. Mortality results for the toxic standard are shown in Table B.937.

Bees exposed after 1 and 5 days after application contained significantly more dead bees in the bee traps than the control on evaluation day 1-2 and 5 but the mean number of dead bees was within the range of biological variation. In bees exposed after 1 day the number of bees dead in the traps was significantly greater at virtually all assessment dates. However, only on evaluation day 1 was an obvious increase observed whilst on evaluation day 2-5 it was within the range of biological variability.

The number of dead bees at the edge of the tents was significantly different for most treatments on evaluation day 1 and 2. However, subsequently differences for these treatments were no longer significant with the exception of the toxic standard.

The foraging activity of A. mellifera exposed to Methomyl 20SL ranged in average from 2.2 to 4.2 bees/20 flowers per minute per day. In the control and toxic standard group the mean number of bees/20 flowers per minute per day was 4.8 and 2.3, respectively. Results are summarised below.
The flight intensity expressed in number of bees leaving or entering the hive per minute in the treatment group ranged in average from 4.9 to 7.2 bees per minute per day, increasing with the time interval between application and exposure. In the control and toxic standard group the mean number of bees per minute per day was 9.1 and 6.0, respectively. Results are summarised in the tables below.
No abnormal behavioural differences between the control bees and the Methomyl 20SL treatment groups were observed. No abnormal developmental differences between the bee brood control and the Methomyl 20SL treatment groups were observed.

Table B.9.37 Mortality observed of *Apis mellifera* after exposure to residues of Methomyl 20SL applied 1, 5, or 10 days prior to exposure

Evaluation Day	Average mortality in dead bee traps and at the edges of the tents (dead bees per hive/day)							
	Days between application and start of exposure							
	10		5		1		Control	
	Ø/BT	Ø/E	Ø/BT	Ø/E	Ø/BT	Ø/E	Ø/BT	Ø/E
1	13.3*	128.7*	10.0*	112.3*	56.0*	119.7*	1.7	54.3
2	5.3*	158.3*	6.0*	120.7	13.7*	213.7*	0.3	86.3
3	5.0	137.0	6.7	74.0	8.0	92.7	1.7	48.3
4	7.0	126.3	3.0	61.0	9.3*	60.7	0.3	49.3
5	5.3*	138.3	3.7*	65.7	6.3*	124.7	0.0	75.0
Ø mortality	7.2	137.7	5.9	86.7	18.7	122.3	0.8	62.7
Ø total mortality	144.9		92.6		141.0		63.5	

BT = Dead bee traps
E = Edge of the test cage
Ø = Average number of bees
*= significantly different from the control (P=0.05)

Table B.9.38 Mortality results for the toxic standard on the different evaluation days

Evaluation day	Mortality in dead bee traps and at edge of field	
	BT	E
1	47.0*	278*
2	39.0*	243.7*
3	62.0*	127.3*
4	18.7*	67.7
5	12.0*	100.0
Average mortality	35.7	163.3
Total mortality	199.0	

BT = Dead bee traps
E = Edge of the test cage
*= significantly different from the control (P=0.05)

Table B.9.39 Effects on foraging activity of *Apis mellifera* on apple trees treated with Methomyl 20SL 1, 5, or 10 days prior to exposure

Evaluation Day	Average number of foraging bees/20 flowers/minute			
	Days between application and start of exposure			Control
	10	5	1	
1	3.9	3.3	1.9	4.3
2	5.8	4.1	2.9	6.3
3	4.0	3.4	2.0	5.0
4	4.4	4.0	2.6	5.4
5	2.9	2.8	1.9	2.9
Ø bees/ 20 flowers per minute per day	4.2	3.5	2.2	4.8

Ø = Average number

Table B.9.40 Effects on flight intensity of *Apis mellifera* after application of Methomyl 20SL to apple trees 1, 5, or 10 days prior to exposure

Evaluation Day	Average number of bees leaving or entering the hive per minute			
	Days between application and start of exposure			Control
	10	5	1	
1	6.0	4.7	3.8	6.0
2	8.6	5.8	7.5	11.8
3	8.0	7.8	4.8	11.0
4	7.4	6.1	4.2	8.3
5	6.1	6.1	4.3	8.4
Ø bees leaving or entering the hive per minute	7.2	6.1	4.9	9.1

Ø = Average number

The report concluded that Methomyl 20SL applied at 450-g methomyl/ha to apple trees had temporary harmful effects on honey bees, if exposed 1 day after treatment at the start of flowering. However, it should be noted that similar numbers of dead bees were also noted when bees were introduced 10 days after treatment application. It should be also be noted that in all treatments and in the control there was a peak in mortality on day 2. This was possibly associated with disturbance when the hives were introduced into the trial. This makes the interpretation of results difficult. However, on day 3 of evaluation these effects were no longer apparent i.e. in total 13 days after the original application. A slight decrease of the foraging activity and flight intensity of the bees was observed if exposed to Methomyl 20SL 1 and 5 days after application. No abnormal behaviour and no incidence for abnormal development of the bee brood were observed, due to Methomyl 20SL.

The study was undertaken to a protocol based on EPPO 170 and to GLP.

(Schur, A (2001) 5470)

The effects of spray deposits of Methomyl 20SL (196 g a.s./l) aged for 2, 6, and 11 days on honey bees were evaluated in a semi-field study. Methomyl 20SL was applied once at a rate of 2.250 l/ha (i.e., 450 g methomyl/ha) to plots of *Phacelia tanacetiflora* enclosed in field cages. A toxic standard Hostathion 40 EC (Triazofos, 40%) was applied at a rate of 0.6 l/ha. The control plots were treated with tap water. The water volume used at all applications was 300 l/ha. Small colonies of bees were placed into the tents in the treatments in the evening 1 day before evaluation. The colonies contained 3 combs and the nuclei met the following criteria: at least 2 brood combs, at least 1 honey and pollen comb and bees free of symptoms of Nosema disease. Foraging on the plants took place 2, 6, and 11 days, respectively post-application of Methomyl 20SL and 2 days post-application of the control treatment. In the reference plot bees started foraging on the day of application. Test substance and control treatment was tested in 3 replicates, the toxic standard treatment in one replicate. Observations were made on mortality, foraging activities, behaviour and development of the brood for 7 subsequent days after inserting the hives into the test cages.

The total mortality of Apis mellifera caused by Methomyl 20SL applied at 450 g methomyl/ha 2, 6, and 11 days prior to exposure was 50.8, 91.2, and 64.8 bees/hive/day, respectively. This was comparable to the mortality observed in the control group which was 62.7 bees/hive/day. In the toxic standard group the total mortality was 73.0 bees/hive/day.
The mean numbers of dead bees at the edges of the plots in the Methomyl 20SL groups exposed 2, 6, and 11 days post-application were 48.1, 89.5, and 63.1 bees/hive/day. The mean-mortality of bees in the control was 61.0 bees/hive/day. The mean number of dead bees in the toxic standard group was 62.7 bees/hive/day. The maximum daily mortality was uniquely observed on day 2 of exposure in all treatment groups Table B.9.41.

The number of dead bees in the dead bee traps in the Methomyl 20SL groups exposed 2, 6, and 11 days post-application were 2.7, 1.7, and 1.7 bees/hive/day and were equal to the control group (1.7 bees/hive/day). The number of dead bees in the toxic standard group was considerably higher with an average of 10.7 bees/hive/day, indicating the validity of the test system. Results are summarised in Table 37. The foraging activity of A. mellifera exposed to Methomyl 20SL ranged in average from 9.1 to 10.8 bees/m2/day and was comparable to the control group (9.8 bees/m2/day). The toxic standard caused a decrease of the foraging activity to an average of 7 bees/m2/day. Results are summarised in the following tables for the control and treatments and in Table B.9.42 for the toxic standard. Differences between the treatments and the control were not significantly different. A comparison of the toxic standard and control was not undertaken.

No abnormal behavioural differences between the control bees and the Methomyl 20SL treatment groups were observed. No abnormal developmental differences between the bee brood control and the Methomyl 20SL treatment groups were observed.

Table B.9.41 Mortality observed in *Apis mellifera* after exposure to spray deposits of Methomyl 20SL applied 2, 6, or 11 days prior to exposure

Evaluation day	Average mortality in dead bee traps and at the edges of the tents (dead bees per hive/day)							
	Days between application and start of exposure							
	11		6		2		Control	
	Ø/BT	Ø/E	Ø/BT	Ø/E	Ø/BT	Ø/E	Ø/BT	Ø/E
1	1.0	11.7	3.0	27.0	5.7	20.7	2.0	10.3
2	2.0	175.7	1.0	210.3	1.3	75.0	2.7	150.3
3	2.3	74.7	1.3	102.7	2.0	72.0	0.3	75.3
4	0.7	16.7	0.7	24.3	2.0	33.7	1.0	28.7
5	2.0	46.0	2.0	73.7	0.3	53.7	0.3	49.7
6	1.7	56.7	1.7	101.0	0.3	43.0	1.0	52.7
7	2.0	60.0	2.3	87.7	7.3	38.3	4.3	59.7
Ø mortality	1.7	63.1	1.7	89.5	2.7	48.1	1.7	61.0
Ø total mortality	64.8		91.2		50.8		62.7	

BT = Dead bee traps
E = Edge of the test cage
Ø = Average number of bees

Table B.9.42 Mortality results for the toxic standard on the different evaluation days

Evaluation day	Mortality in dead bee traps and at edge of field	
	BT	E
1	3	6
2	54	287
3	10	76
4	1	17
5	2	12
6	5	17
7	0	21
Average mortality	10.7	62.3
Total mortality	73	

BT = Dead bee traps
E = Edge of the test cage
A statistical comparison of mortality with the control was not undertaken.

Table B.9.43 Effects on foraging activity of *Apis mellifera* on *Phacelia tanacetiflora* treated with Methomyl 20SL 2, 6, or 11 days prior to exposure

Evaluation day	Average number of foraging bees/m^2			
	Days between application and start of exposure			
	11	6	2	Control
1	15.2	14.8	11.8	13.7
2	16.3	15.5	14.5	15.7
3	0.0*	0.0*	0.0*	0.0*
4	15.2	11.5	9.8	10.5
5	16.7	14.2	12.0	13.3
6	11.0	14.8	13.2	13.3
7	1.1	1.2	2.4	2.1
Ø bees/m^2/day	10.8	10.3	9.1	9.8

Ø = Average number

* Due to rainfall, no foraging activity of the honey bees was observed

The study concluded that Methomyl 20SL applied at 450-g methomyl/ha to *Phacelia tanacetiflora* had no harmful effects on foraging honey bees, if exposed to spray deposits 2, 6, and 11 days after treatment. It should be noted however that whilst total mortality 2 and 11 days after treatment was similar to the control mortality after 6 days was greater, thus making the results difficult to interpret. No Methomyl 20SL related mortality, abnormal behaviour or flight activity was observed. No incidence for abnormal development of the bee brood was observed, due to Methomyl 20SL.

The study was undertaken to a protocol based on EPPO 170 and to GLP.
(Schur, A. (2001) 4446)

B.9.4.2 Risk assessment

Both methomyl and Methomyl 20SL have high acute oral and contact toxicity to honey bees. The oral and contact hazard quotients, determined for methomyl and Methomyl 20SL, are >50 (Table B.9.44) which indicates a potential risk to honey bees due to Methomyl 20SL when used according to Good Agricultural Practice based on laboratory data.

Table B.9.44 Acute and oral hazard quotients for methomyl and Methomyl 20 SL

Test Substance	Exposure route	LD50 (µg a.s./bee)	Methomyl application rate (g a.s./ha)	Hazard quotient (Oral or acute)
Methomyl	oral	0.28	450	1607
Methomyl	contact	0.16	450	2813
Methomyl 20SL	oral	0.20	450	2250
Methomyl 20SL	contact	0.17	450	2647

To address the potential risk on honey bees due the use of Methomyl 20SL, indicated in the laboratory tests, 2 semi-field cage tests were conducted. One semi-field test was performed in flowering *Phacelia tanacetiflora* in Germany and the other semi-field test was conducted in flowering apples in Spain. The aim of both semi-field tests was to quantify the duration of harmful effects on honey bees due to Methomyl 20SL. Foraging honey bees were not directly over-sprayed within the semi-field cages with Methomyl 20SL, because high acute toxicity was clearly predicted from the laboratory tests performed with methomyl and Methomyl 20SL. Instead, the effects of spray deposits of Methomyl 20SL applied at 450-g methomyl/ha aged for 2, 6, and 11 days (*Phacelia tanacetiflora*) or aged for 1, 5, and 10 days (apple trees) were evaluated.

The results from the semi-field trial with *Phacelia tanacetiflora* were stated to show that there was no significant effect on mortality when residues were aged for over 2 days. However, the results need to be treated with some care since effects were greater for residues aged for 6 days than those aged for either 2 or 11 days. In addition, the main effect of the toxic standard was only really noticeable on evaluation day 2. No adverse effects on behaviour, flight activity or incidence of abnormal development were observed relative to the control.

The results from the semi-field trial with apples showed that there was an initial harmful effect. The study concluded that there was a temporary effect if exposed to 1 day old residues and that this effect persisted for 2 days. However, similar effects were noted in the treatment where there were 10 days aging prior to the introduction of the bees. Therefore it is considered that this statement is not supported. Most mortality seemed to occur during the first two days of the evaluation period yet at this time the residues in the different treatment had been aged for different periods. For instance it may have been expected that the effect from residues aged for 2 days may have persisted for longer than those aged for 10 days. However, this does not appear to be the case. Therefore these results also need to be treated with caution. It is possible that adverse effects may have been associated with disturbance to hives during their introduction into the trial as effects were seen across all treatments including the control.

On the basis of the information submitted it is considered that there is a potential risk to bees. The information on residues in the two higher tier field based studies is of limited use in refining this risk. Member States need to consider appropriate measures to manage the risk to bees. This could for instance include measures to avoid applications during periods when bees are known to be active and to the flowering crop.

Overall conclusion on the risk to bees

The laboratory data presented indicate that the hazard quotients are >1600 to a maximum of 2813. Higher tier data were of limited use in refining the risk to bees. Overall the data indicate a risk to bees that should be managed on a Member State basis.

B.9.5 Effects on other arthropod species (IIA 8.3.2, IIIA 10.5)

B.9.5.1 Toxicity

Active substance (IIA 8.3.2)

The results from the laboratory testing of methomyl on non-target arthropods are summarised in the following table.

Table B.9.45 The effect of the metabolite methomyl on non-target arthropods in laboratory toxicity studies using 'Methomyl 20L'.

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Aphidius rhopalosiphi (cereal aphid parasitoid wasp)	Laboratory, glass plate. 1-2 day old adults exposed to freshly dried residues for 48 hours. Surviving females (control and treatment groups with<50% corrected mortality) confined onto aphid infested barley seedlings for 24 h and number of aphid mummies recorded after 11 days. Dimethoate was used as a toxic standard.	0.006 – 0.5 g a.s./ha in spray volume 200l using a compressed air track sprayer	Mortality after 48 h: Control: 2.50% 0.006 g a.s./ha: 12.50% 0.019 g a.s./ha: 10.00% 0.056 g a.s./ha: 15.00% 0.167 g a.s./ha: 25.00%* 0.500 g a.s./ha: 95.00%* LR_{30}: 0.20 g a.s./ha (95% C.I.: 0.15-0.25) LR_{50}: 0.25 g a.s./ha (95% C.I.: 0.20-0.31) * significantly different from control (Fisher's exact test, p=0.05) Reproduction (ratio mummies/female relative to control): [Control: 14.85 mummies/female] 0.006 g a.s./ha: 1.10 0.019 g a.s./ha:0.84 0.056 g a.s./ha:0.88 0.167 g a.s./ha:0.79 Not sig. (Krushal-Wallis Test, $\alpha = 0.05$) No sig. effects on reproduction up to 0.5 g a.s./ha (max. test dose).	Polgar (1988) Mead-Briggs (1992) Barret *et al.* (1994)	Schuld, M. (2000a): DuPont-2669

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Typhlodromus pyri (predatory mite)	Laboratory glass plate exposure of adults for 7 days and the reproduction was determined after a further 7 days exposure. Dimethoate was the toxic standard.	Methomyl 20 L (equiv. 200 l water/ha) 1 g a.s./ha 3 g a.s./ha 9 g a.s./ha 27 g a.s./ha 81 g a.s./ha 1 g a.s./ha 3 g a.s./ha 9 g a.s./ha	7 days exposure corrected mortality (%) 8.7 10.1 33.3* 87.0* 100* 7 day LR50: 12.8 g a.s./ha (CL 9.8 – 15.6 g a.s./ha) LR30: 9.1 g a.s./ha Reproductive capacity (relative to control) 0.9 0.8* 0.8* * sig different to control (0.05).	Louis & Ofer (1995), Overmeer (1988) Barrett *et al.* (1994)	Adelberger, I. (2000: DuPont-2668
Typhlodromus pyri (predatory mite)	14 days exposure to dried deposits on treated apple leaves	Methomyl 20L (equiv. 200 l water/ha) 6.25 g a.s./ha 12.5 g a.s./ha 25 g a.s./ha 50 g a.s./ha 100 g a.s./ha 6.25 g a.s./ha 12.5 g a.s./ha 25 g a.s./ha 50 g a.s./ha	Corrected mortality (%) 21 28* 32* 70* 95* LR50:34.5 g a.s./ha (CL 31.0-38.3) LR25:22.1 g a.s./ha Reproductive capacity (relative to control) 0.63 0.41* 1.26 0.77 * sig different to control (0.05).	Louis & Ofer (1995), Overmeer (1988)	Bruhnke, C (2000) 3766

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Typhlodromus pyri (predatory mite)	Extended laboratory, leaf surface using grapes leaves (‘Riesling’). Protonymphs exposed to freshly dried residues for 14 DAT. Mortality assessed 3 and 7 DAT. Mortality and reproductive success (control and treatment groups with < 50% corrected mortality) monitored for further 7 days. Deltamethrin used as positive control. A second study was also conducted using 7 day old residues for the control and highest concentration only.	22.5 – 450 g a.s./ha in spray volume 800 l/ha using calibrated knapsack sprayer.	Mortality 7 DAT – fresh residues: Control: 8.0% Corrected: 22.5 g a.s./ha: 0.0% 33.75 g a.s./ha: 5.4% 450 g a.s./ha: 73.9%* *significantly different from control (p=0.05) Mortality 7 DAT – 7 day old residues: Control: 10.0% Corrected: 450 g a.s./ha: 3.3% Reproduction (ratio offspring/female relative to control) – fresh residues: [Control: 7.7 offspring/female] 33.75 g a.s./ha: 1.06 Reproduction (ratio offspring/female relative to control) – 7 day old residues: [Control: 9.2 offspring/female] 450 g a.s./ha: 0.79 None of the above are sig. diff from control	Overmeer (1988), Oomen (1988), Blűmel *et al.* (2000)	Adelberger, I. (2001): DuPont-4427

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Orius laevigatus (predatory bug)	Extended lab, leaf surface of grape leaves. Nymphs exposed to either fresh or dried field aged (5, 10 and 20 DAT) residues (see Application rate) for 9 days. Surviving adults moved to mating containers for 5 days, and females transferred to new container and removed 4 days later. Adult mortality and reproductive effects measured. Dimethoate was used as a toxic standard.	450 g a.s./ha in spray volume 300 l/ha water using track sprayer. Either applied as one application or as two with an interval of 14 days.	Mortality: Control: 20%, 7%, 18%, 8% on days 0, 5, 10, 20 resp. Corrected Mortalities: 1 application: 0 day: 100%*[a] 5 days: 29% 10 days: -8% 20 days: 0% 2 applications: 0 days: 100%*[b] 5 days: 9% 10 days: -18%* 20 days: 13% [a]single application of 450 g a.s./ha [b]two applications of 450 g a.s./ha, 14 days apart. * statistically different from control (Fishers Exact test, $p<0.05$) % Reduction in reproduction: 1 application: 5 days: 9% 10 days: 12% 20 days: 11% 2 applications: 5 days: 20% 10 days: 0% 20 days: -17% Egg hatch 1 application 5-day: 91% (control: 95%) 10-day: 69% (control: 60%) 20-day: 87%(control: 87%) 2 applications 5-day:93% (control: 95%) 10-day:69% (control: 60%) 20 day: 89% (control 87%)	Bakker *et al* (2000) EPPO Guideline 142 (1989)	Van Stratum, I. P. (2001a): DuPont 5514

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
*Poecilus cupreus (*ground beetle)	Extended lab, treated sand (LUFA 2.1) aged for 1, 5 and 10 days. 4 week old adult beetles exposed to treated sand for 21 days. Untreated sand (control) and pyrazophos (reference) also used. Untreated fly pupae added as food source. Mortality and prey consumption assessed.	720 – 2880 g a.s./ha in 400 l water.	Mortality: Control: 0% 720 g a.s./ha: Aged 1 day: 0.0% Aged 5 days: 0.0% Aged 10 days: 3.3% 2880 g a.s./ha: Aged 1 day: 90.0%* Aged 5 days: 26.7% Aged 10 days: 36.7% *Statistically significant compared to control (α=0.05) Food consumption relative to control: 0.72 kg a.s./ha: Aged 1 day: -2.6% Aged 5 days: -4.2% Aged 10 days: -2.4% 2.88 kg a.s./ha: Aged 1 day: 56.6%* Aged 5 days: -0.8% Aged 10 days: -0.4% * statistically significant compared to control (α=0.05)	BBA guideline part VI, 23-2.1.8	Drexler, A (2000b): DuPont 3337

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Chrysoperla carnea (lacewing)	Extended lab, leaf surface of grape leaves. Larvae exposed to 0, 4 or 21 day old residues (see Application rate). Mortality and reproductive success measured on days 0, 7, 14 & 21 from first day of single application.	1250 g a.s./ha/appl. 3 apps. in water vol. of 400 l (1st app, plot 1), 1000 l (1st app, plot 2), 1000 l for 2nd & 3rd* *on 1st plot initial app of 1520 g a.s./ha was used instead of 1250 g a.s./ha..	Mortality: Control: 30%, 10%, 6.7% and 13.3% on days 0, 7, 14, 21 resp. Corrected Mortalities: 1 application: 0 day: 100[a]* 7 days: 22.2* 14 days: 7.1 21 days: –7.7 3 applications: 0 days: 100[b]* 4 days: 42.3* 7 days: -3.6 14 days: 20.0* 21 days: 0.0 [a] single application of 1250 g a.s./ha [b] three applications of 1250 g a.s./ha, 4 wks apart * statistically different from control (α=0.05) % Reduction in reproduction: 1 application: 7 days: 11.5 14 days: 70.4 21 days: 4.4 3 applications: 4 days: 8.3 7 days: 17.0 14 days: 5.3 21 days: 27.1 Not sig. diff (α=0.05)	Bigler (1988) *Not standard*	Drexler, A (2001): DuPont 2562

Species	Test substrate and description[1]	Application rate	Treatment effect(s)	Test protocol(s)[1]	Reference
Aleochara bilineata (rove beetle)	Extended lab, treated natural soil (LUFA 2.1). 2-3 day old adults exposed to treated soil for 28 days. Untreated soil (control) and a spray application of Afugan EC 30 was used (reference). Untreated fly pupae were dug into the soil on a weekly basis to be parasitised by the larvae of the beetle. On day 28 adults and pupae were separated from soil. Pupae were washed out and transferred into emergence containers. Emergence of beetles was observed from 4 weeks after exposure and lasted for 14 weeks.	720 & 2880 g a.s./ ha in 400 l water.	Mortality: Control: 0.0% Toxic standard: 1.25% 720 g a.s./ha: Aged 1 day: 21.3% Aged 5 days: 3.8% Aged 10 days: 0.0% 2880 g a.s./ha: Aged 1 day: 88.8% Aged 5 days: 25.0% Aged 10 days: 2.5% % reduction in reproduction compared to control: Toxic standard: 53.6% 0.72 kg a.s./ha: Aged 1 day: 42.0%* Aged 5 days: 5.3% Aged 10 days: -3.9% * sig. diff from control (α=0.05) 2.88 kg a.s./ha: Aged 1 day: 99.8%* Aged 5 days: 94.5%* Aged 10 days: 79.4%* * statistically significant compared to control (α=0.05)	Moreth & Naton (1992) *Not standard*	Drexler, A (2000a): DuPont 3336

[1] All studies conducted according to GLP.

Field trials

Effects of Methomyl 20SL on *Typhlodromus pyri* Scheuten were assessed after two applications at a rate of 2250 ml/ha (i.e., 450-g methomyl/ha) with a spray interval of 14 days and in a water volume of 800 l/ha. The field trial was undertaken in south west Germany (Bruchsal, Nordbaden). Reported endpoints were the number of predatory mites and eggs and the number of spider mites found per leaf. At least 25 leaves were sampled per replicate and treatment group on each assessment event. In total, 6 assessments were carried out, at 3 days prior the 1st application and up to 81 days after the 2nd application. A toxic reference (Decis fluid/25 g deltamethrin/l) was applied at a rate of 12-g as/ha. A control group was treated with tap water. The water volume for all applications was 800 l/ha. Each treatment was replicated five times.

The abundance of *T. pyri* on the leaves treated with Methomyl 20SL was lowered compared to the control at all post-application samplings. A maximum reduction of the predatory mite population of 64% compared to the control was found 28 days after the 2nd application. The population showed recovery at the assessment 81 days after the 2nd application when the reduction in number of predatory mites was 37% compared to the control. The toxic reference resulted in a reduction of the mite population of more than 40%, proving the validity of the test system. During the whole study the mean number of spider mites was low and no predatory mite species different from *T. pyri* were found in either the treatments or controls. Results are summarised in Table B.9.46.

Table B.9.46 Effects of two applications of Methomyl 20SL applied at a rate of 450 g methomyl/ha and a 14-day spray interval on a population of the predatory mite *Typhlodromus pyri* in grape vineyards in Germany, 2000

Test substance	Methomyl 20SL	Toxic standard (Decis)
Application rate	2 × 450-g methomyl/ha	2 x12 g a.s./ha
Test organism	*Typhlodromus pyri*	*Typhlodromus pyri*
Observation period	81 days after 2nd application	81 days after 2nd application
% Reduction in number of predatory mites per leaf compared to control, 14 DAA1	53 *	83 *
% Reduction in number of predatory mites per leaf compared to control, 8 DAA2	55 *	76 *
% Reduction in number of predatory mites per leaf compared to control, 28 DAA2	64 *	89 *
% Reduction in number of predatory mites per leaf compared to control, 56 DAA2	52 *	86 *
% Reduction in number of predatory mites per leaf compared to control, 81 DAA2	37 *	94 *

DAA1 – days after 1st application
DAA2 – days after 2nd application
* Reductions in number of mites were significantly different from the control (Dunnett's t-Test, $p \leq 0.05$)

Methomyl 20SL applied twice at an interval of 14 days at a rate of 2250 ml/ha (i.e., 450-g methomyl/ha) to grapevines in the field had a moderate, temporary effect on the population of *Typhlodromus pyri* with a maximum effect (64% reduction compared to controls) observed 28 days after the 2nd application. Recovery of *T. pyri* populations was observed 81 days after the 2nd application of Methomyl 20SL according to the recommended application scheme.

The study was undertaken in accordance with Heimann-Detlefsen (1991), Bluemel *et al*. (2000), and Barrett *et al*. (1994) and to GLP.

(Muether, J (2001a) 3883.)

Effects of Methomyl 20SL on a population of the predatory mite species *Amblyseius andersoni* (Chant), *Typhlodromus pyri* Scheuten, and *Kampimodromus aberrans* (Oudemans) were assessed after two applications at a rate of 2250 mL/ha (i.e., 450-g methomyl/ha) with an interval of 14 days. The trial was undertaken in Northern Italy at Conselice, Emilia-Romagna. Reported endpoints were the number of predatory mites and eggs and the number of spider mites found per leaf. Twenty-five leaves were sampled per replicate and treatment group on each assessment event. In total 7 assessments were carried out, at 2 days prior to the 1st application and up to 11 months after the 2nd application. A toxic reference (Decis fluid/24.25-g deltamethrin/l) was applied at a rate of 12-g as/ha. A control group was treated with tap water. The water volume for all applications was 1200 L/ha. Each treatment was replicated five times.

The abundance of the mixed predatory mite population of the species, *A. andersoni* (43.6%) *T. pyri* (28.4%) and *K. aberrans* (27.9%) on the grapevine leaves treated with Methomyl 20SL was reduced at all post-application samplings compared to the controls. A maximum reduction of the predatory mite population of 71% compared to the control was found 28 days after the 2nd application. At the last assessment, 338 days after the 2nd application of Methomyl 20SL the reduction of the predatory mite population was 34% in the plots treated with Methomyl 20SL compared to the controls. The toxic reference resulted in a reduction of the mite population of more than 40% proving the validity of the test system. Results are summarised in Table B.9.47.

Table B.9.47 Effects of two applications of Methomyl 20SL applied at a rate of 450 g methomyl/ha and a 14-day spray interval on a mixed population of predatory mites in grape vineyards in Italy, 2000.

Test substance	Methomyl 20SL	Toxic reference (deltamethrin)
Application rate	2 x 450-g methomyl/ha	2 x 12 g a.s./ha
Test organisms	*Amblyseius andersoni* (43.6%) *Typhlodromus pyri* (28.4%) *Kampimodromus aberrans* (27.9%)	*Amblyseius andersoni* (43.6%) *Typhlodromus pyri* (28.4%) *Kampimodromus aberrans* (27.9%)
Observation period	338 days after 2nd application	338 days after 2nd application
% Reduction in number of predatory mites per leaf compared to control, 14 DAA1	69 *	86*
% Reduction in number of predatory mites per leaf compared to control, 7 DAA2	68 *	82*
% Reduction in number of predatory mites per leaf compared to control, 28 DAA2	71 *	89*
% Reduction in number of predatory mites per leaf compared to control, 57 DAA2	60 *	88*
% Reduction in number of predatory mites per leaf compared to control, 84 DAA2	68 *	83*
% Reduction in number of predatory mites per leaf compared to control, 338 DAA2	34	59*

DAA1 = days after 1st application
DAA2 = days after 2nd application
* Reductions in number of mites were significantly different from the control (Dunnett's t-Test, $p \leq 0.05$)

In conclusion, Methomyl 20SL applied twice at an interval of 14 days at a rate of 2250 mL/ha (i.e., 450-g methomyl/ha) to grapevine in the field had a temporary harmful effect on mixed predatory mite populations with a maximum effect (71% reduction compared to controls) observed 28 days after the 2nd application. Recovery of the predatory mite populations was observed 338 days after the 2nd application of Methomyl 20SL.

The trial was undertaken in accordance with the guidelines of Heimann-Detlefsen (1991), Bluemel *et al*. (2000) and was undertaken to GLP.
(Muether, J. (2001b) 4327)

Effects of Methomyl 20SL on a mixed population of the predatory mite species *Kampimodromus aberrans* (Oudemans), *Neoseiulus californicus* (McGregor), and *Typhlodromus pyri* Scheuten were assessed after two applications at a rate of 2250 mL/ha (i.e., 450-g methomyl/ha) with a spray interval of 13 days. The trial was located in southern France, Sorede, Pyrénées-orientales. Reported endpoints were the number of predatory mites and eggs and the number of spider mites found per leaf. At least 25 leaves were sampled per replicate and treatment group on each assessment event. In total, 8 assessments were carried out, at 2 days prior to the 1st application and up to 12 months after the 2nd application. A toxic reference (Decis fluid/25g deltamethrin/l) was applied at a rate of 12- g as/ha. A control group was treated with tap water. The water volume for all applications was 800 L/ha. Each treatment was replicated five times.

The abundance of the mixed predatory mite population of the species *K. aberrans* (98.6%), *N. californicus* (0.9%), and *T. pyri* (0.5%) on the grapevine leaves treated with Methomyl 20SL was reduced at all post-application samplings compared to the controls. A maximum reduction of the predatory mite population of 93% compared to the control was found 56 days after the 2nd application. The predatory mite population showed the tendency to recover at the assessments 81 and 335 days after the 2nd application when the reduction in number of mites was 82% and 73% compared to the control, respectively. At the last assessment, 371 days after the 2nd application of Methomyl 20SL the reduction of the predatory mite population was 23% in the plots treated with Methomyl 20SL compared to the controls. The toxic reference resulted in a reduction of the mite population of more than 40% proving the validity of the test system. During the whole study the numbers of spider mites were low in all treatments. Results are summarised in Table B.9.48.

Table B.9.48 Effects of two applications of Methomyl 20SL applied at a rate of 450 g methomyl/ha and a 13 day spray interval on a mixed population of predatory mites in grape vineyards in France, 2000.

Test substance	Methomyl 20SL	Toxic reference (deltamethrin)
Application rate	2 x 450-g methomyl/ha	2 x 12-g a.s./ha
Test organisms	*Kampimodromus aberrans* (98.8%) *Neoseiulus californicus* (0.9%) *Typhlodromus pyri* (0.5%)	*Kampimodromus aberrans* (98.8%) *Neoseiulus californicus* (0.9%) *Typhlodromus pyri* (0.5%)
Observation period	371 days after 2nd application	371 days after 2nd application
% Reduction in number of predatory mites per leaf compared to control, 12 DAA1	74 *	53*
% Reduction in number of predatory mites per leaf compared to control, 6 DAA2	79 *	45*
% Reduction in number of predatory mites per leaf compared to control, 25 DAA2	90 *	47*
% Reduction in number of predatory mites per leaf compared to control, 56 DAA2	93 *	12
% Reduction in number of predatory mites per leaf compared to control, 81 DAA2	82 *	31
% Reduction in number of predatory mites per leaf compared to control, 335 DAA2	73 *	16
% Reduction in number of predatory mites per leaf compared to control, 371 DAA2	23 *	17

DAA1 = days after 1st application
DAA2 = days after 2nd application
*Reductions in number of predatory mites were significantly different from the control (Dunnett's t-Test, $p \leq 0.05$

In conclusion Methomyl 20SL applied twice at an interval of 13 days at a rate of 2250 mL/ha (i.e., 450-g methomyl/ha) to grapevines in the field had a temporary harmful effect on mixed predatory mite populations with a maximum effect (90% reduction compared to controls) observed 56 days after the 2nd application. Recovery of the predatory mite populations was observed 371 days after the 2nd application of Methomyl 20SL.

The trial was undertaken using the guidelines of Heimann-Detlefsen (1991) and Blumel *et al*. (2000) and was to GLP.

(Muether, J. (2001c) 4326)

The effects of the insecticide Methomyl (DPX-X1179) 20L (containing 200 g methomyl per l) applied twice at an application rate of 2250 mL/ha formulated product (i.e. 450 g methomyl/ha) on predatory mites in vineyards were assessed by conducting a field trial according to BBA guideline Part IV, 23-2.3.4 (The test sites were located in northern Italy near Conselice, Emilia-Romagna.

The trial comprised three treatments: 1.) the test item (Methomyl (DPX-X1179) 20L), 2.) a water treated control and 3.) a toxic reference treatment (24.25 g/l deltamethrin). Each treatment was replicated five times. The population development of predatory mites and spider mites was assessed in all three treatments by determining the number of mites on leaf samples, using the washing method. Leaf samples consisting of 25 leaves were taken 3 days before the first application, immediately before the 2nd application, 6 days, 27 days and 56 days after the 2nd application.
In all treatments 2 sprays were applied the 22 June (Growth stage BBCH 75) and the 6 July 2001 (Growth stage BBCH 79). The test item Methomyl (DPX-X1179) 20L was sprayed at a rate of 2250 mL/ha formulated product (i.e. 450 g methomyl/ha). All sprays were applied with a calibrated knapsack sprayer. The water volume was 1200 L/ha for both applications.

At the test site the predatory mite population was a mixed population of the species *Kampimodromus aberrans* (Oudemans) (69.4 %), *Typhlodromus pyri* Scheuten (17.7 %) and *Amblyseius andersoni* (Chant) (12.9 %).
The following table gives the mean number of predatory mites per leaf and predatory mite eggs per leaf, and the efficacy values according to Abbott (1925):

Table B.9.49 Mean number of predatory mites per leaf, predatory mite eggs per leaf and efficacy values

Evaluation	Date / Timing	Category	Control	Methomyl (DPX-X1179) 20L	Toxic reference
1	19 JUN 2001 3 days before application No. 1	Mites Eggs	1.50 0.32	1.34 0.24	1.78 0.38
2	06 JUL 2001 14 days after application No. 1	Mites Eggs E_A	9.83 1.46	1.91 * 0.21 * 81	1.45 * 0.15 * 85
3	12 JUL 2001 6 days after application No. 2	Mites Eggs E_A	13.31 2.16	2.76 * 0.25 * 79	0.82 * 0.06 * 94
4	02 AUG 2001 27 days after application No. 2	Mites Eggs E_A	3.30 0.13	0.44 * 0.02 * 87	0.10 * 0.00 * 97
5	31 AUG 2001 56 days after application No. 2	Mites Eggs E_A	1.98 0.02	1.48 0.23 * 25	0.54 * 0.05 73

E_A: Effect [%] when compared to control according to Abbott, 1925
* Number statistically significantly different from control (Dunnett test, $p \leq 0.05$)

The toxic reference treatment produced statistically significant predatory mite population reductions at all evaluations done after the first application (Dunnett test, $p \leq 0.05$). An expected level of effect of maximally 97 % was found. This demonstrates the validity of the study.

The treatment with Methomyl (DPX-X1179) 20L produced statistically significant predatory mite population reductions at the first evaluation after the first application and at the first and second evaluation after the second application (Dunnett test, $p \leq 0.05$). A maximum predatory mite population reduction of 87 % compared to the control 4 weeks after the 2nd application was found in the plots treated with Methomyl (DPX-X1179) 20L. At the last assessment 56 days after the 2nd application comparable numbers of predatory mites per leaf were found in the plots treated with Methomyl (DPX-X1179) 20L and in the control plots (Dunnett test, $p > 0.05$), and with an efficacy value according to Abbott (1925) of 25 %.

In conclusion based on the results of this study and according to the corresponding guideline (Heimann-Detlefsen, 1991), the test item Methomyl (DPX-X1179) 20L would be classified as producing harmful effects on predatory mite populations (maximum effect level of 87 % 27 days after the 2nd application compared to the control) when used with a maximum of 2 applications, a minimum spray interval of 14 days and a maximum application rate of 2250 mL/ha formulated product (i.e. 450 g methomyl/ha). However, 56 days following the 2nd application good recovery of the populations was observed with comparable numbers of predatory mites per leaf in the plots treated with Methomyl (DPX-X1179) 20L and in the control plots (Dunnett test, $p>0.05$), and with an efficacy value according to Abbott (1925) of 25 %.

The trial was undertaken using the guidelines of Heimann-Detlefsen (1991) and Blumel *et al*. (2000) and Candolfi *et al*., (2001) and was to GLP.

(Bocksch, S. (2002) 5469)

The aim of this field study was to evaluate the effects of two applications of Methomyl (DPX-X1179) 20L on predatory mites (Acari: Phytoseiidae) in grape vineyards in France according to Blümel, *et al.* (2000). The test site was located in southwest France, at Cars, about 50 km north of Bordeaux.

The study comprised 3 treatments (water control, test item Methomyl (DPX-X1179) 20L and toxic reference item, Danitol) and 5 replicates. A randomised block design was used with 15 plants per plot. The test item was applied on two occasions at 2250 mL Methomyl (DPX-X1179) 20L/ha (450 g Methomyl (DPX-X1179)/ha) and the toxic reference item at 0.75 L Danitol/ha (0.075 g fenpropathrin/ha) in a volume of 350 L water/ha. Spray applications were applied the 5 and 20 July 2001. Both treatments were applied with a calibrated knapsack atomizer. Leaf-samples consisting of 25 or 30 leaves were taken 3 days before the application, 15 days after the first application of treatments and 6, 27, 55 and 83 days after the second application. The number of Phytoseiid mobile forms per plot was counted using the washing method (Kreiter & Sentenac, 1993, adapted method of Boller, 1984).

The species of Phytoseiid mites were checked at the beginning and at the end of the experiment and *Typhlodromus pyri* was the only species of Phytoseiid mites present on the site.
The total effect E was calculated on each post-application leaf-samplings using the Abbott formula (1925) as detailed below:
$E = 100 \times ((C – T) / C)$
C : mean number of Phytoseiid mobile forms per leaf in the water control treatment
T : mean number of Phytoseiid mobile forms per leaf in the test item (or toxic reference item) treatment Phytoseiid mite numbers in the 3 treatments were compared with the analysis of variance and the Dunnett Test using STAT-ITCF software program (Beaux et al., 1991). Results are presented in the table below:

Table B.9.50 Effects of two applications of Methomyl (DPX-X1179) 20L on predatory mites (Acari: Phytoseiidae) in grape vineyards in France

Treatment		Sampling					
		T1 – 3 days	T1 + 15 days	T2 + 6 days	T2 + 27 days	T2 + 55 days	T2 + 83 days
		BBCH 75	BBCH 77	BBCH 79	BBCH 83	BBCH 85	BBCH 92
		02/07/01	20/07/01	26/07/01	16/08/01	13/09/01	11/10/01
Water	Mean number of *T. pyri* per leaf	5.3	6.3	5.2	2.0	2.4	1.1
Test item Methomyl (DPX-X1179) 20L 2250 ml/ha (450 g a.s./ha)	Mean number of *T. pyri* per leaf	5.3	0.3	0.2	0.03	0.2	0.7
	Significant difference with the water control (DUNNETT, $\alpha = 0.05$)	NO	YES	YES	YES	YES	NO
	Total effect E (%)	-	94.6	96.9	98.7	90.7	36.3
Toxic reference item Danitol (0.75 L/ha)	Mean number of *T. pyri* per leaf	5.3	1.2	0.2	0.3	1.6	1.5
	Significant difference with the water control (DUNNETT, $\alpha = 0.05$)	NO	YES	YES	YES	YES	NO
	Total effect E (%)	-	80.7	95.9	87.0	34.6	0*

* = Negative value equivalent to zero.

In conclusion Methomyl (DPX-X1179) 20L in a French vineyard had transient harmful effects on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) when applied twice at 2250 mL Methomyl (DPX-X1179) 20L/ha (450 g Methomyl (DPX-X1179)/ha) and a spray interval of 2 weeks. The predatory mite population remained significantly lower than in the water control treatment (Dunnett test, □=0.05) for approximately two months after the second application. However, 83 days following the 2nd application recovery of predatory mite populations was observed with comparable predatory mite numbers per leaf in the plots treated with Methomyl (DPX-X1179) 20L and in the control plots with an efficacy value according to Abbott (1925) of 36.3 %.

The trial was undertaken to the guideline Bluemel et al. (2000) and was to GLP.

(Lagrasse, S. (2002) DuPont-5659)

Effects of Methomyl 20SL on *Typhlodromus pyri* Scheuten were assessed after one application at a potential drift rate of 112.5 mL/ha (i.e., 22.5-g methomyl/ha). The trial was undertaken in south west Germany (Bruchsal, Nordbaden). Reported endpoints were the number of predatory mites and eggs and the number of spider mites found per leave. Per replicate and treatment group 25 leaves were sampled on each assessment event. In total, 3 assessments were carried out, at 7 days prior, as well as 8 and 27 days after the application. A toxic reference (Decis fluid/25-g deltamethrin/l) was applied at a rate of 12-g as/ha. A control group was treated with tap water. The water volume for all applications was 800 L/ha. Each treatment was replicated five times.

The abundance of *T. pyri* on the leaves treated with Methomyl 20SL was not statistically, significantly lower compared to the control at the post-application samplings (Dunnett's t-Test, $p \geq 0.05$). An increase of the population of 36% and 5% compared to the control was found 8 and 27 days after application, respectively. The toxic reference resulted in a reduction of the mite population of more than 40% proving the validity of the test system. During the whole study the mean number of spider mites was very low and no predatory mite species different from *T. pyri* was found. Results are summarised in Table B.51.*.

Table B.9.51 Effects of one application of Methomyl 20SL applied at 22.5 g methomyl/ha on the predatory mite *Typhlodromus pyri* in grape vineyards in Germany, 2000

Test substance	Methomyl 20SL	Toxic reference
Application rate	22.5-g methomyl/ha	12 g deltamethrin/ha
Test organism	*Typhlodromus pyri*	*Typhlodromus pyri*
Observation period	27 days after application	27 days after application
% Reduction in number of predatory mites per leave compared to control, 8 DAA	- 36	83
% Reduction in number of predatory mites per leave compared to control, 27 DAA	- 5	78*

DAA = days after application
* Number statistically significantly different from control ($p \leq 0.05$)

In conclusion Methomyl 20SL applied at a potential drift rate of 22.5-g methomyl/ha to grapevines in the field had no statistically significant effects on *Typhlodromus pyri*.

The guidelines used were Heimann-Detlefsen (1991), Bluemel *et al*. (2000) and the trial was to GLP.

(Muether, J (2001d) 4330)

Effects of Methomyl 20SL on *Typhlodromus pyri* Scheuten were assessed after one application at a potential drift rate of 168.75 mL/ha (i.e., 33.75-g methomyl/ha). The trial was undertaken in south west Germany (Bruchsal, Nordbaden). Reported endpoints were the number of predatory mites and eggs and the number of spider mites found per leaf. Per replicate and treatment group 25 leaves were sampled on each assessment event. In total 3 assessments were carried out, at 7 days prior to as well as 8 and 27 days after the application. A toxic reference (Decis fluid/25-g deltamethrin/l) was applied at a rate of 12-g as/ha. A control group was treated with tap water. The water volume for all applications was 800 L/ha. Each treatment was replicated five times.

The abundance of *T. pyri* on the leaves treated with Methomyl 20SL was not statistically, significantly lower compared to the control at the post-application samplings (Dunnett's t-Test, p $\geq$0.05). A reduction of the population of 9% compared to the control was found 8 days after application. A maximum reduction of the population of 22% compared to the control was found 27 days after application. The toxic reference resulted in a reduction of the mite population by more than 40% proving the validity of the test system. During the whole study the mean number of spider mites was very low and no predatory mite species different from *T. pyri* were found in the treatments or controls. Results are summarised in Table B.9.52.

Table B.9.52 Effects of one application of Methomyl 20SL applied at 33.75 g methomyl/ha on the predatory mite *Typhlodromus pyri* in grape vineyards in Germany, 2000

Test substance	Methomyl 20SL	Toxic reference
Application rate	33.75-g methomyl/ha	12 g deltamethrin/ha
Test organism	*Typhlodromus pyri*	*Typhlodromus pyri*
Observation period	27 days after application	27 days after application
% Reduction in number of predatory mites per leave compared to control, 8 DAA	9	83*
% Reduction in number of predatory mites per leave compared to control, 27 DAA	22	78*

DAA = days after application

* Number statistically significantly different from control (p≤0.05)

In conclusion Methomyl 20SL applied at a potential drift rate of 33.75-g methomyl/ha to grapevines in the field had no statistically significant effects on *Typhlodromus pyri*.

Guidelines used were Heimann-Detlefsen (1991), Bluemel *et al*. (2000) and the trial was to GLP.

(Muether, J (2001e) 4329)

Adult mortality and reproductive effects (parasitisation rate) were evaluated following a 48-hour exposure period to fresh-dried deposits of Methomyl 20SL on treated plant foliage (barley seedlings). Methomyl 20SL was tested at 1, 3, 9, 27, and 81-g methomyl/ha. Methomyl 20SL was applied in a nominal volume of 200-L water/ha. An untreated control and toxic standard (dimethoate) were also tested. There were 4 replicates per treatments, each containing 10 adult wasps (5 males and 5 females) of *A. rhopalosiphi*. The aphid parasitoids were observed for lethal and sublethal effects. During the reproduction phase of the test, the reproduction rate of the surviving wasps was determined. Fecundity assessments were carried out 14 days after application by counting the number of mummified aphids present in each reproduction unit, and calculating the mean number of parasitised aphids per female.

Adult mortality in the control and toxic standard groups was 0% and 97.5%, respectively (Table B.9.53). Methomyl 20SL, tested at 1, 3, 9, 27, and 81-g methomyl/ha, showed corrected mortalities of 0%, 0%, 27.5%, 77.5%, and 97.5%, respectively. The number of offspring per female were 17.4, 23.0, 19.8, and 11.5 for the Methomyl 20SL treatments sprayed at 1, 3, 9, and 27-g methomyl/ha, respectively. There were no statistically significant effects observed in the reproduction part of the study.

Table B.9.53 Effects on mortality and reproduction of *A. rhopalosiphi* after exposure to deposits of Methomyl 20SL, deionised water (control) or the toxic standard on natural substrate (barley seedlings)

Treatment group	Control	Methomyl 20SL [g methomyl/ha]					Toxic standard
		1	3	9	27	81	
M [%]	0	0	0	27.5$^{(1)}$	77.5$^{(1)}$	97.5$^{(1)}$	97.5$^{(1)}$
Mcorr [%]	-	0	0	27.5	77.5	97.5	97.5
Mean No. of offspring/female	17.8	17.4	23.0	19.8	11.5	n.a.	n.a.
R [%]	-	2.3	-29.2*	-11.2*	35.4	n.a.	n.a.

1) Significantly different from the control (Bonferroni-U-Test, α= 0.05)
M: Mortality based on the number of dead and moribund wasps
Mcorr: Corrected Mortality
R: Reduction of parasitisation according to Abbott in %
n.a.: not assessed
* Negative value means increased parasitisation relative to control

The LR_{50} for 48-hour exposure to Methomyl 20SL deposits on natural substrate was 14.70 (95% confidence intervals ranged from 11.48 to 18.82) g methomyl/ha. The LR_{25} for 48-hour exposure to Methomyl 20SL deposits on natural substrate was 8.33-g methomyl/ha. No statistically significant effects were observed on reproduction up to the maximum test rate of 27 g methomyl/ha.

Guidelines used were Polgar (1988), Mead-Briggs & Longeley (1997), Mead-Briggs *et al*. (1999) and the test was undertaken to GLP.

(Moll, M. (2000) 3764)

Adult mortality and reproductive effects (parasitisation rate) were evaluated following a 48-hour exposure period to either freshly applied, dry spray deposits (Day 0) or to field-aged spray deposits (7 to 28 days) of Methomyl 20SL on grapevine leaves. Three applications were performed in the field according to agricultural practice with an interval between applications of 4 weeks. The test substance (Methomyl 20SL) was applied at 1.25-kg methomyl/ha. A water control and toxic standard (0.6-kg Ultracid 40/ha) were also tested. Bioassays were performed 0, 7, 14, and 21 days after 1st and 3rd application and 28 days after 3rd application.

The effects observed on mortality and reduction in reproduction of *Aphidius rhopalosiphi* relative to the water-treated control are presented in Table B.9.54. An additional application of an untreated plot on the same test side of the test substance was performed in order to repeat the bioassays after the 1st application. The reason was a high deviation of the spraying amount, which occurred during the first application (applied amount was 1520-g methomyl/ha instead of 1250-g methomyl/ha). This repetition of the first application resulted in an actual spraying amount of 1250-g methomyl/ha.

Exposure of *Aphidius rhopalosiphi* to fresh-dried spray deposits of Methomyl 20SL at an application rate of 1250-g methomyl/ha caused 100% mortality. After 7 days of ageing the mortality in the test substance group decreased to either 72.5% or 90% after the first application and 35% after 3 applications. The control mortality of the bioassay, started 7 days after 3 applications, was 37.5%. Therefore, this result is obtained by an invalid bioassay, and is only reported to give an impression about the effects of Methomyl 20SL in *Aphidius rhopalosiphi*. Corrected mortalities were 71.1%, 89.7%, and -4.0%, respectively. The differences observed in acute response among different application may be a result of variable deposition of Methomyl 20SL on leaf surfaces. After 14 days of aging of the treated leaves in the field no significant effects on mortality were observed in any treatment group. Corrected mortality for one and three applications of Methomyl 20SL was 2.8, 22.5, and -2.6%, respectively. No statistically significant reduction of parasitisation efficiency was observed in any of the bioassays conducted after one application of Methomyl 20SL. There was a significant reduction observed in parasitisation on spray deposits aged 14 days following three applications. However, the differences were primarily attributable to high parasitisation in one control replicate (39 mummies). No other statistically significant effects on parasitisation rate were observed.

Table B.9. 54 Effects on mortality and reproduction of the aphid parasitoid, *Aphidius rhopalosiphi*, exposed to fresh-dried and field-aged spray deposits of Methomyl 20SL on grapevine leaves in an extended laboratory study

Number of applications	Bioassay (days after last application)	Mortality (%) (corrected according to Schneider-Orelli, relative to control)	Reduction in reproduction (%)
1[a]	0	100	-
1	7	71.1	-
1	14	2.8	27.8
1	21	-5.7	0.8
1[a,c]	0	100	-
1	7	89.7	-
1	14	22.5	-52.9
1	21	42.5	-31.1
3[b]	0	100	-
3	7	-4.0[d]	-
3	14	-2.6	59.3
3	21	-5.3	16.7
3	28	2.5	-7.2

a 1250-g methomyl/ha applied once

b Three applications of 1250-g methomyl/ha, 4 weeks apart

c Repeat of trial with 1 application of 1250-g methomyl/ha

d Validity criteria in the control group (mortality ≤ 12.5%) was not met because the parasitoids were sick. Control mortality was 37.5%. Therefore, no reproduction testing was performed. The results were only reported to give an impression about the effects on *Aphidius rhopalosiphi*.

In conclusion fresh-dried, and 7-day, field-aged, spray deposits on grapevine leaves resulting from an application with Methomyl 20SL at 1250-g methomyl/ha were harmful to *Aphidius rhopalosiphi* while exposure to 14-day, field-aged deposits proved to be harmless.

Guidelines used were Polgar (1988), Mead-Briggs (1997) and the test was undertaken to GLP.

(Drexler, A. (2000a) 2563)

The effects of Methomyl 20SL on the emergence of adult *Aphidius rhopalosiphi* from parasitised aphids exposed to the test substance were evaluated. Aphids (*Rhopalosiphum padi L.*) sucking on barley were offered to *A. rhopalosiphi* for parasitisation. Mummies, 1 - 2 or 3 - 4 days of age, still naturally fixed on the barley leaves were transferred, facing upwards onto filter paper. Methomyl 20SL was applied at a rate corresponding to 2.25 and 6.75 L/ha (i.e., 450 and 1350 methomyl g/ha) to the prepared mummies. After application the filter papers carrying the mummies were placed in Petri dishes and were covered with a thin layer of untreated quartz sand to avoid contact of the emerged adults to the test substance. A control group was treated with deionised water likewise. Each treatment group comprised 4 replicates with 25 parasitised aphids. The emergence and mortality of adult *A. rhopalosiphi* wasps were assessed for 7 days after start of emergence. Mummies not emerged after this observation period were considered dead.

The emergence and mortality rates are reported in Table B.9.55 below. No significant change in emergence and mortality of *Aphidius rhopalosiphi* compared to the control was observed after application of 450-methomyl g/ha. A slight decrease of emergence and increased mortality of *A rhopalosiphi* were observed at an application rate of 1350-g methomyl/ha, which was not found in the non-GLP rangefinder test. No delay in emergence in any methomyl-treated group compared to the control was observed. The emergence rates in the control groups were over 80%, indicating the validity of the test system.

Table B.9.55 Emergence of wasps and mortality of adult *Aphidius rhopalosiphi* emerged from mummies treated with Methomyl 20SL

Treatment group	Control 1[a)]		Control 2[a)]		Methomyl			
					450 g/ha		1350 g/ha	
Age of mummies [days]	1-2	3-4	1-2	3-4	1-2	3-4	1-2	3-4
Mean emergence rate [%]	96.00	97.00	90.00	92.00	96.04	93.19	59.00[b)]	67.00[b)]
Mean mortality rate [%]	4.00	3.00	10.00	8.00	3.96	6.81	41.00[b)]	33.00[b)]
Reduction in emergence success [%]	-	-	-	-	-0.04	3.93	34.44	27.17

a) The study was performed at two different dates. With each substance treatment group a control group was tested in parallel.

b) Statistically, significantly different compared to the control (Fisher's Exact Test $p \leq 0.05$)

In conclusion Methomyl 20SL, sprayed over mummified aphids at 450-g methomyl/ha had no adverse effects on the emergence and mortality of *Aphidius rhopalosiphi*.

The guideline used was Barrett *et al*. (1994). and the test was undertaken to GLP

(Schuld, M. (2000b) 4630.)

B.9.5.2 Risk assessment

A summary of the toxicity end points for a range of terrestrial non-target arthropods resulting from worst-case laboratory testing and higher tier testing at maximum application rate and minimum spray interval is given in the tables below.

Table B.9.56 Summary of the effects of methomyl on *Typhlodromus pyri*

Species	Test	Endpoint	Effect level (% relative to controls)	Reference
Typhlodromus pyri	Tier 1	Mortality: Reproduction reduction:	LR_{30} = 9.1 g as/ha 20% at 9.0 g as/ha LR_{50}= 12.8 g as/ha	2668
Typhlodromus pyri	Tier 2, apple tree leaves	Mortality: Reproduction reduction:	LR_{25} = 22.1 g as/ha 37% at 6.25 g as/ha LR_{50}= 34.5 g as/ha	3766
Typhlodromus pyri	Tier 2, exposure to field-aged spray deposits on vine leaves treated at: 450 g as/ha, 33.75 g as/ha, 22.5 g as/ha	Mortality: Reproduction reduction:	Fresh-dried deposits: 73.9% at 450 g as/ha 5.4% at 33.75 g as/ha 7-day aged deposits: 3.3% 7 days after treatment at 450 g as/ha Fresh-dried deposits: -6% at 33.75 g as/ha 7-day aged deposits: 21% at 450 g as/ha	4427
Typhlodromus pyri	Field study (Germany, grape vineyards, 2 × 450 g as/ha)	Population reduction:	Max. 64% on day 28 after 2nd application Population reduction: 37% on day 81 after 2nd application	3883
Predatory mites (e.g., *Amblyseius*, *Typhlodromus*, *Kampimodromus*)	Field study (Italy, grape vineyards, 2 × 450 g as/ha)	Population reduction:	Max. 71% on day 28 after 2nd application Population reduction: 34% on *ca*. Day 338 after 2nd application	4327
Predatory mites (e.g., *Kampimo-dromus, Neoseiulus Typhlodromus)*)	Field study (France, grape vineyards, 2 × 450 g as/ha)	Population reduction:	Max. 93% on Day 56 after 2nd application Population reduction: 23% on Day 371 after 2nd application	4326

Species	Test	Endpoint	Effect level (% relative to controls)	Reference
Predatory mites (e.g., *Kampimo-dromus aberrans, Typhlodromus pyri* (Amblyseius Andersoni))	Field study (Italy, grape vineyards, 2 × 450 g as/ha)	Population reduction:	Max. 87% on Day 27 after 2nd application <u>Population reduction:</u> 25% on Day 56 after 2nd application	5469
Predatory mites (e.g., *Typhlodromus pyri)*	Field study (France, grape vineyards, 2 × 450 g as/ha)	Population reduction:	Max. 98.7% on Day 27 after 2nd application <u>Population reduction:</u> 36.3% on Day 83 after 2nd application	5659
Typhlodromus pyri	Field study (Germany, 22.5 g as/ha)	Population reduction:	Max. -36% on Day 8 after application -5% on Day 27 after application	4330
Typhlodromus pyri	Field study (Germany, 33.75 g as/ha)	Population reduction:	Max. 22% on Day 27 after application	4329

Table B.9.57 Summary of the effects on methomyl on *Aphidius rhopalosiphi*, *Poecilus cupreus,* and *Chrysoperla carnea*

Species	Test	Parameter	Effect level (relative to controls)	Reference
Aphidius rhopalosiphi	Tier 1	Mortality: Reproduction reduction:	LR_{30} = 0.20 g as/ha LR_{50} = 0.25 g as/ha 21% at 0.167 g as/ha	2669
Aphidius rhopalosiphi	Tier 2, barley seedlings	Mortality: Reproduction reduction:	LR_{25} = 8.33 g as/ha < 30% at 9 g as/ha LR_{50} = 14.7 g as/ha	3764
Aphidius rhopalosiphi	Tier 2, exposure to field-aged spray deposits on vine leaves treated at: 1250 g as/ha	Mortality: Reproduction reduction:	Fresh-dried deposits: 100% 7-day aged deposits: Max. 89.7% 14-day aged deposits: < 25% 14-day aged deposits: ≤ 27.8% (results from 1520 g a.s./ha)	2563
Aphidius rhopalosiphi	Tier 2, protected life stage treated on barley leaves at: 450 g as/ha, 1350 g as/ha	Mortality/Emergence from mummies:	Max. 7% at 450 g as/ha Max. 41% at 1350 g as/ha	4630
Poecilus cupreus	Tier 2, exposure to field-aged deposits on natural soil treated at: 720 g as/ha, 2880 g as/ha	Mortality: Feeding capacity:	1-day aged deposits: 0% at 720 g as/ha 90% at 2880 g as/ha 1-day aged deposits: -2.6% at 720 g as/ha 56.6% at 2880 g as/ha	3337

Species	Test	Parameter	Effect level (relative to controls)	Reference
Chrysoperla carnea	Tier 2, exposure to field-aged deposits on vine leaves treated once at: 1250 g as/ha	Mortality: Reproduction reduction:	Fresh-dried deposits: 100% 7-day aged deposits: 22.2% 7-day aged deposits: 11.5%	2562
Aleochara bilineata	Worst-case lab (Tier II, exposure to lab-aged spray deposits on natural soil treated at 720 g a.s./ha)	Mortality: Reproduction reduction:	1-day aged spray deposits: 21.3% 5-day aged spray deposits: 3.8% 1-day aged spray deposits: 42.0% 5-day aged spray deposits: 5.3%	3336
Orius laevigatus	Worst-case lab (Tier II, exposure to field-aged spray deposits on vine leaves following 1 and 2 applications at 450 g a.s./ha)	Mortality: Reproduction reduction:	Fresh-dried spray deposits: 100% 5-day aged spray deposits: ≤29% 10-day aged spray deposits: ≤ -15% 5-day aged spray deposits: ≤20% (number of eggs) ≤5% (egg viability)	5514

In field risk assessment

Due to the effects seen on *T. pyri* and *A. rhopalosiphi* under laboratory conditions additional testing was undertaken on two sensitive standard species and two additional crop relevant species. Methomyl 20 SL was generally moderately or highly toxic to all 6 species tested (*T. pyri*, *A. rhopalosiphi*, *C. carnea*, *O. laevigatus, A. bilineata* and *P. cupreus*) in Tier 1 (laboratory glass plate) or Tier 2 (extended laboratory studies) when exposed to freshly applied dry residues. However, effects on *P. cupreus* were only >30% at 2880 g a.s./ha for 1 day aged residues and were <30% at this dose for 1 day aged residues in *A.* bilineata. These findings indicate that it is necessary to consider the additional higher tier data in order to assess the in-field risk.

A number of studies were provided where effects were examined after residues had been aged and results were compared with non-aged residues. The aim of this work was to show that as residues aged their toxicity to non-target species was reduced as may be expected of an active substance with a short half life on foliage. The results are summarised in Table B.9.58.

Table B.9.58 A summary of the toxicity effects on a range of non-target arthropod species with aged and non-aged residues

Species	Tier 2 test system	Test rate (g Methomyl/ha)	Ageing period of spray deposits (days)	Effects on mortality (M) and reproduction (R) feeding (F) (%)
T. pyri	Grapevine leaves field treated field-aged	450	fresh-dried 7	M: 74 M: 3 R: 21
A. rhopalosiphi	Grapevine leaves field treated field-aged	1250	fresh-dried 7 14	M: 100 M: 90 M: < 25 R: < 28
P. cupreus	LUFA 2.1 soil lab treated field-aged	720	1	M: 0 F: - 3
A. bilineata	LUFA 2.1 soil lab treated field-aged	720	1 5	M: 21 R: 42 M: 4 R: 5
C. carnea	grapevine leaves field treated field-aged	1250	fresh-dried 7	M: 100 M: 22 R: 12
O. laevigatus	grapevine leaves lab treated field-aged	450 following the 2nd application	fresh-dried 5	M: 100 M: 9 R: < 25

These results showed that as residues aged, effects declined. Even for *A. rhopalosiphi*, the most sensitive non-target species tested, after 14 days effects on mortality were less than 25% and reproductive effects were less than a maximum of 28%. For all other species effects were even shorter lived with effects (mortality and reproduction) being less than 25% after 7 days. The majority of trials used application regimes that covered the maximum application rate of 450 g a.s./ha with two applications at a 14 day interval. The exceptions were *T. pyri, P. cupreus* and *A. bilineata*. In the case of *T. pyri* the maximum rate used was a single application of 450 g a.s./ha. However, taken together with the other data provided it is likely that residue levels even from two applications are likely to be short lived. This conclusion is also supported by residue trials on foliage where a DT50 of 2 days was determined for methomyl (Section B.9.1.4). *P. cupreus* and *A. bilineata* are ground dwelling species and there is likely to be some crop interception. Therefore testing at 720 g a.s./ha is considered likely to cover the proposed application regime. The residues data indicate that the residues are short lived and therefore indicate there is the potential for re-colonisation within the crop within one year (ESCORT 2).

Impacts on predatory mites were also investigated in 5 field trials. These consisted of trials in grape vineyards in Italy, Germany and France and it is considered that they can be used to support the representative use on grapes in both North and Southern Europe. Two applications of 450 g a.s./ha were made at a 14 day intervals. The maximal effect seen was 98.7% relative to the control on day 27 after the second application (Lagrasse, S. (2002) 5659). In all trials subsequent assessments were made after the time of maximal effect. These are summarised in Table B.9.59.

Table B.9.59 Summary of effects at the last assessment in field trials with *T.pyri* and other predatory mites

Parameter measured	Days after treatment 2	Methomyl 20 SL	Reference
% reduction in no. compared to control	81	37	Muether, J (2001a)
% reduction in no. compared to control	338	34	Muether, J (2001b)
% reduction in no. compared to control	371	23	Muether, J (2001c)
% effect (Abbott 1925)	56	25	Bocksch, S (2002)
% effect (Abbott 1925)	83	36.3	Lagrasse, S (2002)

These trials showed that effects were less than 40% after a maximum period of approximately one year. It should be noted that the period over which recovery of >60% occurred varied in the trials from 56 to 371 days. It is likely that the time taken will be dependent on the availability of prey as well as weather conditions and it therefore expected to be variable. In addition it should be noted that the semi-field results also reflect the low potential for recolonisation of *T. pyri* compared with more mobile species. Data for *A. rhopalosiphi* showed that at 450 g a.s./ha mummies were not adversely effected and subsequent emergence and mortality was equivalent to the untreated control. These data therefore indicate that mummies of *A. rhopalosiphi* may provide a potential source for recolonisation.

It is considered that these data together with the residues data demonstrate the potential for recolonisation within one year. This is the criterion for acceptability as laid down in ESCORT 2 (M.P. Candolfi *et al*. 2000) and therefore the in-field risk to non-target arthropods is acceptable. This risk assessment covers all the representative uses.

Off–field risk assessment

It is also necessary to consider the risk to non-target arthropods occurring outside the cropped area i.e. off-field. A study with field aged residues showed that there was no effects on mortality or reproduction in *T. pyri* at 33.75 g a.s./ha (Adelberger, I. (2001)). Field trials were undertaken with *T. pyri* (Muether, J (2001 d and e)) at application rates of 22.5 and 33.75 g a.s./ha. These showed that there was no significant reduction in predatory mite numbers after application at these rates. The toxic standard used in the trials resulted in a significant reduction in mite numbers indicating the validity of the test system. At a distance of 3m a drift rate of 7.23% is expected from application to grapes at a late growth stage and from application to tall vegetables (ESCORT 2). For the proposed application rate of 450 g a.s./ha drift at this level would result in a rate of 32.5 g a.s./ha i.e. effectively the higher dose tested in the trials. Therefore these data indicate that in late grapes and tall vegetables at a distance of 3 m the risk to *T. pyri* is considered to be acceptable.

No field trials data were provided for *A. rhopalosiphi* at similar drift rates. However, higher tier data with exposure on barley seedlings rather than glass plates indicate that the LR50 values are substantial increased on this more natural substrate. The LR25 value for *A. rhopalosiphi* being 8.3 g a.s./ha on barley seedlings compared with an LR30 value of 0.2 g a.s./ha on glass plates. Thus at a distance of 10 m the spray drift in late grapes and tall vegetables of 1.07% (ESCORT 2) a.s./ha would result in a concentration of 4.8 g a.s./ha (450 g a.s./ha x 1.07%) i.e. a value below the LR25 value. It was also noted that the drift data for *T. pyri* showed that whilst a potential impact may have been predicted based on the laboratory data (LR50 value of 22.1 g a.s./ha on treated apple leaves) this did not actually occur in the field. In addition, data were provided to show that mummies of *A. rhopalosiphi* were not adversely effected by methomyl applied at a rate of 450 g a.s./ha.

A number of studies on a range of species showed that as residues aged effects diminished and data also showed that residues on leaves were short lived (see above).

Therefore it is considered that these data indicate that with appropriate risk mitigation measures the risk to off-field species is likely to be acceptable. On the basis of the information presented Member States should consider the need for risk mitigation measures to protect off-field habitats.

Drift rates in low-growing vegetables will be lower and therefore this risk assessment also covers them.

Overall conclusion for non-target arthropods

The data provided were sufficient to indicate that there was the potential for re-colonisation within one year in the field. In addition, some data were provided to address the risk off-field. It was considered that these data were sufficient to indicate that with appropriate risk mitigation measures the risk off-field is also acceptable.

B.9.6 Effects on earthworms (IIA 8.4, IIIA 10.6.1)

B.9.6.1 Toxicity

Acute toxicity

Active substance

a) Acute toxicity of methomyl (purity 98.6%) to earthworms, *Eisenia fetida* Michaelsen, was determined in a 14-day soil exposure laboratory study. Four replicates of ten clitellated adult earthworms were each exposed to nominal concentrations of 0, 6.25, 12.5, 25, 50, 100, and 200 mg a.s./kg dry soil weight (ppm in dry soil). Controls were replicated four times, with ten earthworms in each replicate. The toxic reference standard, 2-chloroacetamide, was tested at 0, 10, 18, 32, 56, and 100 mg a.s./kg dry artificial soil. Worms were assessed for mortality and behavioural effects after 7 and 14 days of exposure and earthworm body weights were assessed at Day 0 and Day 14.

Cumulative mortality results at 7 and 14 days and weight loss at 14 days are reported in the summary table below. The LC_{50} was calculated as 23 mg a.s./kg dry soil. The NOEC for mortality and weight loss was determined to be 6.25 mg a.s./kg dry soil, and the LOEC for mortality and weight loss was determined to be 12.5 mg a.s./kg dry soil. The lowest treatment causing 100% mortality was 100 mg a.s./kg dry soil. In all of the methomyl test concentrations, earthworms exhibited sublethal effects after 7 and 14 days of exposure. These effects included rigid and inflexible earthworms showing little reaction after mechanical stimulation. The LC_{50} for the toxic reference standard was between 10 and 18-mg/kg dry artificial soil; this is within accepted limits, indicating the validity of this test. Results are shown in Table B.9.60.

Table B.9.60 Acute toxicity of methomyl to earthworms

Treatment mg methomyl/kg dry soil	Cumulative mortality (%)[a]		Cumulative weight loss (%)[b]
	7 days	14 days	14 days
0	0	0	0
6.25	0	0	-10.3
12.5	10	17.5	-17.1
25	20	47.5	-24.7
50	87.5	95	-22.4
100	97.5	100	N/A
200	100	100	N/A

[a] Test mortality for treatments is corrected for control mortality (mortality at 0-mg methomyl/kg dry soil).

[b] Cumulative weight loss (%) is corrected for control weight loss at 0-mg methomyl/kg dry soil.

N/A: Not applicable, this value cannot be calculated

The acute earthworm LC_{50} was determined to be 23 mg a.s./kg soil dry weight.

The study was undertaken to OECD 207 and in accordance with GLP.

(Wachter, S. (1999) 2940)

a. A second study was conducted to determine whether the sublethal effects observed in the first acute test were repeatable. The results are summarised below.

In an acute toxicity study, earthworms (*Eisenia foetida*) were exposed to technical methomyl (purity 98.6%) for 14 days in artificial soil containing 69% industrial sand, 10% sphagnum peat, 20% kaolinite clay, approx. 1% calcium carbonate (pH = 6.0 +/- 0.5). The test was conducted in 1 litre glass vessels. Worms were weighed before being introduced to the test containers. Once the worms were in place, the jars were loosely covered with a glass lid (allowing for air exchange). Nominal concentrations of 0, 0.01, 0.1, 1, 3, 6.25, 12.5, 25, 50, 100 and 200 mg test substance per kg dry artificial soil were tested in 4 replicates of 10 worms each. Mortality was recorded on days 7 and 14. In addition, weight loss was measured on day 14.

The following table gives details of the mortality and changes in weight loss for worms during this acute toxicity study:

Table B.9.61 The mortality and weight loss of earthworms exposed to methomyl for 14 days

Treatment (mg methomyl/kg dry soil)	Cumulative mortality (%)[1]		Cumulative weight loss (%)[2]
	7 days	14 days	
0 (control)	0	0	N/A[3]
0.01	0	0	+2.7
0.1	0	0	+3.9
1	0	2.5	+0.5
3	2.5	2.5	-9.3
6.25	7.5	12.5	-17.5*
12.5	15.0	25.0	-22.4*
25	32.5	57.5	-21.8*
50	87.5	92.5	-23.7*
100	92.5	100	N/A[3]
200	97.5	100	N/A[3]

[1]Test mortality for treatments is corrected for control mortality (mortality at 0 mg methomyl/kg dry soil)
[2]Cumulative weight loss (%) is corrected for control weight loss at 0 mg methomyl/kg dry soil
[3]Not applicable; this value cannot be calculated
*Significantly different from control at p=0.05

This shows that there were significant decreases in weight loss at concentrations of 6.25 mg methomyl/kg dry soil and above when compared with the control. At 3 mg, no significant differences in weight loss occurred.

The LC50 was calculated to be 19.0 mg a.s./kg dry soil. In addition, the NOEC is 3 mg a.s./kg due to significant decreases in weight loss being observed at all concentrations above this.

The study was conducted to OECD 207 and in compliance with GLP.
(Wachter, S. (2001) 3926)

Chronic toxicity

In a 56-day reproduction study, adult earthworms (*Eisenia foetida*) were exposed to methomyl as 'Methomyl 20SL' (purity 200.6 g/l). The test was conducted in 18.3 x 13.6 x 6 cm plastic dishes containing 5 cm of moist soil consisting of 10% sphagnum peat, 20% kaolin clay, 0.5% calcium carbonate (to adjust pH to 6.0 +/- 0.5), and 69.5% fine quartz sand. Cow manure was added weekly as a food source. The test material was mixed with the soil using deionised water at doses equivalent to 1.4, 3.75, 7.5, 15, 30 and 60 mg Methomyl 20 SL/kg dry artificial soil and a control. Once weighed adult earthworms were placed on the test soil directly after it had been mixed. Adult mortality and live weight was assessed after 28 days at which point adult earthworms were removed from the test boxes. After an additional 28 days (day 56 of the study) the number of juveniles was assessed. In addition, feeding activity was also determined.

The table below gives details of the mortality and weight loss of adults after 28 days, earthworm reproduction and feeding activity.

Table B.9.62: Effects of Methomyl 20SL on earthworm growth, reproduction and mortality in a 56 day study

Concentration per dry soil (mg/kg)	Mortality (%)	Body weight change (%)	Reproduction (no. of juveniles)	Amount of food added (g)
Control	0	22.0	291	25.0
1.4	0	24.9	279	24.0
3.75	0	21.4	259	24.0
7.5	0	15.3[1]	281	24.0
15	0	5.8*	186*	19.5
30	0	-5.3*	36*	16.0
60	0	-32.5*	0*	14.0

*Statistically significantly different when compared with the control.
[1]Not statistically significantly different when compared with the control.

No mortality of earthworms was observed in any of the test groups. No significant sublethal effects were seen up to the treatment group of 7.5 mg of formulated product/kg dry artificial soil. In the treatment groups of 15, 30 and 60 mg formulated product/kg dry artificial soil the body weight changes and reproduction rates were significantly different compared to the control. The NOEC is therefore considered to be 7.5 mg/kg Methomyl 20SL/kg dry artificial soil (equiv. to 1.5 mg methomyl/kg dry artificial soil).

This study was conducted to BBA guidelines VI 2-2 (1994) and ISO 11268-2 (1998) and to GLP.

(Lührs, U. (2001) 5503)

Plant protection product (IIIA 10.6.1)

B.9.6.2 Risk assessment

Acute risk for all the proposed uses

Two acute studies were provided for earthworms and the LC50 values derived were 23 and 19 mg a.s./kg soil. The lower of these end points i.e. 19 mg a.s./kg has been used in the risk assessment. This has been compared with the maximum soil PECs for all the proposed uses (B.8.3). The resulting acute TER is shown in Table B.9.63.

Table 9.63 Short term risk to earthworms

Scenario	LC50 (mg a.s./kg))	PEC mg as/kg	Short term TER	Annex VI trigger 91/414 EEC
Tall and short vegetables	LC50: 19	0.493	38.5	10
Grapes -early use	LC50: 19	0.394	48.2	10
Grapes – late use	LC50 19	0.296	64.1	10

The acute or short term risk to earthworms is above the Annex VI trigger value and the risk is acceptable for all the representative uses i.e. on both fruiting vegetables and grapes.

'The Guidance Document on Terrestrial Ecotoxicology under Directive 91/414/EEC SANCO/10329/2002 17 Oct 2002' states that a sub lethal study on earthworms is not required when the DT90f is <100 days and the number of applications is less than three. The laboratory DT90 in soil at reference conditions is 74 days (DT50 22.2 days, first order, see Table B.8.32). Under field conditions the DT90 would be expected to be shorter than this. In addition, only two applications are recommended. Therefore according to the guidance document it is not necessary to undertake an assessment of the long term risk to earthworms.

However, a chronic study for earthworms has actually been provided and therefore this end point can be used in a long term risk assessment.

Chronic risk

i) Early use on grapes (2 applications at 450 g a.s./ha and 60% crop interception)

The maximum PECsoil was 0.394 mg a.s./kg (Section B.8.3) comparing this with the NOEC of 1.5 mg a.s./kg results in a TER of 3.81. This is below the Annex VI trigger value of 5. Therefore although according to the guidance document it is not necessary to undertake a risk assessment for methomyl when one is undertaken the resulting TER is below the required value. It is considered that this TER cannot be ignored and that this risk therefore needs to be further addressed. It is considered that further information is required before an acceptable risk to earthworms can be identified from this use.

ii) Late use on grapes (2 applications at 450 g a.s./ha and 70% crop interception)

The soil PEC for late use on grapes is 0.296 mg a.s./kg (Section B.8.3) comparing this with the NOEC of 1.5 mg a.s./kg the resulting TER is 5.06.

This is above the Annex VI trigger value of 5 and therefore the risk to earthworms from this use is acceptable.

iii) Use on vegetables (2 applications at 450 g a.s./ha and 50% crop interception)

Comparing the soil PEC of 0.493 mg a.s./kg (Section 8.3) with the NOEC of 1.5 mg a.s./kg the resulting TER is 3.04. This is below the Annex VI trigger of 5 and so further information is required before an acceptable use can be identified.

iv) Use on vegetables (2 applications at 250 g a.s./ha and 50% crop interception)

The proposed rate of 250 g a.s./ha is 1.8 times lower than the proposed rate at (iii) of 450 g a.s./ha. Therefore the TER for this use will actually be 1.8 times greater than the TER for use at 450 g a.s./ha i.e. 5.47 (3.04 x 1.8). Therefore the risk from this use is acceptable.

Overall conclusion on the risk to earthworms

The acute risk to earthworms from the maximum proposed dose results in a TER above the Annex VI trigger value i.e. the acute risk is acceptable. Accordingly to the Terrestrial Guidance Document (SANCO/10329/2002) a sub-lethal study on earthworms is not required where the DT90f is <100 days and the number of applications is <3. A DT90f is not available however the laboratory DT90 in soil at reference conditions is 74 days and under field conditions the DT90 would be expected to be shorter than this. In addition there are only 2 applications. Hence according to the guidance a sub-lethal study would not be required. However, such a study was provided. The resulting TER using the maximum soil PEC from early use on grapes and from use on vegetables at 450 g a.s./ha was 3.8 and 3.04 respectively i.e. less than the trigger value of 5. It is considered that this cannot be ignored and more information is required before a conclusion can be reached on the acceptability of the risk to earthworms from these uses.

It should be noted that use post-flowering in grapes results in a lower soil PEC and the resulting chronic TER (5.06) is acceptable. Similarly, use on vegetables at a rate of 250 g a.s./ha results in a chronic TER of 5.47 and so the risk from this use is also acceptable.

Conclusion:

The acute risk from all the proposed uses is acceptable. However the chronic TER for use on early grapes and use on fruiting vegetables at 450 g a.s./ha is below the trigger value. Therefore further consideration of the chronic risk to earthworms for these uses is necessary. For late use on grapes and use on fruiting vegetables at 250 g a.s./ha the chronic risk is acceptable.

Data required before inclusion in Annex I can be considered

Additional information is required to address the chronic risk to earthworms arising from early use on grape and use on veg. (The expectation is that with appropriate additional information it should be possible to address this risk).

B.9.7 Effects on soil non-target macro-organisms (IIIA 10.6.2)

B.9.7.1 Toxicity

No data have been provided.

B.9.7.2 Risk assessment

The laboratory DT90 in soil at reference conditions is 74 days (DT50 22.2 days, first order, see Table B.8.32). Under field conditions the DT90 would be expected to be shorter than this. Therefore neither additional testing on soil macro-organisms nor a soil litter bag test is triggered. No further information is therefore required.

B.9.8 Effects on soil non-target micro-organisms (IIA 8.5, IIIA 10.7)

B.9.8.1 Toxicity

Active substance (IIA 8.5)

No data were provided with the active substance.

Plant Protection Product (IIIA 10.7)

The effects of Methomyl 20SL on short term respiration and nitrogen turnover were examined in a loamy sand soil in a laboratory study. The soil was treated with Methomyl 20SL at a rate equivalent to 0.45 and 4.5-kg as/ha (1-time and 10-times the maximum field application rate). A control and toxic reference (formulation of dinoterb at 20L/ha, i.e., 5 times field application rate) were also tested. Each treatment group contained 3 replicates. For the assessment of nitrogen turnover the soil was amended with Lucerne meal before application. After incubation at 20°C ammonium-N, nitrate-N, and nitrite-N were determined in soil samples. Sampling for both tests took place 3 hours, 14 days, and 28 days after application. For short-term respiration the rate of oxygen uptake was measured for up to 24 hours following the application of glucose.

A summary of the findings is presented in Table B.9.64 and Table B.9.65. Deviations in the nitrogen turnover and short-term respiration in soil treated with Methomyl 20SL compared to control soils were <25% at the end of the study (after 28 days). No nitrite was detected in control soil.

Table B.9.64 Summary of effects (%)[a] of Methomyl 20SL on mineralised nitrogen level (N_{min}) in loamy sand amended with Lucerne meal

Time	Treatment group	
	0.45 kg methomyl/ha	4.5 kg methomyl/ha
3h	-1.72	-1.72
14d	3.51	11.70
28d	19.41	23.63

[a] % Effect: [(measured parameter in treated soil/measured parameter in control soil)-1] x100

Table B.9.65 Summary of effects (%)[a] of Methomyl 20SL on respiration in loamy sand

Time	Treatment group	
	0.45 kg methomyl/ha	4.5 kg methomyl/ha
3h	-10.42	0.00
14d	-5.13	0.00
28d	9.09	-9.09

[a] % Effect: [(measured parameter in treated soil/measured parameter in control soil)-1] x100

It was concluded that Methomyl 20SL, at 1-times and 10-times the recommended maximum application rate had no significant effect (< 25% relative to the control) on soil nitrogen transformation or carbon mineralisation. Methomyl 20SL, therefore, can be categorised as having low risk to soil microflora and no further testing is required.

The study was undertaken in accordance with OECD Guidelines 216 and 217 (2000) and was to GLP.

(Wachter, S. (2001) 4113)

B.9.8.2 Risk assessment

Methomyl 20 SL at rates equivalent to one times and ten times the maximum individual dose rate (0.5 and 5 times the maximum total dose) had no adverse effect on nitrogen transformation or carbon mineralisation. The risk to soil micro-organisms is considered to be acceptable.

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (IIA 8.6)

B.9.9.1 Toxicity

Active substance

No data were provided with the active substance.

B.9.9.2 Plant protection products

A greenhouse phytotoxicity study was conducted on six plant species representing two families of Monocotyledonae and three families of Dicotyledonae. Seedling plants grown in a soil matrix were exposed to foliar applications of Methomyl 20SL at the maximum field use-rate (2.25-L Methomyl 20SL/ha). Visual evaluations of plant response as compared to water-treated control plants were made 21 days after application. Total shoot dry weight was determined. Results are shown in the tables below.

Table B.9.66 Mean plant response (visual % effect at 21 days after treatment)

Application (L/ha)	Monocotyledonae			Dicotyledonae		
	Corn	Oat	Onion	Rape	Soybean	Sugar beet
0 (control)	2.90	6.30	8.00	5.40	3.40	2.00
2.25	3.70	6.60	2.70	3.00	2.70	2.10
% effect relative to control *	0.82	0.32	-5.76	-2.54	-0.72	0.10

* A negative effect is a growth enhancement

Table B.9.67 Mean shoot dry weight (grams at 21 days after treatment)

Application (L/ha)	Monocotyledonae			Dicotyledonae		
	Corn	Oat	Onion	Rape	Soybean	Sugar beet
0 (control)	30.48	5.54	0.19	52.07	16.04	31.90
2.25	31.18	5.19	0.20	53.22	16.29	30.32
% Effect relative to control *	-2.28	6.30	-3.65	-2.21	-1.55	4.97

* A negative effect is a growth enhancement

In conclusion Methomyl 20SL applied at the maximum field use-rate (2.25 L/ha) did not result in plant effects greater than 6.30% for any of the species tested.

The study was undertaken in accordance with U.S. EPA Subdivision J, 122-1 (1984) and draft OPPTS 850.4150 (1996) guidelines and was to GLP.

(Heldreth, K.M. (2001) .)

B.9.9.3 Risk assessment

These data show that the insecticide methomyl had no adverse phytotoxic effects on a range of plant species. The risk to non-target plants is therefore considered acceptable.

B.9.10 Effects on biological methods for sewage treatment (IIA 8.7)

B.9.10.1 Effects

The influence of methomyl (purity 98.02%) on the activity of activated sludge was evaluated by measuring the respiration rate under defined conditions. The respiration rate (oxygen consumption) of an aerobic activated sludge fed with a standard amount of synthetic sewage was measured in the presence of various concentrations of the test item after an incubation period of 3 hours. Concentrations of 100.0, 32.0, 10.0, 3.2, and 1.0-mg methomyl/l; 32.0, 10.0, and 3.2-mg 3,5-dichlorophenol/l and two inoculum controls were tested.

In comparison to the inoculum controls the respiration rate of the activated sludge was inhibited by 4.2% at the lowest test concentration of 1.0-mg methomyl/l. At test concentrations of 3.2 and 10-mg test item/l inhibition rates of 11.5% and 4.2% were determined. Inhibition rates increased up to 13.7% and 23.9% at the two highest methomyl test concentrations of 32 and 100 mg/l. From the determined inhibition rates, the 3-hour EC_{20} was calculated to be 86.7-mg methomyl/l. The 3-hour EC 50 was > 100-mg test item/l. The 3-hour EC_{50} for the positive control 3,5-dichlorophenol, which was tested in the same way as the test item, was found to be 13.2 mg/l and is within the range of 5 to 30 mg/l recommended by the test guidelines; thus, confirming suitability of the activated sludge.

Table B.9.68 Effects of methomyl on biological methods for sewage treatment

Methomyl (mg/l)	Mean respiration rate (mg O_2/l/min)	Inhibition of respiration rate (%)
0	0.452	--
1.0	0.433	4.2
3.2	0.400	11.5
10.0	0.433	4.2
32.0	0.390	13.7
100.0	0.344	23.9

The 3-hour EC_{20} of methomyl was determined to be 86.7 mg/l. The 3-hour EC_{50} was higher than 100 mg methomyl/l.

The study was undertaken in accordance with OECD 209 (1984) and to GLP.

(Hertl, J. (2001)

B.9.10.2 Risk assessment

Given the nature of the proposed use it is unlikely that concentrations of methomyl will reach sewage treatment plants. In any case, this compound had a low bactericidal activity against activated sewage sludge in the study submitted. Hence, the risk to sewage treatment processes is acceptable.

B.9.11 References relied on:

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Aboul-Ela, I.A., Khalil, M.T.	IIA, 8.2.4./06	1987	The acute toxicity of three pesticides on organisms of different trophic levels as parameters of pollution in Lake Wadi El Rayan, El Fayoum, Egypt Department of Zoology, Faculty of Science, University of Ain Shams, Egypt Proceedings of the Zoological Society A.R. Egypt, 13: 31-36 Not applicable GLP: No Published: Yes	N	Authors
Adelberger, I.	IIA, 8.3.2./01	2000	Methomyl 20L: a dose/response test to evaluate the effects on the predatory mite, *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), in the laboratory GAB Biotechnologie, GmbH DuPont-2668 GLP: Yes Published: No	Y	DuPont
Adelberger, I.	IIA, 8.3.2./03	2001	Methomyl (DPX-X1179) 20L: an extended laboratory study to evaluate the effects on the predatory mite, *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), exposed to field-aged residues on grape leaves GAB Biotechnologie, GmbH DuPont-4427 GLP: Yes Published: No	Y	DuPont
Baer, K.N.	IIA, 8.2.2.1./01	1991	Flow-through, 21-day toxicity of DPX-X1179-423 (Lannate® 20L) to rainbow trout (*Oncorhynchus mykiss*) DuPont Haskell Laboratory HLR 34-91 GLP: Yes Published: No	Y	DuPont
Beavers, J.B.	IIA, 8.1.1./01	1983	An acute oral toxicity study in the bobwhite Wildlife International, Ltd. (U.S.A.) HLO 464-83 GLP: No Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Beavers, J.B., Hawrot, R., Jaber, M., Lynn, S.P.	IIA, 8.1.3./02	1991b	H-17, 940: a one-generation reproduction study with the northern bobwhite (*Colinus virginianus*) Wildlife International, Ltd. (U.S.A.) HLO 337-91 GLP: Yes Published: No	Y	DuPont
Beavers, J.B., Hawrot, R., Lynn, S.P., Jaber, M.	IIA, 8.1.3./01	1991a	H-17, 940: a one-generation reproduction study with the mallard (*Anas platyrhynchos*) Wildlife International, Ltd. (U.S.A.) HLO 336-91 GLP: Yes Published: No	Y	DuPont
Bocksch, S.	IIA, 8.3.2./07	2002	Methomyl (DPX-X1179) 20L: A field study to evaluate effects on predatory mites in grape vineyards in Italy, 2001 GAB Biotechnologie GmbH DuPont-5469 GLP: Yes Published: No	Y	DuPont
Boeri, R.L., Wyskiel, D.C., Ward, T.J.	IIA, 8.2.1./01	2000	Methomyl technical: acute, 96-hour, LC_{50} to rainbow trout, *Oncorhynchus mykiss* T.R. Wilbury Laboratories, Inc. DuPont-3725 GLP: Yes Published: No	Y	DuPont
Brittelli, M.R.	IIA, 8.2.5./01	1982	Chronic toxicity of methomyl to *Daphnia magna* DuPont Haskell Laboratory HLR 46-82 GLP: No Published: No	Y	DuPont
Bruhnke, C.	IIA, 8.3.2./02	2000	Methomyl 20L: a extended laboratory dose/response test to evaluate the effects on the predatory mite, *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-3766 GLP: Yes Published: No	Y	DuPont
Drexler, A.	IIA, 8.3.2./13	2000a	Methomyl 20L: extended laboratory toxicity test to study the effects of treated grape vine leaves (field aged residue) on the parasitoid, *Aphidius rhopalisiphi* (Hymenoptera, Aphidiidae) IBACON GmbH DuPont-2563 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Drexler, A.	IIA, 8.3.2./15	2000b	Methomyl 20L: extended laboratory toxicity test to study the effects on natural soil to the carabid beetle, *Poecilus cupreus L.* (Coleoptera, Carabidae) IBACON GmbH DuPont-3337 GLP: Yes Published: No	Y	DuPont
Drexler, A.	IIA, 8.3.2./16	2001	Methomyl 20L: extended laboratory toxicity test to study the effects of treated grape vine leaves (field aged residues) on *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) IBACON GmbH DuPont-2562 GLP: Yes Published: No	Y	DuPont
Green, J.W.	IIA, 8.1.2./03	2003	LC_{50} for mallard dietary acute study DuPont-4379 DuPont Haskell Laboratory DuPont-12888 GLP: No Published: No	N	DuPont
Heldreth, K.M.	IIA, 8.6./01	2001	Methomyl (DPX-X1179) 20L: a greenhouse study to investigate the effects on the vegetative vigor of several terrestrial plants following foliar exposure DuPont Agricultural Products DuPont-3965 GLP: Yes Published: No	Y	DuPont
Hertl, J.	IIA, 8.7./01	2001	Methomyl (DPX-X1179) technical: activate sludge, respiration inhibition test IBACON GmbH DuPont-4482, Revision No. 1 GLP: Yes Published: No	Y	DuPont
Hoke, R.A.	IIA, 8.2.4./03	2002a	Methomyl (DPX-X1179) 20SL: static, acute, 48-hour EC_{50} to *Daphnia magna* DuPont Haskell Laboratory DuPont-10461 GLP: Yes Published: No	Y	DuPont
Hoke, R.A.	IIA, 8.2.4./04	2002b	Methomyl (DPX-X1179) 20SL: a study to determine the effects on adult *Daphnia magna* and their neonates under time-varied exposure DuPont Haskell Laboratory DuPont-11049 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Johnson, W.W., Finley, M.T.	IIA, 8.2.4./07	1980	Handbook of acute toxicity of chemicals to fish and aquatic invertebrates National Fisheries Research Laboratory, Columbia, Missouri, U.S.A., United States Department of the Interior Fish and Wildlife Service, Resource Publication 137: 1-8, 49-50, 86-87, 96-98. EPA MRID 40098401 Not applicable GLP : No Published: Yes	N	Authors
Kennedy, C.M., Dubey, L., Steiner, C., Matni, H.	IIA, 8.1.1.1./01	2002	Magnitude and decline of residues of methomyl in wildlife food items (grass and broadleaf) following two applications of DPX-X1179 20SL – northern/southern Europe, season 2001 Battelle Europe-Centre de Recherche de Geneve DuPont-6059 GLP: Yes Published: No	Y	DuPont
Lagrasse, S.	IIA, 8.3.2./08	2002	Methomyl (DPX-X1179) 20L: A field study to evaluate effects on predatory mites in grape vineyards in France, 2001 Promo-Vert S.A. DuPont-5659 GLP: Yes Published: No	Y	DuPont
Lührs, U.	IIA, 8.4.2./01	2001	Methomyl 20L: effects on reproduction and growth of the earthworm, *Eisenia fetida* (Savigny 1826), in artificial soil IBACON GmbH DuPont-5503 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Mayer, F.L., Ellersieck, M.R.	IIA, 8.2.4./08	1986	Manual of acute toxicity: interpretation and database for 410 chemicals and 66 species of freshwater animals National Fisheries Research Laboratory, Columbia, Missouri, U.S.A., United States Department of the Interior Fish and Wildlife Service, Resource Publication 160: 1-35, 363-368. EPA MRID 40098401 Not applicable GLP: No Published: Yes	N	Authors
Mead, C., Mullee, D.M.	IIA, 8.2.6./01	1999	Methomyl: algal inhibition test Safepharm Laboratories, Limited SPL 282/573 GLP: Yes Published: No	N	Aventis
Mead, C., Mullee, D.M.	IIA, 8.2.6./02	1999	Methomyl: additional algal inhibition test conducted to confirm no observed effect concentration Safepharm Laboratories, Limited SPL 282/594 GLP: Yes Published: No	N	Aventis
Medlicott, B.A., Harris, T.	IIA, 8.1.2./01	2000a	Methomyl (DPX-X1179) technical: avian acute dietary toxicity test with northern bobwhite (*Colinus virginianus*) Genesis Laboratories, Inc. DuPont-4378 GLP: Yes Published: No	Y	DuPont
Medlicott, B.A., Harris, T.	IIA, 8.1.2./02	2000b	Methomyl (DPX-X1179) technical: avian acute dietary toxicity test with the mallard duck (*Anas platyrhynchos*) Genesis Laboratories, Inc. DuPont-4379 GLP: Yes Published: No	Y	DuPont
Moll, M.	IIA, 8.3.2./12	2000	Methomyl 20L: a dose/response test to evaluate the effects on the aphid parasitoid, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae), under extended laboratory conditions IBACON GmbH DuPont-3764 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Muether, J.	IIA, 8.3.2./04	2001a	Methomyl (DPX-X1179) 20L: a field study to evaluate effects on the predatory mite, *Typhlodromus pyri* Scheuten, in grape vineyards in Germany, 2000 GAB Biotechnologie, GmbH DuPont-3883 GLP: Yes Published: No	Y	DuPont
Muether, J.	IIA, 8.3.2./09	2001d	Methomyl (DPX-X1179) 20L: a field study to evaluate effects on the predatory mite, *Typhlodromus pyri* Scheuten, in grape vineyards in Germany, 2000 GAB Biotechnologie, GmbH DuPont-4330 GLP: Yes Published: No	Y	DuPont
Muether, J.	IIA, 8.3.2./10	2001e	Methomyl (DPX-X1179) 20L: a field study to evaluate effects on the predatory mite, *Typhlodromus pyri* Scheuten, in grape vineyards in Germany, 2000 GAB Biotechnologie, GmbH DuPont-4329 GLP: Yes Published: No	Y	DuPont
Muether, J.	IIA, 8.3.2./05	2001b	Methomyl (DPX-X1179) 20L: a field study to evaluate effects on the predatory mite, *Typhlodromus pyri* Scheuten, in grape vineyards in Germany, 2000 GAB Biotechnologie GmbH DuPont-4327 GLP: Yes Published: No	Y	DuPont
Muether, J.	IIA, 8.3.2./06	2001c	Methomyl (DPX-X1179) 20L: a field study to evaluate effects on predatory mites in grape vineyards in France, 2000 GAB Biotechnologie GmbH DuPont-4326 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Pantani, C., Pannunzio, G., De Cristofaro, M., Novelli, A.A., Salvatori, M.	IIA, 8.2.4./05	1997	Comparative acute toxicity of some pesticides, metals, and surfactants to *Gammarus italicus* goedm. and *Echinogammarus tibaldii* pink. and stock (crustacea: amphipoda) Department of Environmental Sciences, University of L'Aquila, Via Vetoio-Localita Coppito, 67100 L'Aquila, Italy. Bulletin of Environmental Contamination and Toxicology, 59:963-967; Springer-Verlag, New York, Inc. Not applicable GLP: No Published: Yes	N	Authors
Rhodes, J.E.	IIA, 8.2.2.2./01	1991	Early life-stage toxicity of IN X1179-394 to the fathead minnow (*Pimephales promelas*) under flow-through conditions ABC Laboratories, Inc. (Missouri) HLO 702-91 GLP: Yes Published: No	Y	DuPont
Schuld, M.	IIA, 8.3.2./11	2000a	Methomyl 20L: a dose/response test evaluate the effects on the aphid parasitoid, *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), in the laboratory GAB Biotechnologie, GmbH DuPont-2669 GLP: Yes Published: Yes	Y	DuPont
Schuld, M.	IIA, 8.3.2./14	2000b	Methomyl (DPX-X1179) 20L: a laboratory study to evaluate the effects on emergence of adult *Aphidius rhopalosiphi* (Destefani-Perez) (Hymenoptera: Braconidae) from sprayed mummified aphids GAB Biotechnologie, GmbH DuPont 4630 GLP: Yes Published: No	Y	DuPont
Schur, A.	IIA, 8.3.1.1./01	2000	Methomyl technical: acute oral and contact toxicity to the honey bee, *Apis mellifera* L GAB Biotechnologie, GmbH DuPont-2738 GLP: Yes Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	EU Data Protection Claimed (Y/N)	Owner
Strawn, T., Rhodes, J.E., Leak, T.,	IIA, 8.2.2.3./01	1993	Full life-cycle toxicity of DPX-X1179-394 (methomyl) to the fathead minnow (*Pimephales promelas*) under flow-through conditions ABC Laboratories, Inc. (Missouri) HLO 47-93 (11 volumes) GLP: Yes Published: No	Y	DuPont
Wachter, S.	IIA, 8.4.1./01	1999	Methomyl technical: acute toxicity to earthworm, *Eisenia foetida* Michaelsen GAB Biotechnologie, GmbH DuPont-2940 GLP: Yes Published: No	Y	DuPont
Wachter, S.	IIA, 8.4.1./02	2001	Methomyl technical: acute toxicity to the earthworm (*Eisenia foetida*) in artificial soil GAB Biotechnologie, GmbH DuPont-3926 GLP: Yes Published: No	Y	DuPont
Wachter, S.	IIA, 8.5./01	2001	Methomyl (DPX-X1179) 20L: assessment of the effects on soil microflora GAB Biotechnologie, GmbH DuPont-4113 GLP: Yes Published: No	Y	DuPont
Ward, T.J., Wyskiel, D.C., Boeri, R.L.	IIA, 8.2.4./02	2001	Methomyl 20SL: static, acute, 48-hour EC_{50} to *Daphnia magna* T.R. Wilbury Laboratories, Inc. DuPont-3726 GLP: Yes Published: No	Y	DuPont
Wetton, P.M., Mullee, D.M.	IIA, 8.2.1./02	1999	Methomyl: acute toxicity to bluegill sunfish (*Lepomis macrochirus*) Safepharm Laboratories, Limited SPL 282/571 GLP: Yes Published: No	N	Aventis
Wetton, P.M., Mullee, D.M.	IIA, 8.2.4./01	1999	Methomyl: acute toxicity to *Daphnia magna* Safepharm Laboratories, Limited SPL 282/572 GLP: Yes Published: No	N	Aventis

Plant Protection Product – Methomyl 20SL

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protection Claimed (Y/N)	Owner
Baer, K.N.	IIIA, 10.2.1./01	1991	Static, acute, 96-hour LC_{50} of DPX-X1179-423 (Lannate® 20L) to rainbow trout (*Oncorhynchus mykiss*) DuPont Haskell Laboratory HLR 29-91 GLP: Yes Published: No	N	DuPont
Baer, K.N.	IIIA, 10.2.1./02	1991	Static, acute, 96-hour LC_{50} of DPX-X1179-423 to bluegill sunfish (*Lepomis macrochirus*) DuPont Haskell Laboratory HLR 30-91 GLP: Yes Published: No	N	DuPont
Drexler, A.	IIIA, 10.5.1./01	2000	Methomyl 20L: Extended laboratory toxicity test to study the effects on Natural Soil to the Rove Beetle *Aleochara bilineata* L. (Coleoptera, Staphylinidae) IBACON GmbH DuPont-3336 GLP: Yes Published: No	N	DuPont
Gurney, A.	IIIA, 10.1.5/01 IIIA, 10.3.1/01	2003	Methomyl: Ecological Risk Assessment for some Groups of Small Birds and Small Mammals RCC Ltd. RCC 851727 GLP: No Published: No	Y	DuPont
Kuhr, R.J.	IIIA, 10.1.5.3/01	1973	The Metabolic Fate of Methomyl in the Cabbage Looper Pest Biochem Physiol Vol. 3 GLP: No Published: Yes	N	Pest Biochem Physiol
Kuhr, R.J., Hessney, C.W.	IIIA, 10.1.5.3/02	1977	Toxicity and Metabolism of Methomyl in the European Corn borer Pest Biochem Physiol Vol. 7 GLP: No Published: Yes	N	Pest Biochem Physiol
Lu, C.C.	IIIA, 10.3.1.2./01	1983	Nudrin® Two-generation reproduction study in rats WIL Research Laboratories, Inc. (USA) WRC RIR-275 (HLO 519-95, 5 volumes) GLP: No Published: No	Y	DuPont

Author(s)	Annex No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	EU Data Protection Claimed (Y/N)	Owner
Sarver, J.W.	IIIA, 10.3.1.2./02	1991a	Acute oral toxicity study with DPX-X1179-394 in male and female rats DuPont Haskell Laboratory, P.O. Box 50, Elkton Road HLR 661-91 GLP: Yes Published: No	Y	DuPont
Schur, A.	IIIA, 10.4.1./01	2000	Methomyl 20L: acute oral and contact toxicity to the honey bee, *Apis mellifera L* GAB Biotechnologie, GmbH DuPont-2739 GLP: Yes Published: No	N	DuPont
Schur, A.	IIIA, 10.4.3./01	2001	Methomyl (DPX-X1179) 20L: a semi-field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; Hymenoptera, Apidae) in apples in Spain in 2001 GAB Biotechnologie, GmbH DuPont-5470 GLP: Yes Published: No	N	DuPont
Schur, A.	IIIA, 10.4.3./02	2001	Methomyl (DPX-X1179) 20L: a semi-field test in Germany to evaluate the effects on the honey bee, *Apis mellifera carnica* (Hymenoptera: Apidae) GAB Biotechnologie, GmbH DuPont-4446 GLP: Yes Published: No	N	DuPont
Troup, R., Baroch, J.	IIIA, 10.1.1./01	2000	Methomyl 20L: an acute oral toxicity study with the northern bobwhite (*Colinus virginianus*) Genesis Laboratories, Inc. DuPont-3394 RV1 GLP: Yes Published: No	N	DuPont
van Stratum, ing P.	IIIA, 10.5.1./02	2001	Methomyl (DPX-X1179) 20L: An extended laboratory test to evaluate the effects on the predatory bug, *Orius laevigatus* (Fieber) (Heteroptera, Anthocoridae) Mitox DuPont-5514 GLP: Yes Published: No	N	DuPont

Additional references relied on by Rapporteur Member State

Annex point	Author	Year	Title/ Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
-	-	2002	Guuidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002 REV 2 final	N	-
		2002	Guidance document on aquatic ecotoxicology in the context of Directive 91/414/EEC SANCO/3268/2001 REV 4 (final)	N	
		2002	Guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC. SANCO/4145/2000	N	
	M.P Candolfi *et al.*	2000	Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods from the ESCORT 2 workshop.	N	

APPENDIX 1

Methomyl

STANDARD TERMS AND ABBREVIATIONS

Technical Terms

A	ampere
Ach	acetylcholine
Ache	acetylcholinesterase
ADI	Acceptable Daily Intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD50	approximate median lethal dose 50%
ALT	alanine aminotransferase (SGPT)
AOEL	Acceptable Operator Exposure Level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi-(x 10^{-2}
°C	degree celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval

CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days pot inoculation
DRES	dietary risk evaluation system
DT	disappearance time
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
ECD	electron capture detector
ECU	European currency unit
ED_{50}	median effective dose
EDI	estimated daily intake
ELISA	enzyme lined immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F_o	parental generation
F_1	filial generation, first
F_2	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionization detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	Good Agricultural Practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector

GC-FID	gas chromatography with flame ionization detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionization detector
HPAEC	high performance anion exchange chromatography
HPLC	high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_s	Shannon-Weaver index
Ht	haematocrit
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration
ICM	integrated crop management
ID	ionization detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number

ISSN	international standard serial number
iv	intravenous
IVF	*in vitro* fertilization
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H)[13]
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography - mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dose letalis media
LCA	life cycle analysis
LC_{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of determination
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
ml	millilitre

MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mol	Mol
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
mM	Milimoles
MRL	maximum residue level
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration)
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nonometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter
op	organophosphorous pesticide
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	Predicted Environmental Concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water

PED	plasma-emissions-detector
PFPD	Pulsed flame photometric detection or detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P_{ow}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
ppp	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion ($10^{-12)}$
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean

SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	Toxicity Exposure Ratio
TER_1	toxicity exposure ration for initial exposure
TER_{ST}	toxicity exposure ration following repeated exposure
TER_{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	Thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)

WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Limited
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (no.)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organisation
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union

EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organisation of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organisation
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organisation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network

RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organisation
WTO	World Trade Organisation
WWF	World Wildlife Fund

APPENDIX 2

Methomyl

Appendix 2 Specific terms and abbreviations

Technical Terms

ADME	adsorption, distribution, metabolism and excretion
ADR	European agreement concerning the international carriage of dangerous goods by road
AR	applied radioactivity
a.s.	active substance
AUC	area under curve
BuChE	Butyrylcholinesterase
C	Carbon
CHO	Chinese hamster ovary
CO	Carbon monoxide
CO_2	Carbon dioxide
EC	emulsifiable concentrate
ETE	Estimated theoretical exposure
HCl	Hydrochloric acid
HDPE	high density polyethylene
HGPRT	hypoxanthine–guanine phosphoribosyl transferase
HPT	hypothalamus-pituitary-testicular
ILV	Independent laboratory validation
K_{ads}	adsorption constant
K_F	Freundlich coefficient
K_{OH}	hydroxyl radical rate constant
K_{OW}	octanol water partition coefficient
KOH	Potassium hydroxide
LC	Liquid chromatography
LH	Luteinizing Hormone
LOQ	limit of quantification
MAC	Maximum Allowable Concentration
MATC	Maximum Acceptable Toxic Concentration
MMAD	mass median aerodynamic diameter
Mbq	Mega becquerels
MS	Member State
MWHC	maximum water holding capacity
n	Number of subjects, organisms, etc
N	Normal (of acids etc)
NaOH	Sodium hydroxide
NESTI	National estimate of short-term intake
NMS	Northern Member State
NNG	Net nuclear grains
OM	Organic Matter
P_0 / P_1	parental generation, first (author dependent)
PCE	polychromatic erythrocytes
PCN	potato cyst nematode
PDE	potential dermal exposure
PEC_a	predicted environmental exposure in air
PEC_{gw}	predicted environmental exposure in ground water
PEC_s	predicted environmental exposure in soil
PEC_{sw}	predicted environmental exposure in surface water
PELMO	Pesticide Leaching Model

PHED	Pesticide Handlers Exposure Database
pKa	dissociation constant
POEM	Predictive Operator Exposure Model
PPE	personal protective equipment
r^2	correlation coefficient
RPE	respiratory protective equipment
RSD	relative standard deviation
s	second
SC	suspension concentrate
SL	Soluble concentrate (formulation)
SMS	Southern Member State
TER	toxicity exposure ratio
TLC	thin layer chromatography
TRR	Total recovered radioactivity
UK	United Kingdom
WP	wettable powder

Organisations and Publications

BBA	Federal Biological Research Centre for Agriculture and Forestry (Germany)
BBCH	BASF–Bayer–Ciba-Geigy–Hoechst growth stage classification
BVL	Federal Office for Consumer Protection and Food Safety (Germany)
Defra	Department for Environment, Food and Rural Affairs (UK)
DIN	German national accrediting/standardisation body
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (USA)
ICAO	International Civil Aviation Organisation
MAFF	(Former) Ministry of Agriculture, Fisheries and Food (UK)
PSD	Pesticides Safety Directorate (UK)
SANCO	Health and Consumer Protection Directorate-General of the European Commission
SCFCAH	Standing Committee on the Food Chain and Animal Health (EC)

APPENDIX 3

Methomyl

MATERIAL SAFETY DATA SHEET

Material Safety Data Sheet of Methomyl Technical

-- SAFETY DATA SHEET --

AGRICULTURAL PRODUCTS DEPARTMENT

REF. 000000056/N/NS
PAGE 2 of 5
PRINT DATE 2001-10-20
REVISION DATE: 2001-10-18

Product name: METHOMYL Technical

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: dry chemical, water spray

Extinguishing media which must not be used for safety reasons: high volume water jet (contamination risk)

Special protective equipment for firefighters: Wear self-contained breathing apparatus and protective suit.

Specific methods: If area is heavily exposed to fire and if conditions permit, let fire burn itself out since water may increase the area contaminated. Cool containers / tanks with spray water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear self-contained breathing apparatus and protective suit. Evacuate personnel to safe areas.

Environmental precautions: Do not flush into surface water or sanitary sewer system.

Methods for cleaning up: Neutralize with sodium hydroxide and allow to stand for 4 hours. Use approved industrial vacuum cleaner for removal. Shovel into suitable container for disposal.

7. HANDLING AND STORAGE

Handling
Technical measures/Precautions: Provide appropriate exhaust ventilation at places where dust is formed. Use only in area provided with appropriate exhaust ventilation.
Safe handling advice: Keep away from heat and sources of ignition. Do not breathe dust. Avoid contact with skin and eyes. In case of insufficient ventilation, wear suitable respiratory equipment.

Storage
Technical measures/Storage conditions: Keep containers tightly closed in a dry, cool and well-ventilated place.
Incompatible products: No materials to be specially mentioned.
Packaging material: No materials to be specially mentioned.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Engineering measures Ensure adequate ventilation, especially in confined areas. In case of insufficient ventilation, wear suitable respiratory equipment.

Control parameters
Methomyl: TLV-TWA = 2,5 mg/m3; A4; BEI; ACGIH(1999)

Personal protective equipment
Respiratory protection: respirator with combination filter for vapour/particulate. or self-contained breathing apparatus.
Hand protection: protective gloves.
Eye protection: tightly fitting safety goggles or face-shield.
Skin and body protection: complete suit protecting against chemicals.

Hygiene measures: Keep away from food, drink and animal feeding stuffs. Wash hands and face before breaks and immediately after handling the product. When using, do not eat, drink or smoke. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace.

Product name: METHOMYL Technical

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Form: solid
Colour: white
Odour: slightly sulphurous

pH: (20 °C) (at 10 g/l H2O)		6,24	
Melting point/range:		79.6 °C	
Decomposition temperature:		192 °C	
Flash point:		Not applicable	
Explosive properties		Not explosive	
Vapour pressure:	(25 °C)	0.72 mPa	
Relative density:	(25 °C)	1.318 g/m3	
Bulk density:		481-609 kg/m3	(loose)
Solubility - water solubility	(25 °C)	55 g/l	
Partition coefficient (n-octanol/water):		1,24	

10. STABILITY AND REACTIVITY

Conditions to avoid: Keep away from heat and sources of ignition. Avoid dust formation in confined areas. Keep at temperatures below 192 °C.

Hazardous decomposition products: hydrogen cyanide, sulphur dioxide, methyl isocyanate.

Further information: Fire or intense heat may cause violent rupture of packages. During processing, dust may form explosive mixture in air.

11. TOXICOLOGICAL INFORMATION

Acute toxicity:

LD50/oral/rat = 32 mg/kg
LD50/dermal/rabbit = > 2000 mg/kg
LC50/inhalation/4h/rat = 0,258 mg/l

Local effects:
Eye irritation: No eye irritation
Skin irritation: No skin irritation

Specific effects: Toxic by inhalation and if swallowed.

Sensitization: Did not cause sensitization on laboratory animals.

Other information of acute toxicity: May be lethal if absorbed through eyes: a rabbit died via ocular exposure.

Further information: This product is a cholinesterase inhibitor carbamate.

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12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Toxicity to fish and other aquatic fauna:
LC50/96h/rainbow trout = 2.49 mg/l
LC50/96h/bluegill sunfish = 0.62 mg/l
EC50/48h/daphnia = 17 ug/l

Toxicity to algae:
EC50/72h/algae = > 100 mg/l

Toxicity to birds:
LC50/5days/bobwhite quail = > 5620 mg/kg
LC50/5days/mallard duck = 3952 mg/kg

Bioaccumulation:
log POW = 0.09

Persistence and degradability: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Further Information: See also section 3 & 15

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: In accordance with local and national regulations.. Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Do not allow material to contaminate ground water system.

Contaminated packaging Do not re-use empty containers If recycling is not practicable, dispose of in compliance with local regulations. Do not contaminate ponds, waterways or ditches with chemical or used container.

14. TRANSPORT INFORMATION UN-No: 2757

ADR/RID
Class: 6.1 Item: 73(b) TREM-CARD: 61G41b-A
Packing group: II HI-No: 60 SI-No: 2757
Hazard labels: 6.1
Proper shipping name: 2757 Carbamate pesticide, solid, toxic (methomyl) 6.1, 73(b) ADR

IMO
Class: 6.1 UN 2757 Packing group: II
Hazard labels: 6.1, MARINE POLLUTANT mark. EmS: 6.1-04
Proper shipping name: Carbamate pesticide, solid, toxic (methomyl 98%) Class 6.1, UN 2757, PG II , MARINE POLLUTANT.

ICAO
According to an internal company decision, DuPont does not allow this product to be transported by air.
Class: 6.1 Number: 2757 Packing group: II
Hazard labels: 6.1
Packing instruction (passenger aircraft): 613 / 25 kg (Forbbiden)
Packing instruction (cargo aircraft): 615 / 200 kg (Forbbiden)
Proper shipping name: Carbamate pesticide, solid, toxic (methomyl) Class 6.1, UN 2757, PG II.

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15. REGULATORY INFORMATION

According to EC-Dir. 67/548, as amended, the product is labelled as follows:

Contains:	Methomyl
Symbol(s):	T - Toxic N - Dangerous for the environment
R-phrase(s):	R23/25 - Toxic by inhalation and if swallowed. R50 - Very toxic to aquatic organisms.
S-phrase(s):	S22 - Do not breathe dust. S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection. S45 - In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). S57 - Use appropriate containment to avoid environmental contamination. S60 - This material and its container must be disposed of as hazardous waste.

16. OTHER INFORMATION

Recommended use technical product for formulation purpose only (insecticides)

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

APPENDIX 4

Methomyl

OPERATOR EXPOSURE ESTIMATES

The following exposure estimates were calculated using the German model and using the UK Predictive Operator Exposure Model (POEM). The following assumptions were used:

i) a work rate of 10 ha *per* day for use *via* field crop sprayers (notifier's stated value for these crops in southern Europe) in addition to the standard work rates of 20 ha *per* day for use *via* field crop sprayers in the German Model and 50 ha *per* 6 hour day for use *via* field crop sprayers in the UK POEM;

ii) a work rate of 8 ha *per* day for use *via* orchard sprayers in the German Model (standard value) and a work rate of 15 ha *per* 6 hour day for use *via* orchard sprayers in the UK POEM (standard value);

iii) a work rate of 1 ha *per* day for use *via* knapsack sprayers in the German Model (standard value) and a work rate of 1 ha *per* 6 hour day (or 400 litres of spray solution *per* 6 hour day) for use *via* knapsack sprayers in the UK POEM (standard value);

iv) a dermal absorption value for methomyl as 'Methomyl 20SL' of 1% for the concentrate and 10% for the spray solution;

v) an operator body weight of 70 kg in the German Model and 60 kg in the UK POEM (standard values);

vi) UK POEM estimates assume that 10 litre packaging is used (resulting in a similar level of operator exposure when handling the concentrate as the proposed 1 litre container and a higher level of operator exposure than the proposed 5 litre container when an equivalent quantity of formulation is decanted);

vii) any assumptions not detailed above will be as given in document SC 8001 (POEM) or the published German model.

Although some values in the exposure estimates are expressed as unrounded figures, this level of precision is not generally warranted considering the various assumptions on which the calculations are based.

The German Model (Geometric mean values)

Tractor-mounted/trailed broadcast air-assisted sprayers — Liquid formulations

Application rate (product)	2.25	l/ha	Dermal absorption:	% absorption
a.s. content	200	g/l	concentrate	1
Work rate	8	ha/day	spray solution	10
Amount of a.s. handled/applied	3.6	kg/day		

	Component		kg a.s. handled		Exposure mg/kg a.s.	Reduction coefficient	% absorption		mg/person/day
No PPE	Im	=	3.6	x	0.0006	1	100	=	0.00216
	Dm	=	3.6	x	2.4	1	1	=	0.0864
	Ia	=	3.6	x	0.018	1	100	=	0.0648
	Da(c)	=	3.6	x	1.2	1	10	=	0.432
	Da(h)	=	3.6	x	0.7	1	10	=	0.252
	Da(b)	=	3.6	x	9.6	1	10	=	3.456
								Total	**4.29336**
With PPE	Im	=	3.6	x	0.0006	0.08	100	=	0.0001728
	Dm	=	3.6	x	2.4	0.01	1	=	0.000864
	Ia	=	3.6	x	0.018	0.08	100	=	0.005184
	Da(c)	=	3.6	x	1.2	0.5	10	=	0.216
	Da(h)	=	3.6	x	0.7	0.01	10	=	0.00252
	Da(b)	=	3.6	x	9.6	0.05	10	=	0.1728
								Total	**0.3975408**

Im	Inhalation exposure (mixing)		
Dm	Hand exposure (mixing)		
Ia	Inhalation exposure (application)		
Da(c)	Head exposure (application)		
Da(h)	Hand exposure (application)		
Da(b)	Body exposure (application)		

PPE	Exposure reduction coefficients		
	Dermal	Component	Inhalation
Gloves	0.01	hands	
Coverall + sturdy footwear	0.05	body	
Broad-brimmed headwear	0.5	head	
Hood and visor	0.05	head	
Filtering facepiece respirator	0.8	head	0.08
Half-mask with filter	0.8	head	0.02

The German Model (Geometric mean values)

Knapsack sprayers (high crops) — Liquid formulations

Application rate (product)	2.25	l/ha	Dermal absorption:	% absorption
a.s. content	200	g/l	concentrate	1
Work rate	1	ha/day	spray solution	10
Amount of a.s. handled/applied	0.45	kg/day		

	Component		kg a.s. handled		Exposure mg/kg a.s.	Reduction coefficient	% absorption		mg/person/day
No PPE	Im	=	0.45	x	0.05	1	100	=	0.0225
	Dm	=	0.45	x	205	1	1	=	0.9225
	Ia	=	0.45	x	0.3	1	100	=	0.135
	Da(c)	=	0.45	x	4.8	1	10	=	0.216
	Da(h)	=	0.45	x	10.6	1	10	=	0.477
	Da(b)	=	0.45	x	25	1	10	=	1.125
								Total	**2.898**
With PPE	Im	=	0.45	x	0.05	0.08	100	=	0.0018
	Dm	=	0.45	x	205	0.01	1	=	0.009225
	Ia	=	0.45	x	0.3	0.08	100	=	0.0108
	Da(c)	=	0.45	x	4.8	0.5	10	=	0.108
	Da(h)	=	0.45	x	10.6	0.01	10	=	0.00477
	Da(b)	=	0.45	x	25	0.05	10	=	0.05625
								Total	**0.190845**

Im	Inhalation exposure (mixing)		
Dm	Hand exposure (mixing)		
Ia	Inhalation exposure (application)		
Da(c)	Head exposure (application)		
Da(h)	Hand exposure (application)		
Da(b)	Body exposure (application)		

PPE	Exposure reduction coefficients		
	Dermal	Component	Inhalation
Gloves	0.01	hands	
Coverall + sturdy footwear	0.05	body	
Broad-brimmed headwear	0.5	head	
Hood and visor	0.05	head	
Filtering facepiece respirator	0.8	head	0.08
Half-mask with filter	0.8	head	0.02

The German Model (Geometric mean values)

Tractor-mounted/trailed field crop sprayers — Liquid formulations

Application rate (product)	2.25	l/ha	Dermal absorption:	% absorption
a.s. content	200	g/l	concentrate	1
Work rate	10	ha/day	spray solution	10
Amount of a.s. handled/applied	4.5	kg/day		

	Component		kg a.s. handled		Exposure mg/kg a.s.	Reduction coefficient	% absorption		mg/person/day
No PPE	Im	=	4.5	x	0.0006	1	100	=	0.0027
	Dm	=	4.5	x	2.4	1	1	=	0.108
	Ia	=	4.5	x	0.001	1	100	=	0.0045
	Da(c)	=	4.5	x	0.06	1	10	=	0.027
	Da(h)	=	4.5	x	0.38	1	10	=	0.171
	Da(b)	=	4.5	x	1.6	1	10	=	0.72
								Total	**1.0332**
With PPE	Im	=	4.5	x	0.0006	0.08	100	=	0.000216
	Dm	=	4.5	x	2.4	0.01	1	=	0.00108
	Ia	=	4.5	x	0.001	0.08	100	=	0.00036
	Da(c)	=	4.5	x	0.06	0.5	10	=	0.0135
	Da(h)	=	4.5	x	0.38	0.01	10	=	0.00171
	Da(b)	=	4.5	x	1.6	0.05	10	=	0.036
								Total	**0.052866**

		PPE	**Exposure reduction coefficients**		
			Dermal	Component	Inhalation
Im	Inhalation exposure (mixing)				
Dm	Hand exposure (mixing)				
Ia	Inhalation exposure (application)	Gloves	0.01	hands	
Da(c)	Head exposure (application)	Coverall + sturdy footwear	0.05	body	
Da(h)	Hand exposure (application)	Broad-brimmed headwear	0.5	head	
Da(b)	Body exposure (application)	Hood and visor	0.05	head	
		Filtering facepiece respirator	0.8	head	0.08
		Half-mask with filter	0.8	head	0.02

The German Model (Geometric mean values)

Tractor-mounted/trailed field crop sprayers — Liquid formulations

Application rate (product)	2.25	l/ha	Dermal absorption:	% absorption
a.s. content	200	g/l	concentrate	1
Work rate	20	ha/day	spray solution	10
Amount of a.s. handled/applied	9	kg/day		

	Component		kg a.s. handled		Exposure mg/kg a.s.	Reduction coefficient	% absorption		mg/person/day
No PPE	Im	=	9	x	0.0006	1	100	=	0.0054
	Dm	=	9	x	2.4	1	1	=	0.216
	Ia	=	9	x	0.001	1	100	=	0.009
	Da(c)	=	9	x	0.06	1	10	=	0.054
	Da(h)	=	9	x	0.38	1	10	=	0.342
	Da(b)	=	9	x	1.6	1	10	=	1.44
								Total	**2.0664**
With PPE	Im	=	9	x	0.0006	0.08	100	=	0.000432
	Dm	=	9	x	2.4	0.01	1	=	0.00216
	Ia	=	9	x	0.001	0.08	100	=	0.00072
	Da(c)	=	9	x	0.06	0.5	10	=	0.027
	Da(h)	=	9	x	0.38	0.01	10	=	0.00342
	Da(b)	=	9	x	1.6	0.05	10	=	0.072
								Total	**0.105732**

		PPE	**Exposure reduction coefficients**		
			Dermal	Component	Inhalation
Im	Inhalation exposure (mixing)				
Dm	Hand exposure (mixing)				
Ia	Inhalation exposure (application)	Gloves	0.01	hands	
Da(c)	Head exposure (application)	Coverall + sturdy footwear	0.05	body	
Da(h)	Hand exposure (application)	Broad-brimmed headwear	0.5	head	
Da(b)	Body exposure (application)	Hood and visor	0.05	head	
		Filtering facepiece respirator	0.8	head	0.08
		Half-mask with filter	0.8	head	0.02

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	Liquid	a.s. concentration	**200** g/l
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
RPE during mix/loading	None	RPE during application	None
PPE during mix/loading	None		
PPE during application: Head	None	Hands None	Body None
Dose	**2.25** l product/ha	Work rate/day	**8** ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	8.64	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	8.64	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.00216	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.00216	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed broadcast air-assisted sprayer

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	1.2	0.7	9.6	
Dermal contamination/day	4.32	2.52	34.56	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	41.4	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.018	mg/kg a.s.
Inhalation exposure/day	0.0648	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0648	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	8.64	mg/day	41.4	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.0864	mg/day	4.14	mg/day
Inhalation exposure to a.s.	0.00216	mg/day	0.0648	mg/day
Total systemic exposure	0.08856	mg/day	4.2048	mg/day

PREDICTED EXPOSURE

Total systemic exposure	4.29336	mg/day
Operator body weight	70	kg
Operator exposure	0.061333714	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	None	Body	None
Dose	**2.25**	l product/ha	Work rate/day	**8**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	8.64	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.0864	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.00216	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.00216	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed broadcast air-assisted sprayer

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	1.2	0.7	9.6	
Dermal contamination/day	4.32	2.52	34.56	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	41.4	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.018	mg/kg a.s.
Inhalation exposure/day	0.0648	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0648	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.0864	mg/day	41.4	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.000864	mg/day	4.14	mg/day
Inhalation exposure to a.s.	0.00216	mg/day	0.0648	mg/day
Total systemic exposure	0.003024	mg/day	4.2048	mg/day

PREDICTED EXPOSURE

Total systemic exposure	4.207824	mg/day
Operator body weight	70	kg
Operator exposure	0.060111771	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer					
Product	**Methomyl 20SL**		Active substance		**methomyl**	
Formulation type	Liquid		a.s. concentration		**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray		**10**	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	None	
Dose	**2.25**	l product/ha	Work rate/day		**8**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	8.64	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.0864	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.00216	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.00216	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed broadcast air-assisted sprayer

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	1.2	0.7	9.6	
Dermal contamination/day	4.32	2.52	34.56	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	38.9052	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.018	mg/kg a.s.
Inhalation exposure/day	0.0648	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0648	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.0864	mg/day	38.9052	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.000864	mg/day	3.89052	mg/day
Inhalation exposure to a.s.	0.00216	mg/day	0.0648	mg/day
Total systemic exposure	0.003024	mg/day	3.95532	mg/day

PREDICTED EXPOSURE

Total systemic exposure	3.958344	mg/day
Operator body weight	70	kg
Operator exposure	0.056547771	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer				
Product	Methomyl 20SL		Active substance	methomyl	
Formulation type	Liquid		a.s. concentration	200	g/l
Dermal absorption from product	1	%	Dermal absorption from spray	10	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear
Dose	2.25	l product/ha	Work rate/day	8	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	8.64	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.0864	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.00216	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.00216	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed broadcast air-assisted sprayer

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	1.2	0.7	9.6	
Dermal contamination/day	4.32	2.52	34.56	
Protective clothing	none	gloves	coverall and sturdy footwear	
Transmission to skin	100	1	5	%
Total dermal exposure to a.s.	6.0732	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.018	mg/kg a.s.
Inhalation exposure/day	0.0648	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0648	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.0864	mg/day	6.0732	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.000864	mg/day	0.60732	mg/day
Inhalation exposure to a.s.	0.00216	mg/day	0.0648	mg/day
Total systemic exposure	0.003024	mg/day	0.67212	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.675144	mg/day
Operator body weight	70	kg
Operator exposure	0.009644914	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**1.75** l/ha	Work rate/day	**15** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	15	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.3	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha			
Application volume	300	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	2%	5%	
Dermal exposure	10	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	121.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.3	ml/day	121.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	60	mg/day	141.4	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.6	mg/day	14.14	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.35	mg/day
Percent absorbed	100	%
Absorbed dose	0.35	mg/day

PREDICTED EXPOSURE

Total absorbed dose	15.09	mg/day
Operator body weight	60	kg
Operator exposure	0.2515	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**1.75** l/ha	Work rate/day	**15** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	15	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.015	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha			
Application volume	300	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	2%	5%	
Dermal exposure	10	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	121.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.015	ml/day	121.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	3	mg/day	141.4	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.03	mg/day	14.14	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.35	mg/day
Percent absorbed	100	%
Absorbed dose	0.35	mg/day

PREDICTED EXPOSURE

Total absorbed dose	14.52	mg/day
Operator body weight	60	kg
Operator exposure	0.242	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**1.75** l/ha	Work rate/day	**15** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	15	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.015	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha			
Application volume	300	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	2%	5%	
Dermal exposure	4	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	85.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.015	ml/day	85.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	3	mg/day	99.4	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.03	mg/day	9.94	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.35	mg/day
Percent absorbed	100	%
Absorbed dose	0.35	mg/day

PREDICTED EXPOSURE

Total absorbed dose	10.32	mg/day
Operator body weight	60	kg
Operator exposure	0.172	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**15** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	15	ha/day
Number of operations	4	/day
Hand contamination	0.4	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.4	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha			
Application volume	450	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	2%	5%	
Dermal exposure	10	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	121.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.4	ml/day	121.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	80	mg/day	121.2	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.8	mg/day	12.12	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.3	mg/day
Percent absorbed	100	%
Absorbed dose	0.3	mg/day

PREDICTED EXPOSURE

Total absorbed dose	13.22	mg/day
Operator body weight	60	kg
Operator exposure	0.220333333	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**15** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	15	ha/day
Number of operations	4	/day
Hand contamination	0.4	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.02	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha

Application volume	450	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	2%	5%	
Dermal exposure	10	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	121.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.02	ml/day	121.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	4	mg/day	121.2	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.04	mg/day	12.12	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.3	mg/day
Percent absorbed	100	%
Absorbed dose	0.3	mg/day

PREDICTED EXPOSURE

Total absorbed dose	12.46	mg/day
Operator body weight	60	kg
Operator exposure	0.207666667	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2.25** l/ha	Work rate/day	**15** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	15	ha/day
Number of operations	4	/day
Hand contamination	0.4	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.02	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha			
Application volume	450	spray/ha		
Volume of surface contamination	400	ml/h		
Distribution	Hands	Trunk	Legs	
	10%	65%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	2%	5%	
Dermal exposure	4	5.2	5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	85.2	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.02	ml/day	85.2	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	4	mg/day	85.2	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.04	mg/day	8.52	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.3	mg/day
Percent absorbed	100	%
Absorbed dose	0.3	mg/day

PREDICTED EXPOSURE

Total absorbed dose	8.86	mg/day
Operator body weight	60	kg
Operator exposure	0.147666667	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Hand-held sprayer: hydraulic nozzles. Outdoor, high level target				
Product	**Methomyl 20SL**		Active substance		**methomyl**
Formulation type	Liquid		a.s. concentration		**200** g/l
Dermal absorption from product	**1** %		Dermal absorption from spray		**10** %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	**2.25** l product/ha		Work rate/day		**1** ha

DERMAL EXPOSURE DURING MIXING AND LOADING					
Hand contamination/kg a.s.	205	mg/kg a.s.			
Hand contamination/day	92.25	mg/day			
Protective clothing	none				
Transmission to skin	100	%			
Dermal exposure to a.s.	92.25	mg/day			
INHALATION EXPOSURE DURING MIXING AND LOADING					
Inhalation exposure/kg a.s.	0.05	mg/kg a.s.			
Inhalation exposure/day	0.0225	mg/day			
RPE	none				
Transmission through RPE	100	%			
Inhalation exposure to a.s.	0.0225	mg/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Hand-held sprayer: hydraulic nozzles. Outdoor, high level target				
	Head		Hands	Rest of body	
Dermal contamination/kg a.s.	4.8		10.6	25	
Dermal contamination/day	2.16		4.77	11.25	
Protective clothing	none		none	none	
Transmission to skin	100		100	100	%
Total dermal exposure to a.s.	18.18	mg/day			
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure/kg a.s.	0.3	mg/kg a.s.			
Inhalation exposure/day	0.135	mg/day			
RPE	none				
Transmission through RPE	100	%			
Inhalation exposure to a.s.	0.135	mg/day			
ABSORBED DOSE					
	Mix/load		Application		
Dermal exposure to a.s.	92.25	mg/day		18.18	mg/day
Percent absorbed	1	%		10	%
Absorbed dose (dermal route)	0.9225	mg/day		1.818	mg/day
Inhalation exposure to a.s.	0.0225	mg/day		0.135	mg/day
Total systemic exposure	0.945	mg/day		1.953	mg/day
PREDICTED EXPOSURE					
Total systemic exposure	2.898	mg/day			
Operator body weight	70	kg			
Operator exposure	0.0414	mg/kg bw/day			

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Hand-held sprayer: hydraulic nozzles. Outdoor, high level target					
Product	**Methomyl 20SL**		Active substance		**methomyl**	
Formulation type	Liquid		a.s. concentration		**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray		**10**	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	None	Body	None	
Dose	**2.25**	l product/ha	Work rate/day		**1**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	205	mg/kg a.s.
Hand contamination/day	92.25	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.9225	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.05	mg/kg a.s.
Inhalation exposure/day	0.0225	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0225	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Hand-held sprayer: hydraulic nozzles. Outdoor, high level target

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	4.8	10.6	25	
Dermal contamination/day	2.16	4.77	11.25	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	18.18	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.3	mg/kg a.s.
Inhalation exposure/day	0.135	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.135	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.9225	mg/day	18.18	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.009225	mg/day	1.818	mg/day
Inhalation exposure to a.s.	0.0225	mg/day	0.135	mg/day
Total systemic exposure	0.031725	mg/day	1.953	mg/day

PREDICTED EXPOSURE

Total systemic exposure	1.984725	mg/day
Operator body weight	70	kg
Operator exposure	0.028353214	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Hand-held sprayer: hydraulic nozzles. Outdoor, high level target				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	None
Dose	**2.25**	l product/ha	Work rate/day	**1**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING		
Hand contamination/kg a.s.	205	mg/kg a.s.
Hand contamination/day	92.25	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.9225	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING		
Inhalation exposure/kg a.s.	0.05	mg/kg a.s.
Inhalation exposure/day	0.0225	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0225	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer: hydraulic nozzles. Outdoor, high level target

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	4.8	10.6	25	
Dermal contamination/day	2.16	4.77	11.25	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	13.4577	mg/day		

INHALATION EXPOSURE DURING SPRAYING		
Inhalation exposure/kg a.s.	0.3	mg/kg a.s.
Inhalation exposure/day	0.135	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.135	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.9225	mg/day	13.4577	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.009225	mg/day	1.34577	mg/day
Inhalation exposure to a.s.	0.0225	mg/day	0.135	mg/day
Total systemic exposure	0.031725	mg/day	1.48077	mg/day

PREDICTED EXPOSURE		
Total systemic exposure	1.512495	mg/day
Operator body weight	70	kg
Operator exposure	0.021607071	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Hand-held sprayer: hydraulic nozzles. Outdoor, high level target				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear
Dose	**2.25**	l product/ha	Work rate/day	**1**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	205	mg/kg a.s.
Hand contamination/day	92.25	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.9225	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.05	mg/kg a.s.
Inhalation exposure/day	0.0225	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0225	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Hand-held sprayer: hydraulic nozzles. Outdoor, high level target

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	4.8	10.6	25	
Dermal contamination/day	2.16	4.77	11.25	
Protective clothing	none	gloves	coverall and sturdy footwear	
Transmission to skin	100	1	5	%
Total dermal exposure to a.s.	2.7702	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.3	mg/kg a.s.
Inhalation exposure/day	0.135	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.135	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.9225	mg/day	2.7702	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.009225	mg/day	0.27702	mg/day
Inhalation exposure to a.s.	0.0225	mg/day	0.135	mg/day
Total systemic exposure	0.031725	mg/day	0.41202	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.443745	mg/day
Operator body weight	70	kg
Operator exposure	0.006339214	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**1.75** l/ha	Work rate/day	**1** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	1	ha/day
Number of operations	20	/day
Hand contamination	2	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	2	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	300	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	102	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	2	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	400	mg/day	119	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	4	mg/day	11.9	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.14	mg/day
Percent absorbed	100	%
Absorbed dose	0.14	mg/day

PREDICTED EXPOSURE

Total absorbed dose	16.04	mg/day
Operator body weight	60	kg
Operator exposure	0.267333333	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**1.75** l/ha	Work rate/day	**1** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	1	ha/day
Number of operations	20	/day
Hand contamination	2	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.1	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target			
Application volume	300 spray/ha			
Volume of surface contamination	50 ml/h			
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6 h			
Total dermal exposure to spray	102 ml/day			

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.1	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	20	mg/day	119	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.2	mg/day	11.9	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.14	mg/day
Percent absorbed	100	%
Absorbed dose	0.14	mg/day

PREDICTED EXPOSURE

Total absorbed dose	12.24	mg/day
Operator body weight	60	kg
Operator exposure	0.204	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**1.75** l/ha	Work rate/day	**1** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	1	ha/day
Number of operations	20	/day
Hand contamination	2	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.1	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target			
Application volume	300	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	20%	18%	
Dermal exposure	1.25	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	49.5	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.1	ml/day	49.5	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	20	mg/day	57.75	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.2	mg/day	5.775	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.14	mg/day
Percent absorbed	100	%
Absorbed dose	0.14	mg/day

PREDICTED EXPOSURE

Total absorbed dose	6.115	mg/day
Operator body weight	60	kg
Operator exposure	0.101916667	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves and impermeable coveralls
Dose	**1.75** l/ha	Work rate/day	**1** ha
Application volume	**300** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	1.75	litres product/ha
Work rate	1	ha/day
Number of operations	20	/day
Hand contamination	2	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.1	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	300	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Impermeable	Impermeable	
Penetration	10%	5%	5%	
Dermal exposure	1.25	0.625	1.25	ml/h
Duration of exposure	6 h			
Total dermal exposure to spray	18.75 ml/day			

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.1	ml/day	18.75	ml/day
Concen. of a.s. product or spray	200	mg/ml	1.166666667	mg/ml
Dermal exposure to a.s.	20	mg/day	21.875	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.2	mg/day	2.1875	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1.166666667	mg/ml
Inhalation exposure to a.s.	0.14	mg/day
Percent absorbed	100	%
Absorbed dose	0.14	mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.5275	mg/day
Operator body weight	60	kg
Operator exposure	0.042125	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**0.889** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.888888889	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	2.7	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	450	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	102	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	2.7	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	540	mg/day	102	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	5.4	mg/day	10.2	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.12	mg/day
Percent absorbed	100	%
Absorbed dose	0.12	mg/day

PREDICTED EXPOSURE

Total absorbed dose	15.72	mg/day
Operator body weight	60	kg
Operator exposure	0.262	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	water-based		a.s. concentration	**200**	mg/ml
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
Container	10 litres 45 mm closure				
PPE during mix/loading	Gloves		PPE during application	None	
Dose	**2.25**	l/ha	Work rate/day	**0.889**	ha
Application volume	**450**	l/ha	Duration of spraying	**6**	h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.888888889	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.135	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	450	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	102	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.135	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	27	mg/day	102	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.27	mg/day	10.2	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.12	mg/day
Percent absorbed	100	%
Absorbed dose	0.12	mg/day

PREDICTED EXPOSURE

Total absorbed dose	10.59	mg/day
Operator body weight	60	kg
Operator exposure	0.1765	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2.25** l/ha	Work rate/day	**0.889** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.888888889	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.135	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	450 spray/ha			
Volume of surface contamination	50 ml/h			
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	20%	18%	
Dermal exposure	1.25	2.5	4.5	ml/h
Duration of exposure	6 h			
Total dermal exposure to spray	49.5 ml/day			

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.135	ml/day	49.5	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	27	mg/day	49.5	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.27	mg/day	4.95	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.12	mg/day
Percent absorbed	100	%
Absorbed dose	0.12	mg/day

PREDICTED EXPOSURE

Total absorbed dose	5.34	mg/day
Operator body weight	60	kg
Operator exposure	0.089	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves and impermeable coveralls
Dose	**2.25** l/ha	Work rate/day	**0.889** ha
Application volume	**450** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.888888889	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.135	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	450	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Impermeable	Impermeable	
Penetration	10%	5%	5%	
Dermal exposure	1.25	0.625	1.25	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	18.75	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.135	ml/day	18.75	ml/day
Concen. of a.s. product or spray	200	mg/ml	1	mg/ml
Dermal exposure to a.s.	27	mg/day	18.75	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.27	mg/day	1.875	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1	mg/ml
Inhalation exposure to a.s.	0.12	mg/day
Percent absorbed	100	%
Absorbed dose	0.12	mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.265	mg/day
Operator body weight	60	kg
Operator exposure	0.03775	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	Methomyl 20SL		Active substance		methomyl
Formulation type	Liquid		a.s. concentration		200 g/l
Dermal absorption from product	1 %		Dermal absorption from spray		10 %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	2.25 l product/ha		Work rate/day		20 ha

DERMAL EXPOSURE DURING MIXING AND LOADING		
Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	21.6	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	21.6	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING		
Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0054	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0054	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head		Hands	Rest of body	
Dermal contamination/kg a.s.	0.06		0.38	1.6	
Dermal contamination/day	0.54		3.42	14.4	
Protective clothing	none		none	none	
Transmission to skin	100		100	100	%
Total dermal exposure to a.s.	18.36	mg/day			

INHALATION EXPOSURE DURING SPRAYING		
Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.009	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.009	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	21.6	mg/day	18.36	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.216	mg/day	1.836	mg/day
Inhalation exposure to a.s.	0.0054	mg/day	0.009	mg/day
Total systemic exposure	0.2214	mg/day	1.845	mg/day

PREDICTED EXPOSURE		
Total systemic exposure	2.0664	mg/day
Operator body weight	70	kg
Operator exposure	0.02952	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Methomyl 20SL**		Active substance		**methomyl**
Formulation type	Liquid		a.s. concentration		**200** g/l
Dermal absorption from product	**1** %		Dermal absorption from spray		**10** %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	None	Body	None
Dose	**2.25** l product/ha		Work rate/day		**20** ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	21.6	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.216	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0054	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0054	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.54	3.42	14.4	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	18.36	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.009	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.009	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.216	mg/day	18.36	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00216	mg/day	1.836	mg/day
Inhalation exposure to a.s.	0.0054	mg/day	0.009	mg/day
Total systemic exposure	0.00756	mg/day	1.845	mg/day

PREDICTED EXPOSURE

Total systemic exposure	1.85256	mg/day
Operator body weight	70	kg
Operator exposure	0.026465143	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	**Methomyl 20SL**		Active substance		**methomyl**	
Formulation type	Liquid		a.s. concentration		**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray		**10**	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	None	
Dose	**2.25**	l product/ha	Work rate/day		**20**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	21.6	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.216	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0054	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0054	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.54	3.42	14.4	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	14.9742	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.009	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.009	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.216	mg/day	14.9742	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00216	mg/day	1.49742	mg/day
Inhalation exposure to a.s.	0.0054	mg/day	0.009	mg/day
Total systemic exposure	0.00756	mg/day	1.50642	mg/day

PREDICTED EXPOSURE

Total systemic exposure	1.51398	mg/day
Operator body weight	70	kg
Operator exposure	0.021628286	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	**Methomyl 20SL**		Active substance		**methomyl**	
Formulation type	Liquid		a.s. concentration		**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray		**10**	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear	
Dose	**2.25**	l product/ha	Work rate/day		**20**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	21.6	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.216	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0054	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0054	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.54	3.42	14.4	
Protective clothing	none	gloves	coverall and sturdy footwear	
Transmission to skin	100	1	5	%
Total dermal exposure to a.s.	1.2942	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.009	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.009	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.216	mg/day	1.2942	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00216	mg/day	0.12942	mg/day
Inhalation exposure to a.s.	0.0054	mg/day	0.009	mg/day
Total systemic exposure	0.00756	mg/day	0.13842	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.14598	mg/day
Operator body weight	70	kg
Operator exposure	0.002085429	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	**2.25**	l product/ha	Work rate/day	**10**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING		
Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	10.8	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	10.8	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING		
Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0027	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0027	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.27	1.71	7.2	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	9.18	mg/day		

INHALATION EXPOSURE DURING SPRAYING		
Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.0045	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0045	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	10.8	mg/day	9.18	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.108	mg/day	0.918	mg/day
Inhalation exposure to a.s.	0.0027	mg/day	0.0045	mg/day
Total systemic exposure	0.1107	mg/day	0.9225	mg/day

PREDICTED EXPOSURE		
Total systemic exposure	1.0332	mg/day
Operator body weight	70	kg
Operator exposure	0.01476	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Methomyl 20SL**		Active substance		**methomyl**
Formulation type	Liquid		a.s. concentration		**200** g/l
Dermal absorption from product	**1** %		Dermal absorption from spray		**10** %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	None	Body	None
Dose	**2.25** l product/ha		Work rate/day		**10** ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	10.8	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.108	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0027	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0027	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.27	1.71	7.2	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	9.18	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.0045	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0045	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.108	mg/day	9.18	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00108	mg/day	0.918	mg/day
Inhalation exposure to a.s.	0.0027	mg/day	0.0045	mg/day
Total systemic exposure	0.00378	mg/day	0.9225	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.92628	mg/day
Operator body weight	70	kg
Operator exposure	0.013232571	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	None
Dose	**2.25**	l product/ha	Work rate/day	**10**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	10.8	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.108	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0027	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0027	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.27	1.71	7.2	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	7.4871	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.0045	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0045	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.108	mg/day	7.4871	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00108	mg/day	0.74871	mg/day
Inhalation exposure to a.s.	0.0027	mg/day	0.0045	mg/day
Total systemic exposure	0.00378	mg/day	0.75321	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.75699	mg/day
Operator body weight	70	kg
Operator exposure	0.010814143	mg/kg bw/day

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Methomyl 20SL**		Active substance	**methomyl**	
Formulation type	Liquid		a.s. concentration	**200**	g/l
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear
Dose	**2.25**	l product/ha	Work rate/day	**10**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	10.8	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.108	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0027	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0027	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.27	1.71	7.2	
Protective clothing	none	gloves	coverall and sturdy footwear	
Transmission to skin	100	1	5	%
Total dermal exposure to a.s.	0.6471	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.0045	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0045	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.108	mg/day	0.6471	mg/day
Percent absorbed	1	%	10	%
Absorbed dose (dermal route)	0.00108	mg/day	0.06471	mg/day
Inhalation exposure to a.s.	0.0027	mg/day	0.0045	mg/day
Total systemic exposure	0.00378	mg/day	0.06921	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.07299	mg/day
Operator body weight	70	kg
Operator exposure	0.001042714	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	**Methomyl 20SL**		Active substance	**methomyl**
Formulation type	water-based		a.s. concentration	**200** mg/ml
Dermal absorption from product	**1**	%	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure			
PPE during mix/loading	None		PPE during application	None
Dose	**2.25**	l/ha	Work rate/day	**50** ha
Application volume	**500**	l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	50	ha/day
Number of operations	12	/day
Hand contamination	1.2	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	1.2	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	1.2	ml/day	41.55	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	240	mg/day	37.395	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	2.4	mg/day	3.7395	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	6.1935	mg/day
Operator body weight	60	kg
Operator exposure	0.103225	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**50** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	50	ha/day
Number of operations	12	/day
Hand contamination	1.2	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.06	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.06	ml/day	41.55	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	12	mg/day	37.395	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.12	mg/day	3.7395	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	3.9135	mg/day
Operator body weight	60	kg
Operator exposure	0.065225	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	**Methomyl 20SL**		Active substance	**methomyl**
Formulation type	water-based		a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %		Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure			
PPE during mix/loading	Gloves		PPE during application	Gloves
Dose	**2.25** l/ha		Work rate/day	**50** ha
Application volume	**500** l/ha		Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	50	ha/day
Number of operations	12	/day
Hand contamination	1.2	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.06	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500 spray/ha			
Volume of surface contamination	10 ml/h			
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	ml/h
Duration of exposure	6 h			
Total dermal exposure to spray	6.45 ml/day			

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.06	ml/day	6.45	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	12	mg/day	5.805	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.12	mg/day	0.5805	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.7545	mg/day
Operator body weight	60	kg
Operator exposure	0.012575	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**10** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	10	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.3	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.3	ml/day	41.55	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	60	mg/day	37.395	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.6	mg/day	3.7395	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	4.3935	mg/day
Operator body weight	60	kg
Operator exposure	0.073225	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**10** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	10	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.015	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.015	ml/day	41.55	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	3	mg/day	37.395	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.03	mg/day	3.7395	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	3.8235	mg/day
Operator body weight	60	kg
Operator exposure	0.063725	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	water-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2.25** l/ha	Work rate/day	**10** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	10	ha/day
Number of operations	3	/day
Hand contamination	0.3	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.015	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500 spray/ha			
Volume of surface contamination	10 ml/h			
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	ml/h
Duration of exposure	6 h			
Total dermal exposure to spray	6.45 ml/day			

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.015	ml/day	6.45	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	3	mg/day	5.805	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.03	mg/day	0.5805	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.054	mg/day
Percent absorbed	100	%
Absorbed dose	0.054	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.6645	mg/day
Operator body weight	60	kg
Operator exposure	0.011075	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	organic solvent-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**0.8** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.8	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	2.7	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	500	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	102	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	2.7	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	540	mg/day	91.8	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	5.4	mg/day	9.18	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.108	mg/day
Percent absorbed	100	%
Absorbed dose	0.108	mg/day

PREDICTED EXPOSURE

Total absorbed dose	14.688	mg/day
Operator body weight	60	kg
Operator exposure	0.2448	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	organic solvent-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	**2.25** l/ha	Work rate/day	**0.8** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.8	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
Dermal exposure to formulation	0.27	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	500	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	None	Permeable	Permeable	
Penetration	100%	20%	18%	
Dermal exposure	10	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	102	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.27	ml/day	102	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	54	mg/day	91.8	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.54	mg/day	9.18	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.108	mg/day
Percent absorbed	100	%
Absorbed dose	0.108	mg/day

PREDICTED EXPOSURE

Total absorbed dose	9.828	mg/day
Operator body weight	60	kg
Operator exposure	0.1638	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	organic solvent-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2.25** l/ha	Work rate/day	**0.8** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.8	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
Dermal exposure to formulation	0.27	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target

Application volume	500	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	20%	18%	
Dermal exposure	1.25	2.5	4.5	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	49.5	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.27	ml/day	49.5	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	54	mg/day	44.55	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.54	mg/day	4.455	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.108	mg/day
Percent absorbed	100	%
Absorbed dose	0.108	mg/day

PREDICTED EXPOSURE

Total absorbed dose	5.103	mg/day
Operator body weight	60	kg
Operator exposure	0.08505	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**Methomyl 20SL**	Active substance	**methomyl**
Formulation type	organic solvent-based	a.s. concentration	**200** mg/ml
Dermal absorption from product	**1** %	Dermal absorption from spray	**10** %
Container	10 litres 45 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves and impermeable coveralls
Dose	**2.25** l/ha	Work rate/day	**0.8** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.1	ml
Application dose	2.25	litres product/ha
Work rate	0.8	ha/day
Number of operations	27	/day
Hand contamination	2.7	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
Dermal exposure to formulation	0.27	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target			
Application volume	500	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Impermeable	Impermeable	
Penetration	10%	5%	5%	
Dermal exposure	1.25	0.625	1.25	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	18.75	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.27	ml/day	18.75	ml/day
Concen. of a.s. product or spray	200	mg/ml	0.9	mg/ml
Dermal exposure to a.s.	54	mg/day	16.875	mg/day
Percent absorbed	1	%	10	%
Absorbed dose	0.54	mg/day	1.6875	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.9	mg/ml
Inhalation exposure to a.s.	0.108	mg/day
Percent absorbed	100	%
Absorbed dose	0.108	mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.3355	mg/day
Operator body weight	60	kg
Operator exposure	0.038925	mg/kg bw/day

APPENDIX 5

Methomyl

Appendix 5: Ecotoxicological modelling (birds and mammals)

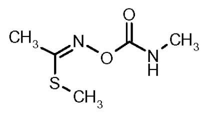
The study on pages 561-578 has been removed for confidentiality reasons.

APPENDIX 6

Methomyl

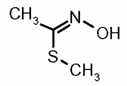
Metabolites and degradation products

DPX-X1179	**CAS name:**	*Z*-methyl *N*-[[(methylamino)carbonyl]oxy]ethanimidothioate		
	Trivial name:	Methomyl		



CAS number:	16752-77-5	**Molecular Weight:**	162.21
Structural formula:	$C_5H_{10}N_2O_2S$		Test substance

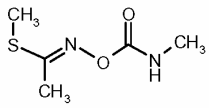
IN-X1177	**CAS name:**	*Z*-methyl *N*-hydroxyethanimidothioate		
	Trivial name:	MHTA, methomyl oxime		



CAS number:	13749-94-5	**Molecular Weight:**	105.16
Structural formula:	C_3H_7NOS	**Observed in:**	Soil, hydrolysis, water/sediment, probable intermediate in livestock and animal metabolism

IN-B1884 **CAS name:** *E*-methyl *N*-[[(methylamino)carbonyl]oxy]ethanimidothioate

Trivial name: Anti-methomyl

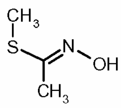


CAS number: 19928-35-9 **Molecular Weight:** 162.21

Structural formula: $C_6H_{10}N_4O_2$ **Observed in:** Probable intermediate in livestock and animal metabolism

IN-B1871 **CAS name:** *E*-methyl *N*-hydroxyethanimidothioate

Trivial name: Anti-MHTA, anti-methomyl oxime

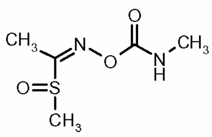


CAS number: 19145-16-5 **Molecular Weight:** 105.16

Structural formula: C_3H_7NOS **Observed in:** Probable intermediate in livestock and animal metabolism

IN-W1602 **CAS name:** *N*-[[(methylamino)carbonyl]oxy]-1-(methylsulfinyl)ethanimine

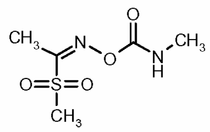
Trivial name: Methomyl *S*-oxide, methomyl sulphoxide



CAS number: 55620-23-0 **Molecular Weight:** 178.21

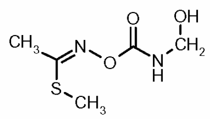
Structural formula: $C_5H_{10}N_2O_3S$ **Observed in:** Not observed

IN-M1284 **CAS name:**	*N*-[[(methylamino)carbonyl]oxy]-1-(methylsulfonyl)ethanimine		
Trivial name:	Methomyl *S,S*-dioxide, methomyl sulfone		



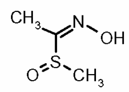
CAS number:	55620-24-0	**Molecular Weight:**	194.21
Structural formula:	$C_5H_{10}N_2O_4S$	**Observed in:**	Not observed

IN-G6520 **CAS name:**	methyl *N*-[[[(hydroxymethyl)amino]carbonyl]oxy]ethanimidothioate		
Trivial name:	Hydroxy methyl methomyl		



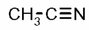
CAS number:	75089-08-6	**Molecular Weight:**	178.21
Structural formula:	$C_5H_{10}N_2O_3S$	**Observed in:**	Not observed, reference standard

IN-A3338 **CAS name:**	*N*-hydroxy-1-(methylsulfinyl)ethanimine		
Trivial name:	MHTA-sulfoxide, methomyl oxime-sulphoxide		



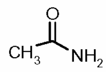
CAS number:	66116-61-8	**Molecular Weight:**	121.16
Structural formula:	$C_3H_7NO_2S$	**Observed in:**	Not observed

IN-07467	**CAS name:**	Acetonitrile		
	Trivial name:	Acetonitrile		



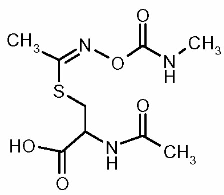
CAS number:	75-05-8	**Molecular Weight:**	41.05
Structural formula:	C_2H_3N	**Observed in:**	Soil photolysis, water/sediment, plants, goat, poultry, and rat

IN-09066	**CAS name:**	Acetamide		
	Trivial name:	Acetamide		



CAS number:	60-35-5	**Molecular Weight:**	59.07
Structural formula:	C_2H_5NO	**Observed in:**	Water/sediment, goat, poultry, and rat

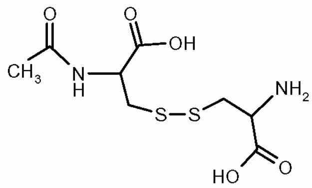
IN-KA129	**CAS name**	*N*-acetyl-*S*-[1-[[[(methylamino)carbonyl]oxy]imino]ethyl]-L-cysteine
	Trivial name:	Methomyl mercapturate



CAS number:	NA	**Molecular Weight:**	277.30
Structural formula:	$C_7H_5NO_4S$	**Observed in:**	Rat, monkey

NA **CAS name** N-acetyl cystine

Trivial name: N-acetyl cystine M2-4-2

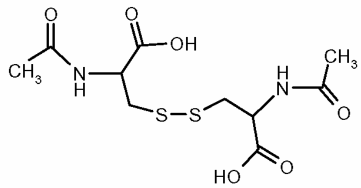


CAS number: NA **Molecular Weight:** 282.34.

Structural formula: $C_8H_{14}N_2O_5S_2$ **Observed in:** Goat

NA **CAS name** Bis-N-acetyl cystine

Trivial name: Bis-N-acetyl cystine M2-7-3

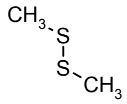


CAS number: NA **Molecular Weight:** 324.38.

Structural formula: $C_{10}H_{16}N_2O_6S_2$ **Observed in:** Goat

CAS name: Dimethyldisulfide

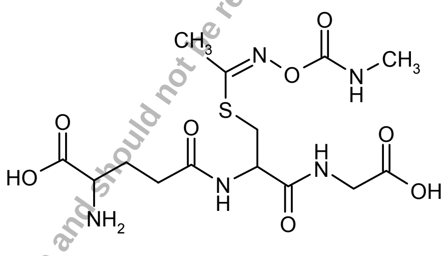
Trivial names: Methyl disulphide, dimethyl disulphide



CAS number:	624-92-0	**Molecular Weight:**	94.20
Structural formula:	$C_2H_6S_2$	**Observed in:**	Anaerobic subsoils, aqueous solutions containing ferrous ions

IN-HUZ56 **CAS name** L-gamma-glutamyl-S-[1-[[[(methylamino)carbonyl]oxy]imino]ethyl]-L-cysteinylglycine

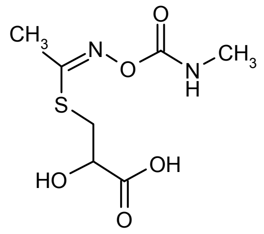
Trivial name: Methomyl glutahione conjugate



CAS number:	499768-18-2	**Molecular Weight:**	421.4
Structural formula:	$C_{14}H_{23}N_5O_8S$	**Observed in:**	Proposed intermediate in plants and animals

IN-HUZ57 **CAS name** 9-hydroxy-6-methyl-3-oxo-4-oxa-7-thia-2,5-diazadec-5-en-10-oic acid

Trivial name: Hydroxy-cysteine derivative of Methomyl

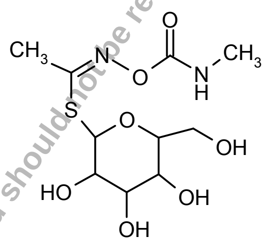


CAS number: 499768-19-3 **Molecular Weight:** 236.2

Structural formula: $C_7H_{12}N_2O_5S$ **Observed in:** Plants, also as glucose conjugate

IN-HHC78 **CAS name** 1-thiohexopyranose 1-[N-[[(methylamino)carbonyl]oxy]ethanimidate]

Trivial name: Methomyl thioglucoside

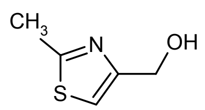


CAS number: 499768-20-6 **Molecular Weight:** 310.3

Structural formula: $C_{10}H_{18}N_2O_7S$ **Observed in:** Plants

IN-NR282 **CAS name** 2-methyl-4-thiazolemethanol

Trivial name: 2-methyl-4-thiazolemethanol

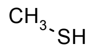


CAS number: 76632-23-0 **Molecular Weight:** 129.2

Structural formula: C_5H_7NOS **Observed in:** Plants (as glucose conjugate)

CAS name: Methanethiol

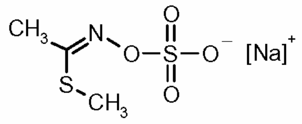
Trivial name: Methyl mercaptan



CAS number:	74-93-1	**Molecular Weight:**	48.11
Structural formula:	C_2H_4S	**Observed in:**	Anaerobic subsoils, aqueous solutions containing ferrous ions

IN-CVA19 **CAS name:** methyl *N*-(sulfooxy)ethanimidothioate sodium salt

Trivial names: Methomyl-oxime sulphate, MHTA-sulphate

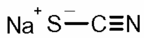


CAS number: Not available **Molecular Weight:** 207.20

Structural formula: $C_3H_6NO_4S_2$ Na **Observed in:** Rat, monkey

NA **CAS name:** Sodium thiocyanate

Trivial name: Thiocyanate ion (shown as sodium salt)

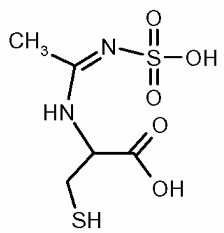


CAS number: 540-72-7 **Molecular Weight:** 97.18

Structural formula: NaSCN **Observed in:** Goat and rat

NA **CAS name** N-[1-(sulfoimino)ethyl]cysteine

Trivial name: Sulphate/N-cysteine conjugate of acetonitrile M1-1-7



CAS number: NA **Molecular Weight:** 247.27

Structural formula: $C_5H_{10}N_2O_5S_2$ **Observed in:** Goat, poultry, monkey