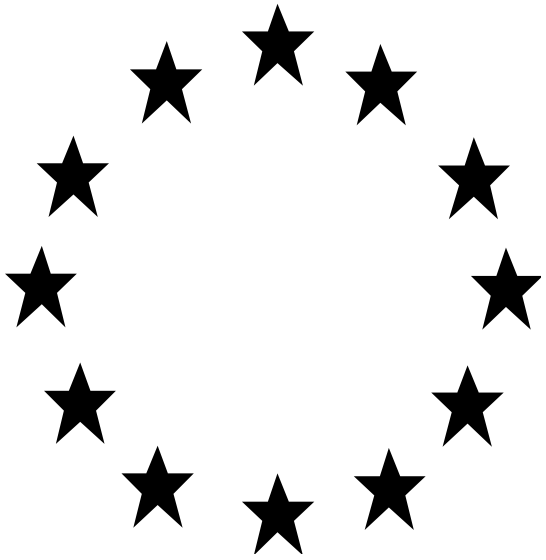

Draft Assessment Report (DAR)

- public version -

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

CHLORIDAZON

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

Volume 3, Annex B, B.9

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Annex B

Chloridazon

B-9: Ecotoxicology

B.9 Ecotoxicology

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

B.9.1.1 Acute oral toxicity (Annex II A 8.1.1, Annex III A 10.1.1)

ACTIVE SUBSTANCE

Reference number: II A 8.1.1/1

Report: Munk R. et al., 1990(a); AVS 2003-168
Avian single-dose oral LD_{50} of Reg.Nr. 13 033; 95 % (= test compound No. 88/174-1) to the bobwhite quail (*Colinus virginianus*)
[redacted]
project # 11W0174/88096, BASF RegDoc# 1990/0296

Guidelines: EPA 71-1, EPA 540/9-85-007

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch No. N 143, purity: 94.1 %; specification dossier document J, test species Bobwhite quail (*Colinus virginianus*) before their first egg-laying (about 5 months old), visually indistinguishable from wild birds. Birds were treated once administering the test substance at doses of 1000 and 2000 mg as/kg body weight (nominal) in a carrier (0.5 % aqueous carboxymethyl cellulose) by gavage into the crop (5 males/ 5 females per dose group). During the 14 days observation period, mortality, clinical signs, feed consumption and body weight were recorded.

Findings
The analytically detected concentrations were between 97.7 % and 101.7 % of the nominal concentrations. Hence, biological results are based on nominal values.
Mortality occurred only in the highest dose group (one male bird at 2000 mg as/kg at day 0). Toxic signs occurred in the 2000 mg as/kg bw dose group with one male in prone position about 1 h - 2 h after administration, and in all dose groups in male and female birds diarrhea was observed on day 1. From day 2 till the end of the study none of the birds showed signs of sickness. The feed uptake was reduced in the female birds of both dose groups and slightly reduced in the male birds of the highest dose group. The body weights of the birds in both dose groups were not statistically lower compared to those from the control group at test termination. Macroscopic examination revealed no abnormalities [see Table B.9.1-1].

Table B.9.1-1: Acute toxicity of chloridazon to the bobwhite quail (*Colinus virginianus*)

Mortality	Dose [mg as/kg bw]
Highest dose causing no compound-related mortality	1000
LD_{50} (14 d)	> 2000
NOEL (14 d)	1000

Valid: yes

Conclusion:
In the acute toxicity test (single-dose oral application) of chloridazon to the bobwhite quail the LD_{50} (14 d) was greater than 2000 mg as/kg bw, the highest concentration tested. The NOEL was found to be 1000 mg as/kg bw.

B.9.1.2 Dietary toxicity (Annex II A 8.1.2, Annex III A 10.1.1)

ACTIVE SUBSTANCE

Reference number: II A 8.1.2/1

Report: Munk R. et al., 1990(b); AVS 2003-169
Avian dietary LC_{50} test of Reg.Nr. 13 033; 95 % (= test substance No. 88/174-1) in the bobwhite quail (*Colinus virginianus*)
[redacted]
project # 31W0174/88093, BASF RegDoc# 1990/0297

Guidelines: EPA 71-2, EPA-SEP 540/9-85-008

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143, purity: 94.1 %, specification Document J, test species Bobwhite quail (*Colinus virginianus*), chicks, hatched from eggs of animals visually indistinguishable from wild birds. Birds were administrated the test substance at doses of 313, 625, 1250, 2500 and 5000 mg as/kg feed (nominal) in the feed with basal diet without test substance for 5 consecutive days, post-exposure period of at least 3 days. Endpoints assessed were mortality, LC_{50}, clinical signs, feed consumption and body weight.

Findings
The concentration control analysis yielded analytically detected concentrations between 97.6 % and 100.2 % of the nominal concentrations. Hence, biological results are based on nominal values.
There was unspecific marginal (10 %) but not concentration dependent compound-related mortality in the three highest dose groups. The highest concentration tested causing no compound-related mortality was 625 mg as/kg diet (the 1/10 dead chicks each in the 313 or 625 mg as/kg is judged not to be compound-related since these 2 birds suffered from severely injured beaks due to aggressiveness of other birds in these groups). Clinical signs were detected only in the highest dose group on day 4 (hanging wings). The other symptoms observed are not believed to be test item related. There was no significant reduction in the mean feed consumption of the test item groups when being compared with the control group. Slightly smaller mean body weights were observed in the two highest dose groups (2500 and 5000 mg as/kg diet) which persisted until the end of the post-administration period [see Table B.9.1-2].

Table B.9.1-2: Avian dietary toxicity of chloridazon to the bobwhite quail (*Colinus virginianus*)

Group	Control	313 mg as/kg	625 mg as/kg	1250 mg as/kg	2500 mg as/kg	5000 mg as/kg
Mortality [%]	0	10	10	10	10	10
Feed consumption [1] [g/bird/day]	5.5	5.7	5.2	5.2	5.7	5.6
Body weight [2] [g]	33.2 n.s.	34.0 n.s.	31.1 n.s.	32.9 n.s.	27.3 n.s.	27.1 n.s.
Symptoms [3]	X4	X2	X2	X2	X3	X2
	Endpoints [mg as/kg diet]					
LC_{50}	>5000					
NOEC	625					

1) mean of days 1-5 exposure period
2) mean body weight at day 8
3) symptoms at day 8, X = injured beak; number after letters denote number of chicks affected
n.s. = not statistically significant when compared to the control (Dunnett test, $\alpha = 0.05$)

Valid: yes

Conclusion:
In an avian dietary test with the bobwhite quail, the LC_{50} (8 d) of chloridazon amounted to > 5000 mg as/kg diet, corresponding to 1318.0 mg/kg bw/d; the NOEC was determined to be 625 mg as/kg diet (104.5 mg/kg bw/d).

Reference number: II A 8.1.2/2

Report: Munk R. et al., 1990(c); AVS 2003-170
Avian dietary LC_{50} test of Reg.Nr. 13 033; 95 % (= test substance 88/174-1) in the mallard duck (*Anas platyrhynchos L.*)
[redacted]
project # 32W0174/88102, BASF RegDoc# 1990/0298

Guidelines: EPA 71-2, EPA-SEP 540/9-85-008

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch N 143, purity: 94.1 %; specification Document J; test species Mallard duck (*Anas platyrhynchos*), chicks, animals visually indistinguishable from wild birds. Birds were administered the test substance at doses of 313, 625, 1250, 2500 and 5000 mg as/kg diet (nominal) for 5 consecutive days, post-exposure period of at least 3 days. Endpoints assessed were mortality, signs of toxicity, feed consumption and body weight.

Findings
The concentration control analysis yielded analytically detected concentrations between 97.4 % and 103 % of the nominal concentrations. Hence biological results are based on nominal values.
Mortality occurred in the three highest dose groups, the highest concentration tested causing no compound-related mortality was 625 mg as/kg diet. No clinical signs of toxicity could be

observed. There was a slight reduction in the mean feed consumption in the 2500 mg as/kg dose group and a clear reduction in the highest dose group (5000 mg as/kg diet) during administration and post-administration periods. There was an observed concentration dependent smaller mean body weight in the two highest test groups at the end of the administration period, which persisted at least in the highest test group (5000 mg as/kg) until the end of the post-administration period. The body weights were not statistically significantly different from that of the control group [see Table B.9.1-3].

Table B.9.1-3: Avian dietary toxicity of chloridazon to the mallard (*Anas platyrhynchos*)

Group	Control	313	625	1250	2500	5000
		mg as/kg	mg as/kg	mg as/kg	mg as/kg	mg as/kg
Mortality [%]	10	0	0	10	20	60
Feed consumption [1] [g/bird/day]	37	41	38	40	31	15
Body weight [2] [g]	192.9 n.s.	209.4 n.s.	216.2 n.s.	191.1 n.s.	175.5 n.s.	126.1 n.s.
Symptoms [3]	None	None	None	None	None	None
	Endpoints [mg as/kg diet]					
LC_{50}	4260					
NOEC	625					

1) mean of days 1-5 exposure period
2) mean body weight at day 8
3) symptoms at day 8, X = injured beak; number after letters denote number of chicks affected
n.s. = not statistically significant when compared to the control (Dunnett test, $\alpha = 0.05$)

Valid: yes

Conclusion
In an avian dietary test with the mallard, the LC_{50} (8 d) of chloridazon amounted to 4260 mg as/kg diet (corresponding to 1601.0 mg/kg bw/d); the NOEC was determined to be 625 mg as/kg diet (corresponding to 173.1 mg/kg bw/d).

B.9.1.3 Subchronic toxicity and reproduction (Annex II A 8.1.3, Annex III A 10.1)

ACTIVE SUBSTANCE

Reference number: II A 8.1.3/1

Report: Zok S., 2000; AVS 2001-160
Reg.Nr. 13 033; 1-Generation reproduction study on the bobwhite quail (*Colinus virginianus*) by administration in the diet [redacted] unpublished, report # 71W0179/99013, BASF RegDoc# 2000/1018810

Guidelines: EPA 71-4, EPA 540/9-86-139, OECD 206

GLP: Yes

Material and methods

Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 198, purity: 93.5 %; specification Document J, test species: Bobwhite quail (*Colinus virginianus*) before their first egg-laying (about 5 months old); visually indistinguishable from wild birds. After an acclimatisation period of 2 weeks the birds were offered the test substance ad libitum at doses of 100, 300 and 1000 mg as/kg body weight (nominal), for a period of 22 weeks (10 weeks pre-egg production, 12 weeks egg production period). Endpoints assessed were mortality, clinical signs, feed consumption, body weight and reproductive parameters.

Findings
The concentration control analysis was performed for all dose levels. The analytically detected concentrations were between 91.8 % and 107.8 % of the nominal concentrations. Hence, biological results are based on nominal values.
No compound-related effects in the parent generation on mortality, birds' health, feed consumption and body weight could be detected. In the 300 mg as/kg diet group isolated findings (like moderate lesions and consequential injuries) were considered to be accidental and not biologically relevant.
There were no treatment effects on any of the reproduction parameters in the lowest dose group (100 mg as/kg diet). For the dose group of 300 mg as/kg diet slight deviations from the control with low statistical significance occurred for the proportion of viable 11-day embryos of eggs initially set and for the proportion of 14-day old surviving chicks of eggs initially set. These effects were considered not to be test item-related.
A decrease in fertility rate and an increase in early embryonic mortalities in the highest dose group (1000 mg as/kg diet) were not considered to be test item-related. There was a statistically significant impairment of late embryonic survival, which was considered to have marginal biological relevance. The hatchability (number of hatched chicks per female and % hatched chicks of fertile eggs) was statistically significantly impaired in the highest dose group, but not considered to be of biological significance (values were still within the range of the values of historical control groups of the last 10 years). A statistically significant reduction occurred in the number of 14-day surviving chicks per hen at the highest dose group, which was considered to be a biological relevant effect. No compound-related effects on chick body weight at hatch and 14 days post hatch.
The "no-observed-adverse-effect-level" (NOAEL) for this study was set at 300 mg as/kg [see Table B.9.1-4].

Valid: yes

Conclusion
The NOAEL for bobwhite quail exposed to chloridazon in the diet during this 22 week study was 300 mg as/kg diet, corresponding to 21.5 mg/kg bw/d.

Table B.9.1-4: Effects of chloridazon on the reproduction of the bobwhite quail (*Colinus virginianus*)

	Experimental group (mg as/kg diet)			
Treatment (mg as/kg feed)	**Control**	**100**	**300**	**1000**
Number of replicates	16	16	16	16
Treatment-related mortality of adult birds	0	0	0	0
Adult body weight [g] (male/female)	228.8	226.5 n.s.	235.3 n.s.	242.5 n.s.
Mean food consumption 1) [g/bird/day]	17.7	17.9 n.s.	18.0 n.s.	17.6 n.s.
No. of eggs laid	974	955 n.s.	968 n.s.	873 n.s.
No. of eggs laid/female bird/week	5.1	5.0	5.1	4.6
No. of cracked and broken eggs	51	38 n.s.	43 n.s.	36 n.s.
Mean egg weight [g]	9.8	9.9 n.s.	9.7 n.s.	9.7 n.s.
Mean egg shell thickness [mm]	0.22	0.23 n.s.	0.23 n.s.	0.23 n.s.
No. of eggs set	863	855	866	776
No. of fertile eggs	843	825	828	706
No. of infertile eggs	20	28	38	70
No. of early embryonic mortalities	6	7	14	22
No. of viable 11-day old embryos	837	818	814	684
No. of late embryonic mortalities	5	7	11	14
No. of viable 18-days old embryos	832	811	803	670
No. of total embryonic deaths	11	15	25	36
No. of “dead-in-shell”	225	190	233	215
No. of chicks hatched	607	621	570	455
No. of 14-day surviving chicks	472	505 n.s.	406 n.s.	346 *
No. of chicks hatched/female bird	3.16	3.23 n.s.	3.00 n.s.	2.38 *
No. of 14-day surviving chicks/female bird/week	2.46	2.63	2.13	1.81
Mean body weight of chicks at hatching [g]	6.21 n.s.	6.23 n.s.	5.99 n.s.	6.16 n.s.
Mean body weight of chicks 14 days after hatching	20.48 n.s.	19.64 n.s.	20.05 n.s.	20.51 n.s.
% eggs cracked of total eggs laid	5.5	4.0	4.8	4.3
% fertile eggs of total eggs set	97.3 n.s.	96.7 n.s.	95.8 n.s.	91.7 *
% early embryonic mortalities of fertile eggs	0.7	0.8 n.s.	1.7 n.s.	3.1 *
% viable 11-day old embryos of eggs set	96.6	95.8 n.s.	94.2 n.s.	88.8 *
% late embryonic mortalities of fertile eggs	0.6	0.8 n.s.	1.2 n.s.	1.9 *
% 14-day survivors of chicks hatched	76.4	81.1	69.0	74.2
% viable eggs at day 18 of eggs set day 11	99.4	99.2 n.s.	98.8 n.s.	98.1 *
% “dead-in-shell” of fertile eggs	26.7	23.0 n.s.	29.8 n.s.	34.1 n.s.
Hatchability (% chicks hatched of total eggs set)	70.1	72.8 n.s.	64.4 n.s.	56.8 *
Hatchability (% chicks hatched of fertile eggs)	72.0	75.3 n.s.	67.3 n.s.	60.9 *
% of 14-days survivors of chicks hatched	76.4	81.1 n.s.	69.0 n.s.	74.2 n.s.
	Endpoints [mg as/kg diet]			
NOAEL	300			

1) mean of week 11-22 (egg-laying period)

* statistically significant when compared to the control (Dunnett test, $\alpha = 0.05$ or Wilcoxon test, $\alpha = 0.05$)

n.s. = not statistically significant when compared to the control (Dunnett test, $\alpha = 0.05$ or Wilcoxon test, $\alpha = 0.05$)

B.9.1.4 Toxicity of the formulation (Annex IIIA 10.1.1)

According to Directive 91/414, Directive 96/12 no acute test with the formulation is required as the formulated product BAS 119 33 H shows no higher mammalian toxicity than the active substance. Furthermore, according to Working Document SANCO/10329/2002: "in case of spray application, residues on green plant acute TER values meet the requirements of the guideline".

B.9.1.5 Other studies (Annex IIIA 10.1.2, 10.1.3, 10.1.4)

B.9.1.5.1 Supervised cage or field trials

According to Directive 91/414, Directive 96/12, no further test is required since TER_a and TER_{st} are > 10 and the TER_{lt} is > 5 and there is no evidence of a risk based on the tests performed with the active substance chloridazon.

B.9.1.5.2 Acceptance of bait, granules or treated seeds by birds

No testing is required since the formulated product BAS 119 33 H will be applied exclusively in spray treatments. Acceptance of bait, granules or treated seed are not applicable.

B.9.1.6 Summary of avian toxicity data

For the assessment of effects of chloridazon on birds, tests with bobwhite quail (*Colinus virginianus*) and mallard (*Anas platyrhynchos*) have been conducted. The results are summarised in Table B.9.1-5.
The tests performed cover a broad range of biological endpoints. Acute mortality, behaviour and clinical symptoms have been assessed in bobwhite. In the single dose acute toxicity study the body weight of bobwhite of both sexes was not statistically lower in the highest dose group when compared to the control group. No compound-related effects of chloridazon (BAS 119 H) were observed in the acute toxicity test with bobwhite.

In the short-term dietary studies with bobwhite quail smaller body weights were observed in the two highest test groups (2500 and 5000 mg as/kg diet). The LC_{50} was determined to be above 5000 mg as/kg diet.
In the short-term dietary studies with mallard reduction of mean feed consumption in the 2500 mg as/kg diet test group and the highest test group (5000 mg as/kg diet) was observed, resulting in a not statistically significant impairment of the development of the body weights in this dose group when compared to the control. The LC_{50} was determined to be 4260 mg as/kg diet.

In the sub-chronic toxicity and reproduction study with bobwhite no treatment-related effects in the parent generation upon mortality, health, feed consumption, body weight and reproductive parameters measured were observed. In the highest dose group (1000 mg as/kg diet) there was a statistically significant decrease in the number of 14-day surviving chicks per hen and week compared to the control. The NOAEL was hence set at 300 mg as/kg diet.

Table B.9.1-5: Summary of effects of chloridazon on birds

Test species	Test system	Results	
		mg as/kg feed	mg as/kg bw
Colinus virginianus	acute oral toxicity		LD_{50} > 2000 NOEL = 1000
Colinus virginianus	short-term dietary toxicity	LC_{50} > 5000 NOEC = 625	LC_{50} > 1318 *
Anas platyrhynchos	short-term dietary toxicity	LC_{50} = 4260 NOEC = 625	LC_{50} = 1601 *
Colinus virginianus	Sub-chronic toxicity and re-production	NOAEL = 300	NOEC = 21.5 *

*) daily dose (mg/kg bw/day) calculated based on study data.

B.9.1.7 Risk assessment

The formulation BAS 119 33 H is a herbicidal product, which contains the active substance chloridazon (BAS 119 H) with a nominal content of 650 g/L.
The recommended use pattern for BAS 119 33 H includes one application per season in beet crops at pre-emergence and/or early post-emergence up to BBCH 19 (weeds should not exceed BBCH 14 - 16) with a single application rate of 4.0 L/ha BAS 119 33 H corresponding to 2.6 kg/ha chloridazon.

The risk assessment is based on one application of 4.0 L product/ha in sugar beets at early post-emergence leading to 2600 g active substance/ha and represents the worst case scenario for birds impact.
In order to consider the worst-case condition it is assumed that birds feed exclusively on contaminated food item. Residue estimation and calculation of the food consumption based on the values given in the Draft Working Document on "Risk assessment for birds and mammals under council Directive 91/414/EEC" (SANCO 4145/2000). Birds may be exposed to chloridazon mainly by the consumption of contaminated feed. Due to the intended uses this may be green plant material, insects, earthworms or fish.

B.9.1.7.1 Metabolites

In sugar beets two metabolites of chloridazon were found, metabolite A and B, exceeding 10 % TRR (BASF DocID 1991/10553). In the metabolism studies in rats (BASF DocID 1991/10524), lactating goats (BASF DocID 1992/5162) and laying hens (BASF DocID 1991/5190) both metabolites could not be identified. Hence metabolites A and B are not covered by hen metabolism study.

Metabolite A is a glycoside, and the development of glycosides is a plant specific metabolic step. Therefore, metabolite A does not appear in rats, goats or hens. Nevertheless, animals are capable of decomposing glycosides. In the case of metabolite A the parent compound chloridazon is released. Therefore, metabolite A is assumed to be covered by the toxicological data on chloridazon.

Metabolite B:
In rats metabolite B is virtually not toxic after acute administration (LD_{50} oral = 5000 mg/kg bw (BASF DocID 1998/10413). It also demonstrated no developmental toxicity (BASF

Do-cID 1997/10597). The overall NOAEL for the short term toxicity (BASF DocIDs 1977/0155, 1996/10817, 1996/10818, 1977/0156) is considered to be 86 mg/kg bw, compared to 20.7 (males) and 23.5 (females) mg/kg bw for the parent compound (BASF Do-cID 1977/0156). Overall metabolite B is less toxic than chloridazon.
In laying hens (BASF DocID 1999/11788) ^{14}C-metabolite B of chloridazon was rapidly and almost completely excreted via the excreta. There was no indication of accumulation of ^{14}C-metabolite B in hen tissues, organs or eggs.

B.9.1.7.2 Risk assessment for the active substance

B.9.1.7.2.1 Exposure assessment

Depending on SANCO 4145/2000 the estimated daily uptake of a compound is given by the following equation:

ETE = (FIR / bw) * C * AV * PT * PD (mg/kg bw/d)

ETE	Estimated daily uptake of compound (= estimated theoretical exposure)
FIR	Food intake rate of indicator species (gram fresh weight per day)
bw	Body weight (g)
AV	Avoidance factor (1 = no avoidance, 0 = complete avoidance)
PT	Fraction of diet obtained in treated area (number between 0 and 1)
PD	Fraction of food type in diet (number between 0 and 1; one type or more types)

In case of multiple applications and/or long-term considerations the concentration C may be expressed as

$C = C_0 * MAF * f_{twa} * IF$

C_0	Initial concentration after a single application calculated from RUD (= Residue Unit Dose) multiplied by the application rate (kg as/ha)
MAF	Multiple application factor (concentration immediately after the last application compared to a single application)
f_{twa}	Time-weighted-average factor (average concentration during a certain time interval compared to the initial concentration after single resp. last application)
IF	Interception factor

Both equations can be combined and converted to the following form, which will be used in this assessment.

ETE = (FIR / bw) * RUD * AV * PT * PD * IF * f_{twa} * MAF * Appl. Rate (mg/kg bw/d)

In the first tier it is assumed that
- the contaminated diet is not avoided (AV = 1)
- animals satisfy their entire food demand in the treated area (PT = 1)
- animals feed on a single food type (PD = 1)

In the case of contaminated plant materials, leafy plants are considered as the most suitable feed item to calculate the “initial residue in food items” in the case for herbivorous birds.
In the case of contaminated insects small insects are considered as feed for insectivorous birds in cereals in the standard scenarios.

The exposure assessments and the resulting worst case exposure levels for chloridazon (BAS 119 H) - applied as BAS 119 33 H- based on default approaches (Tier 1) are laid down in the Guidance Document (SANCO/4145/2000) - are summarised in Table B.9.1-6 for acute exposure, short-term and long-term exposure.

Table B.9.1-6: Exposure assessment for birds, standard scenarios in sugar beet

Culture	Food source	Indicator species	R	MAF	f_{twa}	RUD	FIR/bw	ETE
Acute exposure								
Early/late	leafy crops	medium herbivorous bird	2.6	1	1	87	0.76	171.9
Early/late	small insects	insectivorous bird	2.6	1	1	52	1.04	140.6
Short-term exposure								
Early/late	leafy crops	medium herbivorous bird	2.6	1	1	40	0.76	79.0
Early/late	small insects	insectivorous bird	2.6	1	1	29	1.04	78.4
Long-term exposure								
Early/late	leafy crops	medium herbivorous bird	2.6	1	0.53	40	0.76	41.9
Early/late	small insects	insectivorous bird	2.6	1	1	29	1.04	78.4

B.9.1.7.2.2 Risk assessment (toxicity/exposure ratios)

The risk assessment is to be done with the exposure values of the "estimated theoretical exposure (ETE)". The estimated daily food intakes were calculated for the main uses according to the standard scenarios for the various exposure estimates of SANCO/4145/2000 and are shown in Table B.9.1-6.
As toxicity endpoints for the calculation of the acute and short-term TER-values the LD_{50}-values of the active substance related to body weight were used. For the long-term exposure scenario (TER_{lt}) the NOAEL of the reproduction studies were used. The toxicity data are summarised in Table B.9.1-5.

The TER-values for the acute, short-term and long-term standard scenarios of herbivorous birds are shown in Table B.9.1-7.

Table B.9.1-7: Toxicity/exposure ratios for herbivorous birds

Culture	Feed	Indicator species	LD_{50} oral (mg/kg bw*d)	ETE	TER_a (LD_{50}/ETE)	Trigger TER
Acute exposure						
Sugar beet	leafy plants	medium herbivorous bird	> 2000	171.9	11.6	10
Sugar beet	small insects	insectivorous bird	> 2000	140.6	14.2	10
Short-term exposure						
Sugar beet	leafy plants	medium herbivorous bird	1601	79.0	20.3	10
Sugar beet	small insects	insectivorous bird	1601	78.4	20.4	10
Long-term exposure			**NOAEL (mg/kg bw*d)**			
Sugar beet	leafy plants	medium herbivorous bird	21.5	41.9	0.51	5
Sugar beet	small insects	insectivorous bird	21.5	78.4	0.27	5

The TER values for the acute and short-term exposure of herbivorous and insectivorous birds are higher than the trigger of 10 set by the Annex VI of Directive 91/414EEC for a refined risk assessment.

In conclusion, the acute and short-term risk for herbivorous and insectivorous birds after application of chloridazon according to good agricultural practice is acceptable.

The Tier 1 long-term exposure scenarios indicate a potential risk for herbivorous and insectivorous birds in leafy crops. The TER_{lt} are below the trigger of 5 and a refined risk assessment for long-term exposure is required.

B.9.1.7.3 Refined risk assessment

B.9.1.7.3.1 Refinement of the long-term exposure assessment

Due to the TER < 5 in the first tier assessment for long-term exposure of birds a refinement of the exposure was performed using following options:

Relevant species
Measured residues
PD factor for relevant species
PT factor for relevant species
Interception factor

Relevant species
The Guidance Document considers indicator species for the Tier 1 risk assessment (Table B.9.1-8), which in Tier 2 may need to be refined based on the use pattern specific to the substance in question.

Table B.9.1-8: Indicator species for risk assessment of the Guidance Document

Crop	Crop stage	Indicator species	Example
Leafy crop (sugar beet)	early /late	medium herbivorous bird, 300 g	partridge, pigeon
Leafy crop (sugar beet)	early /late	insectivorous bird, 10 g	wren, tin

To refine the risk assessment for chloridazon it should be noted that the substance is used at pre-emergence and/or early post-emergence to control emerging dicotyledonous weeds. Therefore, in the applied area there will be no contaminated leafy weeds, but the crops itself may contain residues potentially consumed by herbivorous birds. Therefore, the partridge is used as model organism in the exposure assessment for beet crops. This herbivorous bird may occur in uncovered fields and could possibly consume contaminated sugar beet plants.
For the time of application arthropod populations are limited due to tillage of the field ecosystem. Due to the fact that diurnal insects rely on vegetative cover, the uncovered fields lose attraction for herbivorous and subsequently for predatory arthropods. Insectivorous birds will avoid uncovered fields due to the lack of feed; they will frequent off-crop areas with a rich plant cover and an intact ecosystem. Another advantage of off-crop areas compared to uncovered fields is, that they supply shelter against predators. Therefore, concerning the risk assessment for chloridazon the insectivorous scenario was regarded by the notifier to be of no relevance, and hence was not refined by the notifier.
However, the RMS believes that birds feeding on soil invertebrates and preferring unenclosed areas can be exposed via e.g. contaminated earthworms. Earthworms can be contaminated by feeding on chloridazon containing soil and chloridazon containing weeds destroyed after application. An indicator bird for this scenario is the lapwing (*Vanellus vanellus*) (Buxton et al. 1998) and a risk assessment for this bird is performed by the RMS.

Lapwing (*Vanellus vanellus)*
Agricultural land has long been the principal habitat. The lapwing shows a clear association with cattle and sheep, but also attracted to stubble, fallow and newly ploughed fields with highest densities found in areas practising mixed farming. The population has declined sharply where autumn sowing has increased.
Lapwings require ready access to surface and soil invertebrates, usually choosing flat, unenclosed terrain with low growing vegetation giving all-round views. The birds breed from April to August (Buxton et al. 1998). In Sweden, of 252 nests located in a coastal arable area, 56 % were in coastal pasture and 43 % on arable land (almost entirely on spring cereals). During the pre-laying period, arable land was the main foraging habitat (62 %), followed by pasture (23 %) and shoreline mudflats (16 %). Birds foraging on arable land caught more large items (mainly earthworms) than birds on pasture (Blomquist and Johansson, 1995). Among arable crops, vegetation height was an important factor in habitat selection. Older crops with tall, dense vegetation were avoided, with stubbles and new crops used immediately and ploughed land the most preferred (Milsom et al, 1985).

- PD factor for relevant species
Faecal analyses of chicks in different agricultural habitats indicates that earthworms are a major part of the diet of lapwings. The proportion of the different diets were as follows (related to dry weight): lumbricidae (53 - 55 %), coleoptera (15 - 27 %), tipulidae (9 - 22 %) and others (8 - 10 %) (Buxton et al. 1998). Since for the time of application arthropod populations are limited due to tillage of the field ecosystem and due to the fact that diurnal insects rely on vegetative cover, it is assumed that 10 % of the arthropod portion of the diet is collected in the treated field. Thus, a PD of 0.1 is used.

- PT factor for relevant species
The proportion of diet obtained in the treated area is 100 % (PT = 1).

- Residues in earthworms
As a worst case scenario a BCF of 1 is used and the $PEC_{earthworm}$ is equal to the $PEC_{soil\ (twa,\ 3\ weeks)}$ of 3.165 mg/kg soil (see chapter B 8.3). Based on the $logP_{ow}$ of 1.2 for chloridazon and the respective $PEC_{soil\ (twa,\ 3\ weeks)}$ a realistic chloridazon concentration of 0.752 mg as/kg worm can be calculated according to SANCO/4145/2000.

- Interception factor
For the calculation of PEC_{soil} no interception was considered due to worst case application pre-emergence.

Refined exposure assessment

Table B.9.1-9: Refined long-term exposure for earthworm-eating birds

Culture	Indicator species	Food source	R	MAF	RUD	FIR/bw	f_{twa}	PT	PD	IF	ETE
Sugar beet Early	medium insectivorous bird: lapwing	soil invertebrates	2.6	1	1.217	0.62	n.a.	1	0.5	n.a.	1.06
		arthropods in-crop			29	0.31	n.a.	1	0.1	n.a.	2.34
		arthropods off-crop						1	0.40		
	whole diet							1	1.0		3.40

n.a. not applicable
R = application rate in kg as/ha
MAF = multiple application factor
RUD = residue per unit dose (mg as/kg wet weight), calculated with $PEC_{soil\ ftwa\ 21\ d}$ and worst case assumption BCF=1
FIR/bw = food intake rate per body weight (g/kg bw*d) according to Crocker et al (2002) as given in SANCO 4145/2000 (soil invertebrates, 226 g bw bird, 69 % assimilation efficiency for Charadriiformes)
f_{twa} = 1. time-weighted average factor considered in PEC_{soil}. for RUD.
PT = proportion of diet obtained in treated areas
PD = proportion of different food types in the diet
IF = interception factor (FOCUS 2000, 2002)
ETE = estimated theoretical exposure (R*MAF*RUD*FIR)

Grey partridge (*Perdix perdix*)
The grey partridge originally inhabited steppes and forest steppes. Secondarily, it invaded arable land where the species prefers small-scale agriculture interspersed with hedges and fallow land (Dwenger, 1991). A clear preference for cultivated land with a great diversity of crops, pastures and wasteland has been confirmed by the results of several field studies (Middleton and Chitty, 1937; Glänzer et al. 1993; Kaiser, 1998; Panek and Kamieniarz, 2000).
In a radio-tracking study in south-western Germany the clear preference of grey partridges (n = 38) for small-scale agricultural habitats has been confirmed. The average field size of the preferred partridge habitats was 0.4 ha (range: 0.1 – 1.5 ha). The partridges clearly avoided large fields (Glänzer et al., 1993). This was also confirmed by a field study carried out from 1991 to 1995 in 12 areas of Poland, each covering between 10000 ha and 12000 ha. Here, the number of grey partridges was clearly positively correlated with the number of fields per km line transect (Panek and Kamieniarz, 2000).

- Measured residues

In field trials with BAS 119 H the residues reveal values below the default values of the Tier 1 assessment. Treatment and application regime in these studies were comparable to the intended use scheme for BAS 119 33 H. The data were normalised to an application rate of 1 kg as/ha resulting in RUD values which can be directly used in the Tier 2 assessment. Based on SANCO4145/2000 the arithmetic mean residue values will be used for the long-term risk assessment.
The residues measured at different time points after application of the active substance were analysed to obtain a dissipation half-live (DT_{50}) for the decline of chloridazon in sugar beet shoots (Dressler 2003, BASF DocID 2003/1005440. The DT_{50} was found to be 5.2 days resulting in a refined f_{twa} of 0.34.

Table B.9.1-10: Residues of BAS 119 H in sugar beets

Crop	Number of trials	Application	Days after application	RUD range [2] [mg as/kg green matter]	RUD mean [2] [mg as/kg green matter]
sugar beet	11	1 x 2.6 kg as/ha	initial	0.99 – 63.5	16.5

[1] see BASF DocIDs 1999/10348, 2000/1013266, 2001/1009078, 2002/1011935, 2002/1011936
[2] residue unit dose (RUD), corresponding to 1 kg as/ha.

- PD factor for relevant species
The diet of the grey partridge is diverse consisting of plant material (green matter, roots, seed, fruits) and animal matter (mainly arthropods and gastropods). The proportion of the respective food items varies seasonally. In spring partridges feed on green matter of plants (~ 62 % of volume), seed (~ 34 %) and animal matter (~ 4 %). In summer they feed on seed (~ 56 %) green matter of plants (~ 28 % of volume) and animal matter (~ 16 %). The green matter and seed proportions rely on at least 50 % weed species (Dwenger, 1991).
The grey patridge thus represents the potential medium herbivorous species of concern for the early crop stages, and thus would potentially be exposed to BAS 119 W.

- PT factor for relevant species
In the Tier 1 risk assessment it is assumed that individuals obtain all their dietary requirements from the treated area. However, exclusive feeding on a treated diet is unlikely to occur. The landscape is scattered with different types of habitats, and a potentially applied field is only one of them.
The foraging behaviour of grey partridges was evaluated in a most comprehensive field study in south-western Germany (Glänzer et al., 1993). A total of 38 grey partridges were radio-tracked with an average of 78.8 days per individual (total n = 2730 h). In addition to telemetry, the birds were visually observed. The data are summarised in Table B.9.1-11. Since the visual observations can lead to deceivingly biased results in the higher vegetation, the data have been recalculated for radio-tracking locations only.

The visual data (see Table B.9.1-11) are considered to be arbitrary as the birds are very difficult to spot in high vegetation and the data supposed to over-represent habitats that are easy to survey. Hence, only the radio-tracking data should be considered.
The data presented in Table B.9.1-11 suggest that grey partridges prefer cereal fields (early growth stages), bare soil (freshly ploughed and harrowed fields), grassy tracks, grassland, hedges, gardens, weedy areas and special fields made to attract game.

Table B.9.1-11: Habitat use of grey partridges in southern Germany (n = 38) according to Glänzer et al. (1993)

Habitat element	Prop. habitat element [%]	Radio-tracking locations (n = 1127) [%]	Visual observations [%]	Habitat use [1] [%]	Preference [2]	
					telemetry only	habitat use
Roads	3.59	3.80	0.87	2.33	1.06	0.65
Grassy tracks	5.64	6.56	22.51	14.53	1.16	2.58
Bare soil	20.79	30.89	27.71	29.30	1.49	1.41
Cereal fields	26.01	33.13	30.30	31.72	1.27	1.22
Orchards	2.75	2.67	3.03	2.85	0.97	1.04
Settlements	12.94	0.78	0.43	0.60	0.06	0.05
Turnip/beets	5.54	3.02	3.09	3.46	0.55	0.62
Grassland	4.12	4.83	2.60	3.72	1.17	0.90
Hedges	0.55	1.04	-	0.52	1.89	0.95
Potatoes	0.18	0.17	-	0.09	0.94	0.50
Maize	3.82	4.23	5.19	4.71	1.11	1.23
Gardens	1.49	2.07	0.87	1.47	1.39	0.99
Gravel	1.36	1.21	-	0.60	0.89	0.44
Weedy areas	0.38	2.93	0.87	1.90	7.71	5.00
Cereal stubbles	0.07	0.09	-	0.04	1.29	0.57
Forest	8.02	0.17	0.43	0.30	0.02	0.04
Game fields	0.52	1.29	-	0.65	2.48	1.25
Miscellaneous	1.76	1.12	1.30	1.21	0.63	0.74

1) Geometric mean of proportion of radio-tracking locations and visual observations
2) Proportion between habitat use/telemetry data and habitat element; figures > 1 indicate preference, < 1 avoidance

In the following this most comprehensive field data are analysed to obtain an estimate on the relative use of a specific crop type:
The total foraging habitat area comprised 37 % cultivated (i.e. omitting the cereal stubbles) arable field habitat area (i.e. cereals, turnip/beets, potatoes, maize and gardens) and of 63 % off-crop habitats.
In this field study, which was conducted in a prime partridge habitat in Baden-Württemberg, Germany, 43 % of the radio-tracking locations (n = 1127) of partridges were made in cultivated arable habitats and 57 % in off-crop habitats.

The radio-tracking data (see Table B.9.1-11) imply that in prime habitat, i.e. a landscape consisting of at least 50 % of non forested off-crop habitat, partridges tend to use crop fields according to their proportion of area. No obvious preferences were found with the exception of turnip/beet fields, which were used much less than would be expected according to their proportion of area. For turnip/beet fields an avoidance factor of 0.5 can additionally be considered (see Table B.9.1-11). Generally, it can be concluded that patridges spend 50 % of their time off-crop as confirmed by Buxton et al. (1998).
The average home range of partridges during the breeding season (April to June) is around 6.4 ha. Assuming an off-crop proportion of 50 % results in 3.2 ha in-crop habitat related to the average partridge home range during the breeding season. Field size for sugar beets is usually between 2 and 10 ha. A realistic approach would be to assume that half of this area consists of a sugar beet field.
Thus, a realistic estimate of the portion of time spent in the treated area (PT) would be a factor of 0.25.

- Interception factor (IF)
Interception factors are not included in the refined exposure assessment, since measured residues were used as residue unit dose (RUD).

Refined exposure assessment
The refined exposure assessments for birds in leafy crops considering grey partridge , PT and PD factors, as well as measured residues are provided in Table B.9.1-12.

Table B.9.1-12: Refined long-term exposure for herbivorous birds

Culture	Food source	Indicator species	R	MAF	RUD	FIR/bw	f_{twa}	PT	PD	IF	ETE
Sugar beet early	leafy crops, sugar beets	medium herbivorous bird: grey partridge	2.6	1	16.5	1.92	0.34	0.25	0.31	1	2.17
	non-grass herbs		2.6	1	16.5	0.76	0.34	0.25	0.31	1	0.86
	weed seeds		2.6	1	40	0.10	n.a.	0.25	0.34	1	0.88
	insects		2.6	1	29	0.27	n.a.	0.25	0.04	1	0.20
	whole diet								**1.0**		**4.12**

n.a. = not applicable
R = application rate in kg as/ha
MAF = multiple application factor
RUD = initial residue per unit dose (mg as/kg wet weight), measured at day 0 for leafy crops and non-grass herbs, other values from SANCO 4145/2000
FIR/bw = food intake rate per body weight (g/kg bw*d), according to Crocker et al (2002) as given in SANCO 4145/2000
f_{twa} = time-weighed average factor. Default value from SANCO 4145/2000
PT = proportion of diet obtained in treated areas
PD = proportion of different food types in the diet
IF = interception factor (FOCUS 2000/2002)
ETE = estimated theoretical exposure (R*MAF*RUD*FIR)

B.9.1.7.3.2 Refined risk assessment for long-term exposure

The refined long-term TER_{lt} for a standard indicator species of the Guidance Document (SANCO/4145/2000) in leafy crops for BAS 119 H and a relevant bird feeding on soil invertebrates based on residue data measured by the notifier are given in Table B.9.1-13.

Table B.9.1-13: Refined toxicity/exposure ratios for birds for long-term exposure

Culture	Food type	Indicator species	NOAEL oral (mg/kg bw*d)	ETE	TER_{lt} (NOAEL/ETE)	Trigger TER
Herbivorous birds						
Sugar beet, early	leafy crops, non-grass herbs, weed seeds, insects	medium bird: grey partridge	21.5	4.1	5.2	5
Birds, feeding on soil invertebrates and insects						
Sugar beet, early	soil invertebrates (earthworms)	medium bird; lapwing	21.5	3.4	6.3	5

The refined exposure assessment of the Tier 2 risk assessment results in long-term TER_{lt} for birds, which are higher than those in the Tier 1 assessment and higher than the trigger of 5 as laid down in Annex VI of Directive 91/414 EEC.
Therefore, for birds predominantly feeding on soil invertebrates and for herbivorous birds the worst case risk assessment indicates that the risk is acceptable.

In conclusion: the long-term risk for birds feeding on soil invertebrates and insects or on leafy crop after application of chloridazon according to good agricultural practice is acceptable.

Comment of the RMS:
The above presented refinement of the risk assessment was performed by the RMS and is based on a conservative approach. The aim is to simulate a realistic worst case for birds preferably feeding on green plants or soil invertebrates and insects in arable habitats. This approach should enable an easy transfer of the exposure assessment to other European scenarios.

The notifier provided additional specific information about the indicator species grey partridge for the refinement of the long-term exposure assessment. Very specific data regarding habitat and foraging behaviour were used to reduce the respective assessment factors for the refinement. The information and the refinement of the PT factor derived by the notifier are summarised below. The assumptions of the RMS are based on a realistic sugar beet field size between 2 and 10 ha.

Information provided by the notifier:
As a prime partridge habitat the study area comprised small-scale agriculture with an average field size of 0.4 ha. The average home range of partridges during the breeding season (April to June) is 6.4 ha. Assuming an off-crop proportion of 50 % results in 3.2 ha in-crop habitat related to the average partridge home range during the breeding season. Given the average field size of 0.4 ha these 3.2 ha comprise eight individual fields. In such a small-scale agriculture a realistic approach would be to assume that two out of the eight fields (as 0.8 ha) share the same type of crop. Related to the average home range 12.5 % of the home range area is supposed to consist of the same crop type.

The radio-tracking data (see Table B.9.1-11) imply that in prime habitat, i.e. a landscape consisting of at least 50 % of non forested off-crop habitat, partridges tend to use crop fields according to their proportion of area. No obvious preferences were found with the exception of turnip/beet fields, which were used much less than would be expected according to their proportion of area. For turnip/beet fields an avoidance factor of 0.5 has to be considered additionally (see Table B.9.1-11).
In conclusion, based on a comprehensive field study in south-western Germany (Glänzer et al., 1993) the proportional habitat use of grey partridges would be 12.5 % for annual crops such as cereals, maize, potatoes, vegetables etc., but 6.0 % for turnip / beets.
Thus, a realistic estimate of the portion of time spent in the treated area (PT) would be a factor of 0.125. The resulting TER value of 7.5 is above the trigger of 5 of Annex VI.

B.9.1.7.4 Bioaccumulation and food chain behaviour

The log P_{ow} of the active substance chloridazon was determined to be 1.2 (BASF DocID 1987/5075). Hence, a bioaccumulation study was not required, and due to the low lipophilicity no risk of bioaccumulation is assumed.

In addition, chloridazon was rapidly and almost completely excreted by laying hens via the excreta (BASF DocID 1999/11788). There was no indication of accumulation of chloridazon in tissues, organs or eggs.
Therefore, it can be concluded that the application of BAS 119 33 H in sugar beets does not give rise for concern of secondary poisoning by the active substance chloridazon.

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

B.9.2.1 Toxicity data

B.9.2.1.1 Fish – acute toxicity

ACTIVE SUBSTANCE

Reference number: II A 8.2.1/1

Report: Munk R., Kirsch P., 1990(b); WAT 2003-450
Report on the study of the acute toxicity. Reg.Nr. 13 033. Rainbow trout (*Salmo gairdneri* RICH.). BASF AG, Ludwigshafen/Rhein, Germany; unpublished, BASF RegDoc# 1990/0187

Guidelines: EPA 72-1, EPA-SEP 540/9-85-006

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143, purity: 94.1 %; specification Document J., test species: Rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792 former *Salmo gairdneri* RICH.), mean body length 7.2 (6.5 - 7.9) cm, mean body weight 3.5 (2.5 - 4.5) g.
Ten fish per aquarium (loading about 0.35 g fish/L) and per concentration were exposed to test substance concentrations of 14.7, 21.5, 31.6, 46.4, 68.1 and 100.0 mg as/L (nominal) and a water control in a static system for 96 h. Endpoints were mortality, LC_{50} and sublethal effects.

Findings
The analytically detected concentrations were initially in the range of 94.2 % - 94.6 % and after about 96 hours at test termination between 94.6 % - 97.8 % of the nominal concentrations, confirming the theoretical values. Hence, the biological results are based on the nominal concentrations. Chloridazon caused no significant mortality to the rainbow trout at a concentration of up to 31.6 mg as/L. Symptoms like apathy and narcotic-like state could be observed in the 31.6 mg as/L group and convulsions, accelerated respiration and narcotic-like state in the 46.4 mg as/L dose group after 96 h (Table B.9.2-1).

Table B.9.2-1: Acute toxicity (96 h) of chloridazon to rainbow trout (*Oncorhynchus mykiss*, former *Salmo gairdneri)*

Concentration (nominal) [mg as/L]	Control	14.7	21.5	31.6	46.4	68.1	100.0
Mortality [%]	0	0	0	0	80	100	100
Symptoms [1)]	none	none	none	A, N	K, N, X	--	--
Endpoints [mg as/L]							
LC_{50}	> 31.6 < 46.4						
NOEC	21.5						

1) Symptoms: A = apathy; K = convolutions; N = narcotic-like state; X = accelerated respiration

Valid: yes

Conclusion
The median lethal concentration LC_{50} of chloridazon for rainbow trout was > 31.6 < 46.4 mg/Lmg as/L. Using the regression analysis method 'moving averages' the LC_{50} was determined to be 41.3 mg/L. The NOEC was determined to be 21.5 mg as/L.

Reference number: II A 8.2.1/2
Report: Munk R., Kirsch P., 1990(a); WAT 2003-451
Report on the study of the acute toxicity. Reg.Nr. 13 033. Bluegill (*Lepomis macrochirus* RAF.) BASF AG, Ludwigshafen/Rhein, Germany; unpublished; BASF RegDoc# 1990/0186

Guidelines: EPA 72-1, EPA-SEP 540/9-85-006

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143, purity: 94.1 %; specification Document J; test species Bluegill sunfish (*Lepomis macrochirus* Raf.), mean body length 6.4 (5.6 - 7.4) cm, mean body weight 3.4 (2.1 - 4.8) g. Ten fish per aquarium (loading about 0.34 g fish/L) and per concentration were exposed to test substance concentrations of 21.5, 31.6, 46.4, 68.1, 100.0 and 147.0 mg as/L (nominal) and a water control in a static system for 96 h. Endpoints were mortality, LC_{50} and sublethal effects.

Findings
The analytically detected concentrations were initially in the range of 95.8 % - 97.9 % and after about 96 hours between 96.6 % - 98.8 % of the nominal concentrations. Hence, the biological results are based on the nominal concentrations.
Chloridazon caused no compound-related mortality to bluegill at nominal concentrations up to 68.1 mg as/L. Symptoms like narcotic-like state, tumbling and accelerated respiration could be observed in the 68.1 mg as/L and 100 mg as/L dose group. No other substance-related effects could be observed (Table B.9.2-2).

Table B.9.2-2: Acute toxicity (96 h) of chloridazon to Bluegill (*Lepomis macrochirus* Raf.)

Concentration (nominal) [mg as/L]	Control	21.5	31.6	46.4	68.1	100.0	147.0
Mortality [%]	0	0	10	0	0	70	100
Symptoms [1)]	none	none	none	none	N, T	N, T, X	--
Endpoints [mg as/L]							
LC_{50}	93.0						
NOEC	46.4						

1) Symptoms: N = narcotic-like state, T = tumbling, X = accelerated respiration

Valid: yes

Conclusion
The median lethal concentration LC_{50} of chloridazon on the bluegill was about 93 mg as/L. The NOEC was determined to be 46.4 mg as/L.

METABOLITES

Reference number: II A 8.2.1/3

Report: Munk R., Kirsch P., 1990(c), WAT 2003-452
Report on the study of the acute toxicity. Chloridazon-B-metabolite/Reg. No. 14 456. Rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792), unpublished. BASF RegDoc# 1990/0315

Guidelines: EPA 72-1, EPA-SEP 540/9-85-006

GLP: Yes

Material and methods
Metabolite B of chloridazon (Reg. No. 14 456), batch no. L 34-200, purity: 98.0 %, test species: Rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792), mean body length 6.2 (5.5 - 7.0) cm, mean body weight 3.0 (2.2 - 4.1) g. Ten fish per aquarium (loading about 0.3 g fish/L) and per concentration were exposed to test substance concentrations of 50 and 100 mg/L (3 replicates) (nominal) and a water control in a static system for 96 h. Endpoints were mortality, LC_{50} and sublethal effects.

Findings
The analytically detected concentrations were in the range of 95.8 % - 99.0 % of nominal values and after about 96 hours between 96.2 % and 99.0 % of the nominal concentrations. The biological results based on the nominal concentrations.
No adverse effects, neither mortality nor any toxic signs of the test item on the rainbow trout were observed up to a concentration of 100 mg/L, the highest concentration tested (Table B.9.2-3).

Table B.9.2-3: Acute toxicity (96 h) of metabolite B of chloridazon to the rainbow trout (*Oncorhynchus mykiss*)

Concentration (nominal) [mg/L]	Control	50	100	100 [1)]	100 [1)]
Mortality [%]	0	0	0	0	0
Symptoms	none	none	none	none	none
Endpoints [mg/L]					
LC_{50}	> 100.0				
NOEC	100.0				

1) for statistical reasons 3 replicates with 100 mg/L were tested, according to the requirements of the EPA-Guideline

Valid: yes

Conclusion
The LC_{50} of Metabolite B of chloridazon on rainbow trout was > 100.0 mg/L. The NOEC was determined to be 100.0 mg/L.

Reference number: II A 8.2.1/4

Report: Zok S., 1999; WAT 2003-454
Metabolite B-1 - Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792) in a static system (96 hours).
BASF AG, Ludwigshafen/Rhein, Germany; project # 12F0396/985118, unpublished,
BASF RegDoc# 1999/11845

Guidelines: EEC 84/449

GLP: Yes

Material and methods
Metabolite B-1 of chloridazon, batch no. 01196-259, purity: 99.7 %, test species rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792), mean body length 6.07 (5.8 - 6.6) cm, mean body weight 2.14 (1.8 - 2.7) g. Ten fish per aquarium (loading about 0.4 g fish/L) and per concentration were exposed to test substance concentrations of 1.00, 2.15, 4.64 and 10.00, 21.50, 21.50, 46.40, 100.00 mg (nominal) and a water control in a static system for 96 h. Endpoints were mortality, LC_{50} and sublethal effects.

Findings
The analytically detected concentration of the 100 mg/L test concentration was 99.3 % of nominal concentration at study start and 111.7 % of the nominal concentration at study end. Hence, the biological results are based on the nominal concentrations.
No mortality was observed up to a rate of 100 mg/L, the highest concentration tested. No other treatment-related effect could be observed (Table B.9.2-4).

Table B.9.2-4: Acute toxicity of Metabolite B-1 of chloridazon to rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L]	Control	Control	1.00	2.15	4.64	10.00	21.50	21.50	46.40	100.00
Mortality [%]	0	0	0	0	0	0	0	0	0	0
Symptoms	none	none	none	none	none	none	none	none	none	None
Endpoints [mg/L]										
LC_{50}	> 100.00									
NOEC	100.00									

Valid: yes

Conclusion
The median lethal concentration LC_{50} of Metabolite B-1 of chloridazon for rainbow trout was > 100 mg/L, the NOEC was 100 mg/L.

FORMULATED PRODUCTS

Reference number: III A 10.2.1/1

Report: Zok S., 2002; WAT 2003-223
BAS 119 33 H - Acute toxicity study on the rainbow trout (Oncorhynchus mykiss) in a static system over 96 hours BASF AG, Ludwigshafen/Rhein, Germany; report # 12F0775/005079, report # 12F0775/005079; unpublished
BASF DocID 2002/1008601

Guidelines: EPA 72-1, OECD 203, EEC 92/69 A V C 1

GLP: Yes

Materials and methods
BAS 119 33 H, batch no. 2001-1, content of active substance: 65.5 % Reg. No.13 033, test species rainbow trout (*Oncorhynchus mykiss*), obtained from "Forellenzucht Trostadt", Trostadt, Germany; mean body length 5.8 (5.2 - 6.5) cm, mean body weight 1.8 (1.3 - 2.4) g. Ten fish per aquarium (loading about 0.36 g fish/L) and per concentration were exposed to test substance concentrations of 5, 10, 22, 50 and 100 mg/L (nominal) and a water control in a static system for 96 h. Endpoints were mortality, LC_{50} and sublethal effects.

Findings
The analytically detected concentrations of BAS 119 33 H were within a range of 98.5 % - 100.6 % of the nominal value at test initiation and between 98.8 % - 100.8 % at test termination. Therefore, the biological results are based on nominal concentrations.

BAS 119 33 H caused no mortality up to a concentration of 50 mg/L. At 100 mg/L all fish had died at study termination. Symptoms like tottering, swimming at the bottom and apathy could be observed in fish of the two highest test item concentrations. Besides, no other substance-related effects could be observed during the study conduct (Table B.9.2-5).

Table B.9.2-5: Acute toxicity (96 h) of BAS 119 33 H to rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] nominal	Control	5	10	22	50	100
Mortality [%]	0	0	0	0	50	100
Symptoms [1)]	none	none	none	T, D	A	--
Endpoints [mg/L]						
LC_{50} (96 h)	50.0					
NOEC (96 h)	10.0					

1) Symptoms: A = apathy; D = swimming at the bottom; T = tottering

Valid: yes

Conclusion
In a static acute toxicity study on rainbow trout with BAS 119 33 H the LC_{50} (96 h) was 50.0 mg/L. The NOEC (96 h) was determined to be 10.0 mg/L (nominal).

B.9.2.1.2 Fish – prolonged toxicity

B.9.2.1.2.1 Chronic toxicity test on juvenile fish

ACTIVE SUBSTANCE

Reference number: II A 8.2.2.1/1

Report: Munk R., Kirsch P, 1989; WAT 2003-453
Sublethal toxic effects on rainbow trout (*Salmo gairdneri* RICH.) of Reg.Nr. 13 033; isomer reduced (chloridazon techn.) BASF AG, Ludwigshafen/Rhein, Germany; unpublished; project # 42F0174/885090;
BASF RegDoc# 1989/10059

Guidelines: OECD 204

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143, purity: 94.1 %; specification Document J, test species rainbow trout *Salmo gairdneri* RICH (*Oncorhynchus mykiss* WALBAUM 1792), mean body length 5.7 (5.2 - 6.1) cm, mean body weight 2.4 (1.9 - 2.8) g. Twenty fish per aquarium and per concentration were exposed to test substance concentrations of 0.1, 0.316, 1.0, 3.16, 10.0 and 31.6 mg as/L (nominal) and a water control in a flow-through system (28 days), flow rate of the test solution 10 L/h/aquarium. Endpoints were mortality, sublethal effects body weight and length.

Findings
The analytically detected concentrations of the test item in the water of the aquaria were initially in the range of 91 % and 104.7 % of the nominal concentrations and at the end of the

study in the range of 82 % and 103.8 %. The biological results are therefore based on the nominal concentrations.
Mortalities only occurred in the highest test concentration (31.6 mg as/L.) starting day 4. In this test group all fish were dead on day 21. The highest concentration tested with no mortalities was 10 mg as/L. Thus, the threshold level of lethal effects was greater 10 mg as/L and smaller 31.6 mg as/L. Compound-related toxic signs (reduced or no feed consumption, discoloration, apathy, accelerated respiration, convulsions, spasms, side position, lying on the bottom of the aquaria) were observed only in the 31.6 mg as/L test item concentration starting on day 1 and lasting until all fish had died. The individual body weights and lengths were close together in all test item groups, except in the 10.0 mg as/L test item concentration. The mean body length of the 10.0 mg as/L test item concentration showed statistically significant differences compared to the control (Dunnett-test, $\alpha = 0.05$) (Table B.9.2-6).

Table B.9.2-6: Sublethal toxicity (28 d) of chloridazon to rainbow trout (*Oncorhynchus mykiss*)

Concentration (nominal) [mg as/L]	Control	0.1	0.316	1.0	3.16	10.0	31.6
Mortality [%]	0	0	0	0	0	0	100
Symptoms	none	none	none	none	none	none	none
Mean weight [g]	7.48	7.68	7.49	7.71	7.54	6.36 n.s.	--
Mean length [cm]	8.4	8.67	8.60	8.58	8.54	7.84 *	--
Endpoints [mg as/L]							
NOEC	3.16						

* statistically significant differences compared to the control (Dunnett-test; $\alpha = 0.05$)
n.s. = no statistically significant differences compared to the control (Dunnett-test; $\alpha = 0.05$)

Valid: yes

Conclusion
Under conditions of this study the overall NOEC (including symptoms and growth) after 28 days was determined to be 3.16 mg as/L (nominal) for rainbow trout.

B.9.2.1.2.2 Fish early life stage toxicity test

The test item is of low chronic toxicity to fish (NOEC = 3.16 mg/L), there is no indication for bioconcentration (see below) or other chronic concerns, thus a fish early life stage study is not required.

B.9.2.1.2.3 Fish life cycle test

The test item is of low chronic toxicity to fish (NOEC = 3.16 mg/L), there is no indication for bioconcentration (see below) or other chronic concerns, thus a fish life cycle test is not required.

B.9.2.1.3 Bioconcentration in fish

B.9.2.1.3.1 Bioconcentration potential of the active substance

The active substance chloridazon is a rather polar compound with a partition coefficient log P_{OW} of 1.2 [1987/5075 Patel J.R. 1987]. Therefore, a bioconcentration study in fish is not necessary and was not conducted.

B.9.2.1.3.2 Bioconcentration potential of metabolites, degradation and reaction products

Reference number: II A 8.2.3/1

Report: Daum A., 2002; WAT 2003-455
Determination of the n-octanol/water partition-coefficient of Reg. No. 035 375 (BAS 119 H metabolite B-1) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF RegDoc# 2002/1010433

Guidelines: OECD 117

GLP: Yes

Material and methods
The regression line of log P_{OW} = f (log k') of 5 calibration items was used to determine the log P_{OW} - value of Reg. No. 35375 (metabolite B-1 of chloridazon) by linear interpolation.
C18-RP-HPCL with two different effluent mixtures was used to obtain the k' values at 20 °C.

Findings
Metabolite B-1 of chloridazon has a log P_{OW} of 0.43 and 0.23 at 20 °C at neutral pH conditions. Methanol/water mixtures were used as the mobile phases. The accuracy ranges were 0.13 and 0.08, respectively. The log P_{OW} mean value was calculated to be 0.33 (P_{OW} = 2).

Reference number: II A 8.2.3/2

Report: Redeker J., 1989; WAT 2003-456
Determination of the Octanol/water-partition coefficient of LAB 14456. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF RegDoc# 1989/10166

Guidelines: OECD 107

GLP: Yes

Material and methods
The regression line of log P_{OW} = f (lg k') of 5 reference items was used to determine the log P_{OW} value of metabolite B (LAB 14456) by linear interpolation. RP18-HPCL was used to receive the k' values.

Findings
With the effluent mixture of 30/70 methanol water the log P_{OW} was 0.56, with a mixture of 20/80 methanol/water the log P_{OW} was 0.57. The P_{OW} of metabolite B has uncertainty values of 0.09 and 0.1, respectively. LAB 14456 has a log P_{OW} average of ca. 0.57 ± 0.10.

Valid: yes

Conclusion
Chloridazon metabolite B is more polar than the parent compound with a log P_{OW} of 0.57 [1989/10166, Redeker J., 1989]. The octanol/water partition coefficient (log P_{OW}) of chloridazon metabolite B-1 was determined to be 0.33, thus being in a similar range [2002/1010433, Daum A., 2002].
Accordingly, these metabolites have no potential for accumulation in fish and a respective study was not performed.

B.9.2.1.4 Invertebrates – acute toxicity

ACTIVE SUBSTANCE

Reference number: II A 8.2.4/1

Report: Jatzek H.-J., 1990; WAT 2001-546
Determination of the acute toxicity of chloridazon techn. Reg.Nr. 13 033 to the waterflea *Daphnia magna* STRAUS BASF AG, Ludwigshafen/Rhein, Germany; report # 1/0537/2/89-1890537; unpublished; BASF RegDoc# 1990/10074

Guidelines: EEC 79/831 A V C 2

GLP: Yes

Materials and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143, purity: 94.1 %; specification Document J., test species waterflea (*Daphnia magna* STRAUS), neonates with age at test initiation less than 24 hours. 4 replicates with 5 daphnids in each were exposed to test substance concentrations of 12.5, 25, 50, 100 and 200 mg as/L (nominal) and a water control in a static system. Assessment of immobility (and other effects) was done after 0, 3, 6, 24 and 48 hours, endpoints were EC_{50} and number of immobile daphnia.

Findings
Analytical verification of test item was carried out using three concentrations at time zero and at the end of the test after 48 hours. The measured values ranged from 99.9 % to 102.5 % of nominal at the beginning of the test, from 99.8 % to 100.9 % with daphnids and from 99.8 % to 101.9 % without daphnids at the end of the test (recalculated from original data). The test

concentrations were thus confirmed and the following biological results are based on nominal concentrations.
Chloridazon had no significant effects on daphnia immobility (i.e. immobility above the allowed range or 10 % for controls) up to a concentration of 100 mg as/L. No other effects were observed.

Table B.9.2-7: Effect of chloridazon on *Daphnia magna* immobility

Concentration (nominal) [mg as/L]	Control	12.5	25	50	100	200
Immobile (24 h) [%]	0	0	0	0	0	25
Immobile (48 h) [%]	0	0	0	0	10	100
Endpoints [mg as/L]						
EC_{50} (48 h)	132.0					
NOEC (48 h)	100.0					

Valid: yes

Conclusion
In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} of chloridazon was determined to be 132.0 mg as/L, the NOEC was 100.0 mg as/L (nominal).

METABOLITES

Reference number: II A 8.2.4/2

Report: Elendt-Schneider B., 1991; WAT 1999-328
Determination of the acute toxicity of chloridazon-metabolite B (PS. Nr. 14 456) to the water flea *Daphnia magna* STRAUS
BASF AG, Ludwigshafen/Rhein, Germany; report # 1/90/0128/5072; unpublished; BASF RegDoc# 1991/10120

Guidelines: EEC 79/831 A V C 2

GLP: Yes

Material and methods
Metabolite B of chloridazon (Reg. No. 14 456), batch No. L 34/200, purity: 98 %, test species water flea (*Daphnia magna* STRAUS), neonates collected from in house culture supplied by Institut National de Recherche Chimique Appliquée, France, age at test initiation less than 24 hours. 4 replicates with 5 daphnids in each were exposed to test substance concentrations of 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg/L (nominal) and a water control in a static system. Assessment of immobility (and other effects) was done after 0, 3, 6, 24 and 48 hours, endpoints were EC_{50} and number of immobile daphnia.

Findings
Analytical verification of test item was conducted in each concentration at the beginning and at the end of the test. Measured values at test initiation ranged from 100.8 % to 102.9 % of nominal, from 104.7 % to 108.9 % without daphnids and from 102.4 % to 103.5 % with

daphnids of nominal at test termination, confirming the theoretical concentrations. Therefore, the following biological results are based on nominal concentrations.
Immobility of the daphnids was not observed.

Table B.9.2-8: Effects of metabolite B of chloridazon on *Daphnia magna* immobility

Concentration (nominal) [mg/L]	Control	1.56	3.13	6.25	12.5	25	50	100
Immobile (24 h) [%]	0	0	0	0	0	0	0	0
Immobile (48 h) [%]	0	0	0	0	0	0	0	0
Endpoints [mg/L]								
EC_0 (48 h)	100.0							
EC_{50} (48 h)	> 100.0							
EC_{100} (48 h)	> 100.0							

Valid: yes

Conclusion
In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} (48 h) of metabolite B of chloridazon was determined to be > 100 mg/L, the EC_0 (48 h) was 100 mg/L (nominal).

Reference number: II A 8.2.4/3

Report: Jatzek H.J., 1999; WAT 2003-457
Determination of the acute effect of BH 119-BI on the swimming ability of the water flea *Daphnia magna* STRAUS according to OECD 202 and GLP, EN 45001 and ISO 9002 BASF AG, Ludwigshafen/Rhein, Germany; project # 99/0080/50/1 unpublished; BASF RegDoc# 1999/10560

Guidelines: EEC 92/32 A V C 2, OECD 202, EPA 850.1010, ISO 6341, ISO/DIS 10706

GLP: Yes

Material and methods
Metabolite B-1 of chloridazon (Reg. No. 035 375), batch no. 01196-259, purity: 99.7 %, test species waterflea (*Daphnia magna* STRAUS), supplied by the Institut National de Recherche Chimique Appliquée, France, age at test initiation less than 24 hours. 4 replicates with 5 daphnids in each were exposed to test substance concentrations of 3.13, 6.25, 12.5, 25, 50 and 100 mg/L (nominal) and a water control in a static system. Assessment of immobility (and other effects) was done after 0, 24 and 48 hours, endpoints were EC_{50} and number of immobile daphnia.

Findings
Analytical verification of test item was conducted for 100 mg/L, 25 mg/L and 3.13 mg/L at the beginning and at the end of the test. Measured values at test initiation ranged from 100.1 % to 102.1 % of nominal, at test termination without daphnids from 100.5 % to 102.1 % of nominal and with daphnids from 101.6 % to 102.2 %, confirming the theoretical

concentrations. Therefore, the following biological results are based on nominal concentrations.
No significant immobility of the daphnids was observed. At the end of the test the daphnids in the highest concentration (100 mg/L) were moving less agile than in the controls and the other concentrations.

Table B.9.2-9: Effects of metabolite B-1 of chloridazon on *Daphnia magna* immobility

Concentration (nominal) [mg/L]	Control	3.13	6.25	12.5	25	50	100
Immobile (24 h) [%]	0	0	0	0	0	0	0
Immobile (48 h) [%]	0	0	0	0	0	0	5
Endpoints [mg/L]							
EC_0 (48 h)	100.0						
EC_{50} (48 h)	> 100.0						

Valid: yes

Conclusion
In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} (48 h) of metabolite B-1 of chloridazon was determined to be > 100 mg/L, the EC_0 (48 h) was 100 mg/L.

FORMULATED PRODUCTS

Reference number: III A 10.2.1/2

Report: Dohmen P., 2000; WAT 2003-468
Effect of BAS 119 33 H on the immobility of *Daphnia magna* STRAUS in a 48 hour static, acute toxicity test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 58106; unpublished;
BASF RegDoc# 2000/1011469

Guidelines: OECD 202, EPA 72-2, EPA 850.1010, EEC 79/831 A V C 2

GLP: Yes

Materials and methods
BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13 033, test species waterflea (*Daphnia magna* STRAUS), neonates, less than 24 hours old, source: clone of daphnia originally derived from INRA, France, neonates collected from in house culture. Four replicates with 5 daphnids in each were exposed to test substance concentrations of 10, 18, 32, 56 and 100 mg/L (nominal) and a water control in a static system. Assessment of immobility (and other effects) was done after 24 and 48 hours, endpoints were EC_{50} and number of immobile daphnia.

Findings
Analytical verification of the test item concentrations was conducted in each concentration at the beginning and at the end of the test. Measured values at test initiation ranged from 101.6 % - 106.5 % (average 102.9 %). At test termination the measured values ranged from 101.3 % - 103.5 % (average 102.7 %) of nominal, confirming the nominal values. Therefore, the following biological results are based on nominal concentrations.
65 % of the daphnids exposed to 100 mg/L and 30 % exposed to 56 mg/L were immobile after 48 hours. No other effects were observed at lower concentrations (Table B.9.2-10).

Table B.9.2-10: Effect of BAS 119 33 H after 24 h and 48 h on *Daphnia magna* immobility

Concentration [mg/L] nominal	Control	10	18	32	56	100
Immobile (24 hours) [%]	0	0	0	0	0	0
Immobile (48 hours) [%]	0	0	0	0	30	65
Endpoints [mg/L]						
EC_{50} (48 h)	79.5 (95 % confidence limits: 65.5 - 96.5 mg/L)					

Valid: yes

Conclusion
In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 119 33 H was determined to be 79.5 mg/L, the NOEC is 32 mg/L.

B.9.2.1.5 Invertebrates – long-term toxicity

ACTIVE SUBSTANCE

Reference number: II A 8.2.5/1

Report: Dohmen G.P., 1994; WAT 2003-459
Effect of BAS 119 H on the reproduction of *Daphnia magna* STRAUS in a chronic toxicity test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; report # 3967; unpublished; BASF RegDoc# 1994/10205

Guidelines: OECD 202, EEC XI/681/86

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 185, purity: 93.69 %; specification Document J. First instars of *Daphnia magna* STRAUS (< 24 h old, 10 x 1 animal per concentration) under static renewal conditions were exposed for 21 d to nominal concentrations of 1.5, 3.0, 6.0, 10, 20 and 40 mg as/L plus control. Assessment was made on parent mortality and reproduction capacity.

Findings
Measured values at test initiation ranged between 96.4 % and 103.6 % and between 74.6 % and 90.9 % at test termination, confirming in general the theoretical values. The following biological results are thus based on nominal concentrations.
Only concentrations of chloridazon greater than 10 mg as/L had a significant negative effect on daphnid reproduction. At 20 mg as/L aborted eggs were observed. Mortalities occurred in the two highest dose groups (at the highest test concentration all daphnids died on day 4).

Table B.9.2-11: Effect of chloridazon of *Daphnia magna* STRAUS on the reproduction and parent mortality

Concentration (nominal) [mg as/L]	Control	1.5	3.0	6.0	10.0	20.00	40.00
Offspring/parent	132	138	145	139	123	8.3*	0*
Parent-mortality [%]	0	0	0	0	0	50*	100*
Endpoints [mg as/L]							
NOEC (21 d)	10.0						
LOEC (21 d)	20.0						

***** statistically significant difference from control

Valid: yes

Conclusion
In a 21-day static renewal chronic toxicity study with *Daphnia magna* the NOEC of chloridazon was determined to be 10 mg as/L (nominal).

Reference number: National data, included by RMS

Report: Jatzek H.-J., 1989; WAT 1999-333
Bestimmung der Langzeitwirkung von Chloridazon tech. Reg.-Nr. 13033 N 143 auf die parthenogenetische Reproduktionsrate des Wasserflohs *Daphnia magna*. BASF AG, Germany, project # 03/0537/89; unpublished

Guidelines: EEC XI/681/86

GLP: yes

Material and methods
Chloridazon (Reg. No. 13 033), batch no. N 143, purity: 94.1 %. First instars of *Daphnia magna* STRAUS (< 24 h old, 10 x 1 animal per concentration) under static renewal conditions were exposed for 21 d to nominal concentrations of 7.81, 15.6, 31.2, 62.5, 125.0 and 250 mg as/L plus control. Assessment was made on parent mortality and reproduction capacity.

Findings
Analytical determination of the test substance concentrations showed values between 99.1 % and 100.0 % at test initiation and between 100.0 % and 101.3 % at test termination, confirming the theoretical values. The following biological results are thus based on nominal concentrations.

Effects on daphnid reproduction as reduction of the reproduction rate were seen in every concentration, subitane eggs were found in the 7.81, 15.6 and 31.2 mg/L variants. 100 % mortality of the parent animals occurred from 62.5 mg/L on. The determination of a NOEC was not possible. But due to the clear dose-response relationship of the effects, an EC_{10} of 6.23 mg/L was termined by probit analysis.

Table B.9.2-12: Effect of chloridazon of *Daphnia magna* STRAUS on the reproduction and parent mortality

Concentration [mg as/L]	Control	7.81	15.6	31.2	62.5	125.00	250.00
Reproduction rate	113.5	79.8	91.2	21.3	0	0	0
Parent-mortality [%]	0	0	0	10.0	100.0	100.0	100.0
Endpoints [mg as/L]							
NOEC (21 d)	<7.81						
EC_{10} (21 d)	6.23						

Conclusion:
In a 21-day static renewal chronic toxicity study with *Daphnia magna* an EC_{10} for chloridazon was determined to be 6.23 mg as/L.

B.9.2.1.6 Algae

ACTIVE SUBSTANCE

Reference number: II A 8.2.6/1

Report: Dohmen G.P., 1992; WAT 2001-545
Effect of Reg. No. 13 033 on the growth of the green alga *Ankistrodesmus bibraianus* BASF AG, Agrarzentrum Limburgerhof, Limburgerhof,
Germany; report # 3383; unpublished; BASF RegDoc# 1992/11796

Guidelines: OECD 201

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 143. purity: 93.75 %; specification Document J. Unicellular fresh water green alga *Ankistrodesmus bibraianus* (Reinsch) Korshikov (syn.: *Selenastrum capricornutum*), SAG B 61.81, stock obtained from „Sammlung Algenkulturen", Göttingen (FRG), cultures maintained in-house, were exposed under static conditions (shake cultures) for 72 h to concentrations of 0.03, 0.1, 0.25, 0.50, 1.0 and 3.0 mg as/L (nominal), each with 5 replicates plus control (ten replicates). Initial cell densities were 3×10^4 cell/mL. Endpoints had been effects on growth rate and development of biomass after exposure over 72 hours.

Findings
Average measured test concentrations were initially between 102.0 % and 107.8 % of nominal and between 102.0 % and 102.8 % of nominal at the end of the test. Therefore, the following results are based on nominal concentrations.

No morphological effects on the algae could be observed (Table B.9.2-13).

Table B.9.2-13: Effect of chloridazon on the growth of *Ankistrodesmus bibraianus*

Concentration [mg as/L]	0.03	0.1	0.25	0.50	1.00	3.00
Growth inhibition [%]	- 10.4	10.3	25.8	43.0	71.2	89.1
Endpoints [mg as/L]						
E_rC_{50} (0-72 h)		> 3.0	(extrapolated: 3.7; 95 % limits: 3.13 - 4.56)*			
E_rC_{10} (0-72 h)		0.42	(95 % limits: 0.32 - 0.52)*			
E_bC_{50} (0-72 h)		0.6	(95 % limits: 0.51 - 0.69)*			
E_bC_{10} (0-72 h)		0.11	(95 % limits: 0.07 - 0.15)*			
NOEC		0.10				

* recalculated by RMS using ToxRat ® 2.07. ToxRat Solutions GmbH, Ahlsdorf, Germany

Valid: yes

Conclusion
In a 72-hour algae test with *Ankistrodesmus bibraianus* the E_bC_{50} of chloridazon was determined to be 0.6 mg as/L, the E_bC_{10} was 0.11 mg as/L. The E_rC_{50} was > 3.0 mg as/L and the E_rC_{10} was 0.42 mg as/L.

Comment of RMS:
Since EC-values for growth rate were not reported by the notifier, these values were calculated by the RMS based on the raw data of the report. The recalculated EC-values for biomass are identical with the reported values. The obtained EC-values for the active substance are in good agreement with the EC-values for the formulation related to the active substance content. The tests confirm that the E_rC_{50} is > 1 mg/L.

Reference number: II A 8.2.6/2

Report: Kubitza J, 1999; WAT 2001-544
Effect of BAS 119 H on the growth of the blue-green alga *Anabaena flos-aquae* BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany, report # 43924; unpublished; BASF RegDoc# 1999/10036

Guidelines: ASTM E 1218-90, OECD 201, EPA 850.1000

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 185, purity: 93.7 %; specification Document J. Blue-green alga *Anabeana flos-aquae* (Lyngbye) de Brèbisson, SAG B 30.87, stock obtained from „Sammlung Algenkulturen“, Göttingen (FRG), cultures maintained in-house, were exposed under static conditions (shake cultures) for 96 h to concentrations of 0.03, 0.1, 0.3, 1.0, 3.0, 10.0 and 30.0 mg as/L (nominal), each with 5 replicates plus control (ten replicates). Initial cell densities were 3 x 10^4 cell/mL. Endpoints had been effects on growth rate and development of biomass after exposure over 96 hours.

Findings
Average measured test concentrations ranged at test initiation from 99.5 % to 108.9 % (average 104.6 %) of nominal and from 103.1 % to 113.4 % (average 107.0 %) of nominal at the end of the test. Therefore, the following results are based on nominal concentrations.
No morphological effects on the algae could be observed, the effects on growth are summarised in the following table (Table B.9.2-14).

Table B.9.2-14: Effect of chloridazon on the growth of blue-green alga *Anabaena flos-aquae*

Concentration [mg as/L]	0.03	0.1	0.3	1.0	3.0	10.0	30.0
Inhibition (biomass) [%]	7.2	7.8	11.4	36.0	64.6	85.4	93.6
Inhibition (growth rate) [%]	4.1	3.4	5.1	19.3	39.3	67.8	84.2
Endpoints [mg as/L]							
E_rC_{50} (0-96 h)	4.57 (95 % limits: 2.75 - 8.36)						
E_rC_{10} (0-96 h)	0.31 (95 % limits: 0.12 - 0.59)						
E_bC_{50} (0-96 h)	1.60 (95 % limits: 0.96 - 2.63)						
E_bC_{10} (0-96 h)	0.13 (95 % limits: 0.05 - 0.25)						

Valid: yes

Conclusion
In a 96-hour algae test with *Anabaena flos-aquae* the E_rC_{50} was determined to be 4.57 mg/L, the E_bC_{50} of chloridazon was determined to 1.6 mg as/L.

METABOLITES

Reference number: II A 8.2.6/3

Report: Jatzek H.-J., 2002; WAT 2003-458
Reg. No. 14456 (metabolite of BAS 119 H, chloridazon) - Determination of the inhibitory effect on the cell multiplication of unicellular green algae
BASF AG, Ludwigshafen/Rhein, Germany; project # 02/0125/60/1; unpublished; BASF RegDoc# 2002/1006171

Guidelines: EEC 92/69, OECD 201, EPA 850.5400

GLP: Yes

Material and methods
Metabolite B of chloridazon (Reg. No. 14 456), batch no. 41-216, purity: 99.8 %. Unicellular fresh water green algae, *Pseudokirchneriella subcapitata* Korshikov, SAG 61.81, stock obtained from „Sammlung Algenkulturen“, Göttingen, Germany; cultures maintained in-house, were exposed under static conditions (shake cultures) for 72 h to concentrations of 6.25, 12.5, 25.0, 50.0 and 100.0 mg/L (nominal), each with 3 replicates plus control (five replicates). Initial cell densities were 1 x 10^4 cell/mL. Endpoints had been effects on growth rate and development of biomass after exposure over 72 hours.

Findings
Mean measured test concentrations ranged from 100 % to 103 % of nominal at the beginning and from 90.9 % to 98.7 % at the end of the test. Therefore, the following results are based on nominal concentrations. No morphological effects were observed at concentrations up to 100 mg/L. The relative growth inhibition values at different concentrations of metabolite B of chloridazon are depicted below (Table B.9.2-15).

Table B.9.2-15: Effect of metabolite B of chloridazon on the growth of *Pseudokirchneriella subcapitata*

Concentration [mg/L]	Control	6.25	12.5	25.0	50.0	100.0
Inhibition (biomass) [%]	0	- 1.46	2.92	1.37	19.4	26.8
Inhibition (growth rate) [%]	0	0.54	1.10	- 0.37	6.09	6.80
Endpoints [mg/L]						
E_rC_{50} (72 h)	> 100.0					
E_rC_{10} (72 h)	> 100.0					
E_bC_{50} (72 h)	> 100.0					
E_bC_{10} (72 h)	34.8					

Valid: yes, see comment of the RMS

Conclusions
In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_bC_{50} of metabolite B of chloridazon was determined to be > 100 mg/L, the E_bC_{10} was 34.8 mg/L. No morphological effects could be observed.

Comment of the RMS:
Study accepted in consideration to the reported calibration curves produced independently of the studies in time intervals of approximately three month.

Reference number: II A 8.2.6/4

Report: Reuschenbach P., 1999; WAT 2003-460
Determination of the inhibitory effect of BH 119-BI on the cell multiplication of unicellular green algae according to OECD 201 and GLP, EN 45001 and ISO 9002 BASF AG, Ludwigshafen/Rhein, Germany; report # 99/0080/60/1; unpublished; BASF RegDoc# 1999/10544

Guidelines: EEC 92/32 A V C 3, OECD 201, EPA 850.5400

GLP: Yes

Material and methods
Metabolite B-1 of chloridazon (Reg. No. 035375), batch no. 01196-259, purity: 99.7 %. Unicellular fresh water green algae *Scenedesmus subspicatus* Chodat, SAG 86.81, stock obtained from „Sammlung Algenkulturen“, Göttingen, Germany; cultures maintained in-house, were exposed under static conditions (shake cultures) for 72 h to nominal concentrations of 0.78, 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg/L, plus controls, each with 3 replicates. Initial cell

densities were 1 x 10^4 cell/mL. Endpoints had been effects on growth rate and development of biomass after exposure over 72 hours.

Findings
The analytical results vary between 99.2 % and 102.2 % of the nominal concentrations at test initiation and between 94.2 % to 97.3 % at test termination. The analytical results confirm the theoretical concentrations in the carrier. Therefore, all biological results are related to the nominal concentrations of the test item.
No morphological effects on the algae could be observed; the effects of metabolite B-1 on the algae are summarised in the following table (Table B.9.2-16).

Table B.9.2-16: Effect of metabolite B-1 of chloridazon on the growth of *Scenedesmus subspicatus*

Concentration [mg/L] nominal	Control	0.78	1.56	3.13	6.25	12.5	25	50	100
Inhibition (biomass) [%][1)]	0	-20.9	-11.3	-14.1	-23.3	26.9	67.5	83.1	95.0
Inhibition (growth rate) [%][1)]	0	-4.9	-2.0	-2.8	-5.3	10.0	35.3	61.1	93.6
	Endpoints [mg/L]								
E_rC_{50} (0-72 h)	37.1								
E_rC_{10} (0-72 h)	12.5								
E_bC_{50} (0-72 h)	18.6								
E_bC_{10} (0-72 h)	9.90								

1) Negative values indicate stimulated growth

Valid: yes, see comment of the RMS

Conclusion
In a 72-hour algae test with *Scenedesmus subspicatus* the E_rC_{50} of metabolite B-1 of chloridazon was determined to be 37.1 mg/L, the E_bC_{50} was 18.6 mg/L (nominal).

Comment of the RMS:
Study accepted in consideration to the reported calibration curves produced independently of the studies in time intervals of approximately three month.

FORMULATED PRODUCTS

Reference number: III A 10.2.1/3

Report: Kubitza J., 2000; WAT 2001-548
Effect of BAS 119 33 H on the growth of the green alga *Pseudokirchneriella subcapitata* BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 58104; unpublished; BASF RegDoc# 2000/1011468

Guidelines: OECD 201

GLP: Yes

Materials and methods

BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033. Unicellular fresh water green algae, *Pseudokirchneriella subcapitata* Korshikov (Reinsch) (syn. *Selenastrum capricornutum* Prinz) SAG 61.81, stock obtained from „Sammlung Algenkulturen", Göttingen, Germany; cultures maintained in-house, were exposed under static conditions (shake cultures) for 72 h to nominal concentrations of 0.05, 0.12, 0.3, 0.7, 1.7, 4 and 10 mg/L, each with 5 replicates plus control (ten replicates). Initial cell densities were 1 x 10^4 cell/mL. Endpoints had been effects on growth rate and development of biomass after exposure over 72 hours.

Findings

Analytical verification of test item concentrations was conducted in each concentration at test initiation and at test termination. Measured values ranged from 102.1 % - 114.4 % (average of 106.5 %) of the nominal concentration at test initiation. At the end of the test 97.5 % - 103.9 % (average of 101.4 %) of the nominal concentration were detected, confirming the nominal values. Therefore, the following biological results are based on nominal concentrations.

No morphological effects on the algae could be observed; the effects of BAS 119 33 H on alga growth are summarised in the following table (Table B.9.2-17).

Table B.9.2-17: Effect of BAS 119 33 H on the growth of the green alga *Pseudokirchneriella subcapitata*

Concentration (nominal) [mg/L]	Control	0.05	0.12	0.3	0.7	1.7	4	10
Inhibition in 72 h (biomass) [%][1)]	0	-0.2	9.0	9.4	26.4	72.1	92.7	98.5
Inhibition in 72 h (growth rate) [%]	0	0.1	2.1	1.9	5.4	25.1	53.3	75.4
Endpoints [mg/L]								
E_rC_{50} (0-72 h)	4.01 (95 % limits: 3.78 - 4.26 mg/L)							
E_rC_{10} (0-72 h)	0.73 (95 % limits: 0.68 - 0.80 mg/L)							
E_bC_{50} (0-72 h)	0.99 (95 % limits: 0.95 - 1.04 mg/L)							
E_bC_{10} (0-72 h)	0.24 (95 % limits: 0.23 - 0.26 mg/L)							

1) Negative values indicate stimulated growth

Valid: yes

Conclusion

In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_bC_{50} of BAS 119 33 H was determined to be 0.99 mg/L, the E_bC_{10} was 0.24 mg/L (nominal).

B.9.2.1.7 Aquatic plants

ACTIVE SUBSTANCE

Reference number: II A 8.2.8/1

Report: Dohmen P., 2000; WAT 2001-543
Effect of BAS 119 H on the growth of *Lemna gibba* in a seven day static toxicity test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 43972; unpublished; BASF RegDoc# 2000/1011448

Guidelines: EPA 850.4400, EPA 123-2, ASTM E 1415-91

GLP: Yes

Material and methods
Chloridazon (BAS 119 H, Reg. No. 13 033), batch no. N 185, purity: 93.4 %; specification Document J. Duckweed, (*Lemna gibba* G3), stock obtained from the Ecotoxicology department of Ciba Geigy, Basel, cultures maintained in-house, was exposed to nominal test substance concentrations of 0.003, 0.01, 0.032, 0.1, 0.316, 1.0 and 3.16 mg as/L under static conditions for 7 days. Each treatment was run with 3 replicates plus a control with 6 replicates; 2 plants with four fronds and 2 plants with three fronds, total number of fronds at test initiation: 14. Growth and other effects were assessed on day 3, 5 and 7, effects on growth rate and development of biomass after exposure over 7 days.

Findings
Analytical verification of test concentrations was carried out in each concentration. Mean measured values were 98.2 % of nominal at test initiation (ranging from 94.6 % - 100.4 %) and 98.8 % (93.6 % - 102.3 %) of nominal at the end, confirming the theoretical concentrations. Therefore, the following biological results are based on nominal concentrations.
A statistically significant reduction in growth was observed at the highest test concentration, a smaller reduction was observed in the 0.316 mg as/L dose group. At the highest concentration the new fronds also remained smaller as compared to the control (Table B.9.2-18).

Table B.9.2-18: Effect of chloridazon on duckweed (*Lemna gibba*)

Concentration [mg as/L] nominal	0.003	0.01	0.032	0.1	0.316	1.0	3.16
Inhibition (growth rate) [%]	4.1	2.1	2.9	2.6	5.8	9.4	22.6
Inhibition (frond nc.) [%]	11.8	6.1	8.4	7.6	15.9	24.8	50.0
Endpoints [mg as/L]							
E_rC_{50}	> 3.16						
E_rC_{20}	3.35 (95 % limits: 2.10 - 5.34)						
E_bC_{50}	3.03 (95 % limits: 2.67 - 3.39)						
NOEC	0.1						
LOEC	0.316						

Valid: yes

Conclusion
In a 7-day aquatic-plant test with *Lemna gibba* the E_rC_{50} of chloridazon was determined to be > 3.16 mg/L, the E_bC_{50} was 3.03 mg as/L.

B.9.2.1.8 Sediment-dwelling organisms

Even though > 10 % of applied radioactivity of active substance were found in the sediment from day 1 on, no study on sediment dwelling organism is required, since the NOEC in the *Daphnia* reproduction test is > 0.1 mg as/L (SANCO/3268/2001 Aquatic Guidance Document on Aquatic Ecotoxicology).

B.9.2.1.9 Microcosm or mesocosm study

No study performed. No study required.

B.9.2.2 Summary of aquatic toxicity data

The effects of the active substance chloridazon, the formulation and the metabolites on aquatic organisms are summarised below (Table B.9.2-19).

Acute toxicity
As expected for a herbicide, effects on aquatic plants were more pronounced. The active substance chloridazon is very toxic for algae based on biomass inhibition. The biomass EC_{50} of the active substance was determined using the green alga *Pseudokirchneriella subcapitata* with 0.6 mg/L and was the lowest EC_{50} value. The EC_{50} for inhibition of growth rate related to the active substance was found to be 2.6 mg as/L. Since chloridazon is used as a herbicide, additional tests with an algal species from a different taxonomic group and with aquatic macrophytes are required. The sensitivity of these organisms was comparable or slightly smaller compared to *Pseudokirchneriella subcapitata.*
Fish and daphnids are less sensitive than algae at acute exposure, based on their LC_{50} and EC_{50} of 41.3 and 132 mg as/L respectively. Therefore, the product can be classified as toxic to aquatic organisms.
The acute toxicity of the formulation is in the concentration range as expected from the active substance content. The LC_{50} and EC_{50} are 32.8 and 52 mg as/L, respectively. Regarding daphnia toxicity, the factor of 2.5 is in the range of normal laboratory variation.

Chronic toxicity
Long-term effects on fish and daphnia were performed with the active substance. Of the two chronic tests the NOEC for juvenile growth of 3.16 mg as/L was the most sensitive endpoint beside the NOEC for biomass of the 72 h algae growth inhibition test of 0.1 mg as/L.

Metabolites
The main metabolite (metabolite B) proved to be of low acute toxicity to fish, daphnia and algae with EC_{50} values > 100 mg/L. The minor metabolite B-1 is also of low toxicity to fish and daphnia (EC/LC_{50} > 100 mg/L), however, the E_bC_{50} of 18.6 mg/L indicate that metabolite B-1 is harmful to algae.
In the submitted water/sediment study the parent compound BAS 119 H and metabolite B are the relevant residues, which appeared in concentrations up to 43 % in the water but only up to

7 % in the sediment. However, tests with water organisms showed that the metabolite is of clearly lower toxicity than the parent compound and can be considered to be ecotoxicologically non-relevant.

Table B.9.2-19: Summary of effects of chloridazon and its metabolites on aquatic organisms

Species	Test system Duration	Parameter	NOEC (mg/L)	EC / LC_{50} (mg/L)	Related to conc:[4)]
Chloridazon as BAS 119 H					
O. mykiss	static - 96 h	Mortality	21.5	41.6	nominal
L. macrochirus	static - 96 h	Mortality	46.4	93.0	nominal
D. magna	static - 48 h	Immobilisation	100.0	132.0	nominal
O. mykiss	flow-through - 28 d	Juvenile growth	3.16	n.d.	nominal
D. magna	static renewal - 21 d	Reproduction	6.23 [2)]	n.d.	nominal
D. magna	static renewal - 21 d	Reproduction	10.0	n.d.	nominal
P. subcapitata[1)]	static - 72 h	Biomass Growth rate	0.1 [2)] 0.42 [2)]	0.6 > 3.0	nominal
A. flos-aquae	static - 96 h	Biomass Growth rate	0.13 [2)] 0.31	1.60 4.57	nominal
L. gibba	static - 7 d	Frond no. Growth rate	0.1 0.1	3.03 > 3.16	nominal
Formulation BAS 119 33 H					
O. mykiss	static - 96 h	Mortality	10.0 (6.55 as)	50.0 (32.8 as)	nominal
D. magna	static - 48 h	Immobilisation	32 (20.6 as)	79.5 (52 as)	nominal
P. subcapitata	static - 72 h	Biomass Growth rate	0.24 (0.16 as) [2)] 0.73 (0.48 as) [2)]	0.99 (0.65 as) 4.01 (2.62 as)	nominal
Metabolite B					
O. mykiss	static - 96 h	Mortality	100	> 100	nominal
D. magna	static - 48 h	Immobilisation	> 100 [3)]	> 100	nominal
P. subcapitata	static - 72 h	Biomass Growth rate	34.8 [2)] > 100 [2)]	> 100 > 100	nominal
Metabolite B-1					
O. mykiss	static - 96 h	Mortality	100	> 100	nominal
D. magna	static - 48 h	Immobilisation	> 100 [3)]	> 100	nominal
S. subspicatus	static - 72 h	Biomass Growth rate	9.9 [2)] 12.5 [2)]	18.6 37.1	nominal

[1)] = *A. bibraianus* [2)] EC_{10} [3)] EC_0

[4)] concentrations were measured in all tests. If deviation of measured conc. from nominal value < 20 %, effects were related to nominal concentrations.

n.d. = not determined

B.9.2.3 Risk assessment

TER calculations for the active substances and relevant metabolites

The following calculations of the toxicity exposure ratios for chloridazon are based on the comparison of the toxicity with the predicted environmental concentration of chloridazon in surface water (PEC_{sw}) resulting from pre-emergence spray application on sugar beet fields. The PEC_{sw} were calculated using the STEP 3 approach of the European surface water assessment of Plant Protection Products (FOCUS, 2001). In the European surface water

scenarios different entry routes of the substance into surface water like spray drift, run-off and drainage are considered.

The intended application pattern of BAS 119 33 H in the EU includes one application with 4.0 kg BAS 119 33 H/ha corresponding to 2.6 kg/ha chloridazon pre-emergence or up to three applications post-emergence with a total of up to 2.6 kg as/ha cumulative. The single application with the full rate constitutes the worst case with respect to potential surface water contamination.

The contamination of estuarine and marine environments is considered to be minimal compared to freshwater habitats adjacent to agricultural land according to the use pattern, the potential route of contamination and dissipation of the compound.

The TER values of the active substance obtained with the most sensitive aquatic species and the different European surface water scenarios are summarised in Table B.9.2-20. The data for the metabolite B is shown in Table B.9.2-21.

Table B.9.2-20: Chloridazon - TER-values for most sensitive aquatic species of each group

Species	LC/EC_{50} [µg as/L]	Location*	Water body	PEC_{sw} Global max. [µg as/L]	TER_a	Trigger TER
Acute						
P. subcapitata (A. bibraianus)	600	D3	ditch	13.62	44	10
		D4	pond	2.082	288	
		D4	stream	11.46	52	
		R1	pond	1.332	450	
		R1	stream	19.26	31	
		R3	stream	130.9	**5**	
Daphnia magna	132000	D3	ditch	13.62	3031	100
		R3	stream	130.9	316	
O. mykiss	41300	D3	ditch	13.62	6989	100
		R3	stream	130.9	1009	
Long-term	**NOEC [µg as/L]**			**$PEC_{sw\ twa}$ [µg as/L] ****	**TER_{lt}**	
D. magna 21 d	6230	D3	ditch	0.661	9425	10
		R3	stream	5.48	1136	
O. mykiss 28 d	3160	D3	ditch	0.496	6371	10
		R3	stream	4.11	768	

* D scenarios: main routes of entry are spray drift and drainage
R scenarios: main routes of entry are spray drift and run-off
** only maximal values of R and D sceanrios are considered

Table B.9.2-21: Metabolite B - TER-values for most sensitive aquatic species

Species	LC/EC_{50} [µg as/L]	Location*	water body	PEC_{sw} Global max. [µg as/L]	TER_a	Trigger TER
Acute						
P. subcapitata (A. bibraianus)	600	D3	ditch	7.43	7340	10
		D4	pond	28.67	48031	
		D4	stream	14.99	8724	
		R1	pond	0.043	75075	
		R1	stream	0.858	3193	
		R3	stream	2.28	764	
Long-term	no tests performed, not required					

* D scenarios: main routes of entry are spray drift and drainage
R scenarios: main routes of entry are spray drift and run-off

The TER calculations for the most sensitive species based on European surface water scenarios demonstrate a safe use of chloridazon in 5 out of 6 locations. The data indicate a potential risk only for algae at the stream location R3.
The acute and long-term TER values for daphnids and fish meet the standard triggers considering spray applications and drainage or run-off of chloridazon according to the FOCUS scenarios.
The TER_a of metabolite B meets the respective trigger values indicating an acceptable risk for aquatic organisms.

B.9.2.4 TER-calculation for the formulated product BAS 119 33 H

Studies on the acute toxicity to fish, daphnids and green algae have been performed using the formulation BAS 119 33 H.
The toxicity data are generally expressed in terms of nominal values since analytical concentration measurements in the test water did largely confirm the nominal values for BAS 119 33 H throughout the experimental phase. For the risk assessment the effect concentrations are related to the active substance.

The following table presents the TER-values of BAS 119 33 H based on FOCUS STEP 3 calculations of PEC_{sw} for applications in sugar beet, the worst case scenario after one application at a maximum single application rate of 4.0 kg/ha.

Table B.9.2-22: Product BAS 119 33 H - TER-values for most sensitive aquatic species

Species	LC/EC_{50} [µg as/L]	Location*	Water body	PEC_{sw} Global max. [µg as/L]	TER_a	Trigger TER
Acute						
P. subcapitata (A. bibraianus)	650	D3	ditch	13.62	48	10
		D4	pond	2.082	312	
		D4	stream	11.46	57	
		R1	pond	1.332	488	
		R1	stream	19.26	34	
		R3	stream	130.9	**5**	
Long-term	no tests performed, not required					

* D scenarios: main routes of entry are spray drift and drainage
R scenarios: main routes of entry are spray drift and run-off

The TER calculations for the most sensitive species based on European surface water scenarios demonstrate a safe use of the formulation BAS 119 33 H in 5 out of 6 locations. The data indicate a potential risk only for algae at the stream location R3.

Conclusion and Comment of RMS

The TER values using the STEP 3 approach of the European surface water assessment of Plant Protection Products (FOCUS, 2001) for PEC_{sw} calculations demonstrate a safe use of chloridazon in 5 out of 6 locations regarding 1 annual application with 2.6 kg as/ha pre-emergence in sugar beet fields.

The acute and long-term TER values for daphnids and fish meet the standard triggers of Directive 91/414/EEC considering spray applications and drainage or run-off of chloridazon according to the FOCUS scenarios. The data indicate a potential risk only for algae at the stream location R3.

The TER_a of metabolite B meets the respective trigger values indicating an acceptable risk for exposed aquatic organisms.

According to the national approach of the German Federal Environmental Agency for calculating PEC_{sw} values which distinguishes between the different routes of entry (spray drift, run-off and drainage), a safe use could be demonstrated considering spray application in a distance of 1 m to shallow surface water ($PEC_{sw\ ini}$ spray drift 24.01 µg as/L, run-off 48.69 µg as/L, drainage 7.91 µg as/L).

B.9.2.5 Assessment of the relevance of the metabolites

Surface water

According to SANCO/3268/2001 metabolite B is identified as major metabolite due to its concentration > 10 % of applied radioactivity in the water phase of the water/sediment study. In sediment at most 7.3 % was found. Based on the current knowledge metabolite B does not pose higher or comparable risk to aquatic organisms compared to the active substance (Table B.9.2-23).

Ground water

The chloridazon metabolites were found in lysimeter studies at annual average concentrations exceeding 0.1 µg/L in the leachates. According to the Guidance Document on the Assessment

of the Relevance of Metabolites in Groundwater (SANCO/221/2000) such substances are subject to further assessment.
Groundwater concentrations of the chloridazon metabolite B were estimated to be partly above 10 µg/L and of metabolite B-1 to be between 2.4 and 6.8 µg/L (see B.8.6.3. PEC_{gw}) using the FOCUS groundwater models and scenarios. They should be assessed with regard to their biological activity (Stage 1 of Step 3 SANCO(221/2000). On the basis of the maximum levels resulting from the maximum application rate, the effects of the metabolites on a range of target organisms should be compared to the activity of the parent compound on weight or molar equivalents (Table B.9.2-23).
It could be demonstrated that if the endpoint could be determined the biological activities of the metabolites were clearly less than 50 % of the activity of the parent molecule.
Referring to the Groundwater Guidance Document the metabolites are not considered to be relevant, which means that they are allowed to exceed the groundwater level of 0.1 µg/L.

Table B.9.2-23: Comparison of the relative effect potential of chloridazon and its metabolites on aquatic organisms

Substance	Species	NOEC* (mg/L)	relative activity in % of as weight equivalents
Chloridazon	*O. mykiss*	21.5	100
Metabolite B	*O. mykiss*	100	21.5
Metabolite B-1	*O. mykiss*	100	21.5
Chloridazon	*D. magna*	100	100
Metabolite B	*D. magna*	> 100	< 100
Metabolite B-1	*D. magna*	> 100	< 100
Chloridazon	*P. subcapitata*	0.1	100
Metabolite B	*P. subcapitata*	34.8	0.29
Metabolite B-1	*P. subcapitata*	9.9	10

* NOEC was selected since more exact concentrations were obtained in the test. EC/LC_{50} values were mostly > highest test concentrations.

Conclusion for Aquatic Risk Assessment
The active substance is of low toxicity to fish and daphnia (EC/LC_{50} > 40 mg/L; NOEC > 3 mg/L). As expected for a herbicide, more pronounced effects were observed in aquatic plants. Green alga were the most sensitive group with an E_bC_{50} of 0.6 mg/L.
The main metabolite (metabolite B) proved to be non toxic to fish, daphnia and algae (EC/LC_{50} > 100 mg/L). Metabolite B-1 is also non-toxic to fish and daphnia and of low toxicity to algae (E_bC_{50} = 18.6 mg/L, E_bC_{10} = 9.9 mg/L). The TER calculations demonstrate that also for the most sensitive organisms (the green algae) the risk of chloridazon applications close to surface water (1 m buffer) is low, even considering only worst case standard assumptions.

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

B.9.3.1 Summary of effects on terrestrial vertebrates

Neither toxicity studies with wild mammals nor field studies were performed. For the assessment of effects of chloridazon on mammals, tests with rats and mice have been evaluated. The

acute oral toxicity of the formulation (BAS 119 33 H) was investigated with rats and of the active substance (BAS 119 H) with rats and mice.
Information about toxic endpoint are taken from chapter B.6 "Toxicology and Metabolism" of the draft assessment report. The data generated with the formulation are comparable to the results of the active substance. Since the product is applied by spraying, the test results obtained with the active substance are relevant for the risk assessment.
The most sensitive ecologically relevant endpoints of the acute, short-term and long-term toxicity studies are summarised in the following tables (Table B.9.3-1 to Table B. 9.3-3).

Note
From about the mid of the 1980's on an isomer reduced form of chloridazon (BAS 119 H) with higher purity and containing a lower amount of the herbicidally inactive isomer isochloridazon could be provided. Several studies were performed to prove that these two different purities do not differ in their toxicological profile.

Table B.9.3-1: Acute toxicity of chloridazon

Species	Study type	Test substance	LD_{50} (mg/kg bw/d)	
			males	females
Rat	acute, oral	isomer reduced chloridazon	> 3830	2140
Mouse	acute, oral	isomer reduced chloridazon	605	598

Table B.9.3-2: Short-term toxicity of chloridazon*

Species	Study type	NOAEL (mg/kg bw/d)	
		males	females
Rat	oral – 28 days	40 (LOEAL 400)	40 (LOEAL 400)
Rat	oral – 90 days increased liver weight, hepatocyte enlargement, decreased glycogen content	21	23.5
Mouse	oral – 90 days males: reduced body weight, triglyceride, cholesterol values; both sexes: increased liver weight	65	467

* no major differences between isomer rich and isomer reduced chloridazon

Table B. 9.3-3: Long-term toxicity of chloridazon

Species	Study type	NOAEL (mg/kg bw/d)	
		males	females
Rat	oral - 25 months reproduction study reduced body weight, blood parameter	13	18
Mouse	oral - 24 months reduced body weight gain, relative liver weight increase	134	158
		maternal toxicity	**developmental toxicity**
Rat	2-generation study	37; 148 fertility	37
Rat	prenatal toxicity	10	250
Mouse	pre-, peri-, postnatal toxicity	905	905
Rabbit	prenatal toxicity	55	495

The acute oral toxicity of isomer reduced chloridazon in rats is low. Female rats were more sensitive than males. Chloridazon with higher isomer content appears to be slightly more toxic, however, a different rat strain might have also influenced the results. For the risk assessment the values obtained with the isomer reduced chloridazon are used.

In preliminary short-term tests no major differences in the toxicity between isomer rich and isomer reduced chloridazon could be observed. The short-term oral toxicity of chloridazon was characterised by effects on the body weight and liver in all species tested. At high dose levels liver function was impaired in rats and mice resulting in clinical chemical changes, whereas at lower dose levels only liver weight increases were observed.

Long-term studies in rats and mice identified kidney, blood and skeletal muscle as target organs. Chloridazon was not carcinogenic or oncogenic in rats and mice. There were no adverse effects on reproduction and fertility and also no adverse effects in foetuses of rats, mice and rabbits.

Metabolites
In sugar beets two metabolites of chloridazon were found, metabolite A and B, exceeding 10 % TRR (BASF DocID 1991/10553). In the metabolism studies in rats (BASF DocID 1991/10524), lactating goats (BASF DocID 1992/5162) and laying hens (BASF DocID 1991/5190) both metabolites could not be identified. Hence, metabolites A and B are not covered by the toxicological studies.

Metabolite A is a glycoside, and the development of glycosides is a plant specific metabolic step. Therefore, metabolite A does not appear in rats, goats or hens. Nevertheless, animals are capable of decomposing glycosides. In the case of metabolite A, the parent compound chloridazon is released. Therefore, metabolite A is assumed to be covered by the toxicological data on chloridazon.

Metabolite B: In rats the chloridazon metabolite B was demonstrated to be non-toxic after acute oral administration up to the highest dose of 5000 mg/kg body weight per day. The metabolite did not show mutagenic or genotoxic properties and demonstrated no developmental toxicity. In short-term feeding studies the target organs were liver and kidney. The chloridazon metabolite B-1 was moderately toxic after acute oral administration, it was neither mutagenic nor genotoxic.
In lactating goats (BASF DocID 1999/11787) ^{14}C-metabolite B of chloridazon was rapidly and almost completely excreted via the urine and faeces. There was no indication of accumulation of ^{14}C-metabolite B in goat tissues, organs and milk.

It can thus be concluded that the risk assessment for the parent compound chloridazon provided in the following chapters would cover the potential risk form the two major plant metabolites. The toxicity data of the chloridazon metabolites are summarised in the following table.

Table B.9.3-4: Toxicity of chloridazon metabolites

Species	Test substance	Study type		LD_{50} /NOAEL (mg/kg bw/d) males
Rat	metabolite B (Reg.-No. 14456)	oral – acute LD_{50}	males	5000
			females	> 5000
		short-term toxicity, kidney and urinary tract toxicity		15
		prenatal toxicity	maternal toxicity	60
			developmental toxicity	120*
Rat	metabolite B-1 (Reg.-No. 035 375)	oral – acute LD_{50}		1200
		short-term toxicity, 90 days		50*
		prenatal toxicity	maternal toxicity	50*
			developmental toxicity	10

* highest dose tested

B.9.3.2 Exposure assessment for mammals

BAS 119 33 H with the active substance chloridazon is an existing herbicide (trade names: Pyramin WG or Pyramin DF) with its main use in beta beets.
The application rate is 4.0 kg/ha of the chloridazon preparation BAS 119 33 H. In terms of active substance, this is 2600 g as/ha. The intended method of application is spraying. The number of applications is one to three. The timing of the application is between pre-seeding and pre-emergence, resp., up to crop growth stage 19 (BBCH Code). The growth of weeds should not exceed the growth stage 14 - 16 (BBCH Code).

Depending on SANCO/4145/2000 the estimated theoretical exposure (ETE) of a compound is given by the following equation:

$$ETE = (FIR / bw) * C * AV * PT * PD \text{ (mg/kg bw/d)}$$

ETE	Estimated daily uptake of compound (= estimated theoretical exposure)
FIR	Food intake rate of indicator species (gram fresh weight per day)
bw	Body weight (g)
AV	Avoidance factor (1 = no avoidance, 0 = complete avoidance)
PT	Proportion of diet obtained in treated area (number between 0 and 1)
PD	Proportion of different food types in the diet (number between 0 and 1; one type or more types)
C	Concentration after application in the fresh diet (mg/kg)

In case of multiple applications and/or long-term considerations the concentration C may be expressed as

$$C = C_0 * MAF * f_{twa} * IF$$

C_0	Initial concentration after a single application calculated from RUD (= Residue Unit Dose) multiplied by the application rate (kg as/ha)
MAF	Multiple application factor (concentration immediately after the last application compared to a single application.
f_{twa}	Time-weighted-average factor (average concentration during a certain time interval compared to the initial concentration after single resp. last application.

Both equations can be combined and converted to the following form, which will be used in this assessment:

ETE = (FIR / bw) * RUD * AV * PT * PD * f_{twa} * MAF * Appl. Rate (mg/kg bw/d)

In the first tier it is assumed that the contaminated diet is not avoided (AV = 1), the animals satisfy their entire food demand in the treated area (PT = 1), the animals feed on a single food type (PD = 1) and the concentration in the fresh diet is comparable to the maximum annual application rate.
In the case of contaminated plant materials leafy plants (sugar beets) are considered as the most suitable feed item to calculate the "initial residue in food items" in the case for herbivorous mammals. Due to the application scheme of the herbicide, only the standard scenario "early crop stage" is considered.
The acute and long-term exposure assessments for the active substance chloridazon (BAS 119 H) - applied as BAS 119 33 H - based on a default approach (Tier I) laid down in SANCO/4145/2000 - are summarised in Table B.9.3-5.

Table B.9.3-5: Exposure assessment for mammals (standard scenarios)

Culture/ use	Food source	Indicator species	Application rate (kg as/ha)	MAF	f_{twa}	RUD (mg as/kg wet weight)	FIR (g wet weight /g bw*d)	ETE (mg as/kg bw)
Acute								
Sugar beet, early/late	leafy crops	medium herbivorous mammal	2.6	1	1	87	0.28	63.3
Long-term								
Sugar beet, early/late	leafy crops	medium herbivorous mammal	2.6	1	0.53	40.0	0.28	15.4

MAF = multiple application factor
RUD = nitial residue per unit dose (mg as/kg wet weight), measured at day 0 for leafy crops and non-grass herbs, other values from SANCO 4145/2000
FIR/bw = food intake rate per body weight (g/kg bw*d) according to Crocker et al (2002) as given in SANCO 4145/2000
f_{twa} = time-weighed average factor. Default value from SANCO 4145/2000
ETE = estimated theoretical exposure (R*MAF*RUD*FIR)
R = application rate in kg as/ha

The acute worst case exposure for medium herbivorous mammals was calculated with 63.3 mg as/kg bw. In the long-term situation 15.4 mg as/kg bw were calculated for medium herbivorous mammals.

B.9.3.3 Risk assessment for the active substance (TERs)

The following risk assessment is based on a comparison of toxicity and possible exposure of wild mammals to the active substance chloridazon. Free-living mammals may be exposed to residues of this active substance mainly by the consumption of contaminated food. The risk assessment will be based on the maximum single application rate of 2.6 kg/ha chloridazon in sugar beets.
Directive 91/414 EEC, amended by CD 97/57/EC (Annex VI), beside acute and long-term TERs also requests short-term TERs to be calculated. However, based on most recent Guidance Documents (SANCO/4145/2000; SANCO/10329/2002) the short-term risk is covered by the long-term risk assessment. Therefore, this risk assessment is focused on the acute and long-term TERs.

Toxicity/**E**xposure **R**atios (TERs) are calculated by relating the mammalian toxicity end-points (LD_{50}, NOAEL in mg as/kg bw/d; Table B.9.3-1 and Table B. 9.3-3) to the theoretical exposure (ETE in mg as/kg bw/d; Table B.9.3-5).

In a Tier I assessment it is considered that the presumptions are highly conservative in assuming default residues, no degradation in the acute and short-term time frame, exclusive feeding on a single treated material, a constant exposure to a residue, no interception by vegetation/crop and availability of the default feed item in the crop. The TERs based on the Tier I risk assessment are summarised in Table B.9.3-6.

Table B.9.3-6: Toxicity/exposure ratios (TER) for mammals

Culture	Feed	Endpoint	mg/kg x bw	ETE	TER_a (LD_{50}/ETE)	Trigger TER
Acute						
Sugar beet. early/late	leafy plants medium herbivorous mammal	LD_{50} oral	2140 (rat)	63.3	**34**	10
Long-term						
Sugar beet early/late	leafy plants medium herbivorous mammal	NOAEL	37 (rat)	15.4	**2.4**	5

ETE = estimated theoretical exposure (R*MAF*RUD*FIR)

The TER_a values for acute exposure in leafy plants are higher than the trigger of 10 set by Annex VI of Directive 91/414 EEC for a refined risk assessment.
The long-term exposure scenarios indicate a potential risk for herbivorous mammals in cereals and in leafy crops. The TER_{lt} values are below the trigger of 5 and need to be refined.

B.9.3.4 Refined risk assessment

B.9.3.4.1 Refinement of the exposure assessment

Due to the TER < 5 in the first tier assessment for long-term exposure of herbivorous mammals a refinement of the exposure was performed using following options:

Measured residues
Relevant species
PD factor for relevant species
PT factor for relevant species
Chronic toxicity endpoint
Interception factor

a) Measured residues
In field trials with BAS 119 33 H the residues reveal values below the defaults. Treatment and application regime in these studies were comparable to the scheme for BAS 421 12 F in the provided dossier. The data were normalised to an application rate of 1 kg as/ha resulting in RUD values which can be directly used in the Tier II assessment. Based on SANCO 4145/2000 the arithmetic mean residue values will be used for the long-term risk assessment.
The measured residue concentrations were taken from the dossier of the notifier (chapter M-II 6). Only values measured in Germany, Belgium, Northern Italy and Northern Spain with com-

parable climate directly after the last application (day 0) with the intended application rates were used.
The residues measured at different time points after application of the active substance were analysed to obtain a dissipation half-live (DT_{50}) for the decline of chloridazon in sugar beet shoots (Dressler, 2003, BASF DocID 2003/1005440). The DT_{50} was found to be 5.2 days resulting in a refined f_{twa} of 0.34.

Table B.9.3-7: Initial residues of chloridazon in sugar beets [1]

Crop	Number of trials	Applications	RUD range [2)] [mg as/kg green matter]	RUD mean [2)] [mg as/kg green matter]
Sugar beet [4]	11	1 x 2600 mg as/ha	0.99 – 63.5	16.5

[1] See Doc M II, 6.3 or BASF DocIDs 1999/10348, 2000/1013266, 2001/1009078, 2002/1011935, 2002/1011936
[2] Residue unit dose (RUD), corresponding to 1 kg as/ha.

b) Relevant species
BAS 119 33 H is intended for a single annual application at BBCH 14-19. At this time the beet crops provide no shelter for small mammals, since these small herbivorous mammals predominantly inhabit undisturbed areas like set asides, meadows and permanent crops (prime/optimal habitats) where the food supply and the burrows are not destroyed upon harvesting and by seasonal soil tillage.
The **hare (*Lepus europaeus*)** represents a typical inhabitant of open areas, and thus may be found in sugar beet fields sprayed with BAS 119 33 H.

c) PD factor
The hares´ diet consists of plant material (80 %), pods (5 %), cereal grain (8 %), and fruit (2 %) as estimated from Zörner (1989). Pods, cereal grain and fruit would not be available in beet crop fields, and hence, would not be exposed. Also, after an application of BAS 119 33 H the weed plants would die down within a few days, and thus would not add to the diet. Therefore, young beet plants would be the only plant feed item being available in a treated field.

d) PT factor
The above mentioned arguments imply that a hare would need to feed in an area that is wider than the scale of a typical beet field. The generic literature (Marboutin and Aebischer (1996)) confirms that the hare has a large home range of 190 ± 53 ha (137 - 243 ha), and it can be assumed that a hare would not feed 100 % of its time in an ordinary 10 ha cereal field. However, in the tier 2 risk assessment a worst case scenario is laid down in assuming a portion of time spent in the treated area of 100 %.
The notifier assumed that a beet crop field would not exceed 10 ha in size regarding a conservative estimate on the portion of time spent in the treated area to obtain feed (PT). He further assumed that these fields would not be of specific attraction for the hare, the time spent in an area would be directly proportional to the feeding time. Under these assumptions a hare would feed 5.3 to 7.3 % of its time in a 10 ha beet crop field, and thus a realistic estimate for PT would be a factor of 0.053 - 0.073.
Contrary to these assumption the RMS used a more conservative approach with a PT factor of 1. The specific assumptions of the notifier would result in a higher TER_{lt} than obtained with the worse case scenario of the RMS and is presented at the end of the chapter.

e) Ecologically relevant chronic toxicity endpoint

In the two-generation reproduction study chloridazon (Reg. No. 13003; BASF DocID 1993/10632) was administered to groups of 24 male and 24 female young Wistar rats (F0 parental generation) as a constant homogeneous addition to the feed in concentrations of 0, 100, 400 or 1600 mg as/kg feed (corresponding to 0, 9, 37 or 148 mg/kg bw/d). F0 animals were mated to produce two litters (F1a and F1b). Groups of 24 male and 24 female selected from F1a pups as F1 parental generation were offered diets containing 0, 100, 400 or 1600 mg as/kg feed of the test substance post weaning, and the breeding program was repeated to produce the F2 litter. Thus, chloridazon was constantly administered to rats over several consecutive generations thus representing a long-term like exposure (e.g. pre-exposure of 70 or 98 days before mating F0 or F1 animals). Field exposure of chloridazon to wild mammals, instead, is characterised by 1 application per year with a peak residue level on the items wild mammals may feed on, and a consecutive decline of residues following the day of application. As compared to the two-generation study, wild mammals feed on items with fluctuating levels of residues, with lower levels of residues (maximum initial default residue of 213.2 mg as/kg feed), and over shorter periods of time (max. 1 application).
The results of the two-generation study should thus be evaluated in the light of this consideration:
The NOAEL (no observed adverse effect level) for reproductive performance and fertility was shown to be 1600 mg as/kg feed (about 148 mg/kg body weight/day) for the F0 and F1 parental rats. The 1600 mg as/kg feed dose level represents the highest concentration tested.

The NOAEL for general toxicity/systemic effects was established to be 400 mg as/kg feed (about 37 mg/kg body weight/day) for the F0 and F1 parental animals and their offspring.
At 1600 mg as/kg feed increased absolute and relative liver weights in few of the F0 and F1 parental animals were observed, which is considered to be an adaptive response to increased functional (metabolic) demand primarily as a consequence of the long-term like exposure.
Also, at 1600 mg as/kg feed reduced mean body weight (F0 up to 4.6 %; pups up to 6.6 %) and reduced body weight gain (F0 up to 5.7 %; pups up to 7.6 %) was determined for certain days of exposure. This study was conducted under controlled conditions (homogeneous genetics, environmental factors, exposure level) allowing a low variation and a high statistical power. It is therefore concluded that the observed magnitude of effects at 1600 mg/kg would remain undetected under natural conditions.
In view of these results a residue level of 1600 mg as/kg feed should be considered to be the level that poses wild mammals not at risk and should thus be employed for risk evaluation purposes.

The NOAEL for developmental toxicity (growth and development of the offspring) is not given in the study. However, since no developmental effects are reported for the F1 and F2 progeny at 1600 mg as/kg feed (about 148 mg/kg body weight/day), this concentration is seen as the NOAEL for developmental toxicity. The 1600 mg as/kg feed dose level represents the highest concentration tested.
With respect to wild mammal risk evaluation - based on ecologically relevant aspects - it is thus concluded that a level of 1600 mg as/kg feed (corresponding to 148 mg/kg bw/d) should be derived from the results of the two-generation study to constitute the NOAEL.

f) Interception factor
Interception factors are not included in the refined exposure assessment, since measured residues were used as residue unit dose (RUD).

Refined exposure assessment

The exposure assessment for chloridazon (BAS 119 H) - applied as BAS 119 33 H - based on the conservatively refined approach of the RMS laid down in SANCO4145/2000 - is summarised in Table B.9.3-8.

Table B.9.3-8: Refined long-term exposure assessment for mammals

Culture /use	Food source	Indicator species	Appl. rate (kg as/ha)	MAF (kg as /ha)	f_{twa}	RUD (mg as/ kg wet weight)	FIR (g wet weight/ g bw*d)	PT	PD	ETE (mg as/ kg bw)
Sugar beet Early/late	leafy crops	medium herbivorous mammal: hare	2.6	1	0.34	16.5	0.28	1	1	4.1

MAF = multiple application factor
PT = proportion of diet obtained in treated areas
PD = proportion of different food types in the diet
IF = interception factor (FOCUS 2000/2002)
ETE = estimated theoretical exposure (R*MAF*RUD*FIR)
R = application rate in kg as/ha
f_{twa} = time-weighted average factor. Default value from SANCO 4145/2000
RUD = initial residue per unit dose (mg as/kg wet weight), measured at day 0 for leafy crops and non-grass herbs, other values from SANCO 4145/2000
FIR/bw = food intake rate per body weight (g/kg bw*d) according to Crocker et al (2002) as given in SANCO 4145/2000

B.9.3.4.2 Refinement of the risk assessment

The refined long-term TER in cereals and leafy crops for BAS 119 H based on residue data measured by the notifier and on the species of concern are given in Table B.9.3-9.

Table B.9.3-9: Refined toxicity/exposure ratios (TER) for mammals

Culture	Feed	Indicator species	NOAEL mg/kg bw*d	ETE	TER_{lt} (NOAEL/ETE)	Trigger TER
Long-term						
Sugar beet	leafy plants	medium herbivorous mammal: hare	148	4.1	36	5

The Tier 2 exposure assessment, based on conservative assumptions, results in long-term TER_{lt} for mammals, which are higher than those in the Tier 1 assessment and also higher than the trigger of 5 set by the Annex VI of Directive 91/414 EEC.

In conclusion, the acute and long-term risk for terrestrial mammals feeding on crop after application of chloridazon according to good agricultural practice is acceptable.

Comment of the RMS:
In the following, the refined risk assessment of the notifier is summarised:

Table B.9.3-10: Refined long-term exposure assessment for mammals as provided by the notifier

Culture /use	Food source	Indicator species	Appl. rate (kg as/ha)	MAF (kg as /ha)	f_{twa}	RUD (mg as/ kg wet weight)	FIR (g wet weight/ g bw*d)	PT	PD	ETE (mg as/ kg bw)

Sugar beet. Early/late	leafy crops	medium herbivorous mammal: hare	2.6	1	0.53	16.5	0.28	0.073	1	0.47

The refined TER_{lt} for chloridazon calculated by the is given in the following table.

Table B.9.3-11: Refined toxicity/exposure ratios (TER) for mammals as provided by the notifier

Culture	Feed	Indicator species	NOAEL mg/kg bw*d	ETE	TER_{lt} (NOAEL/ETE)	Trigger TER
Long-term						
Sugar beet	leafy plants	medium herbivorous mammal: hare	148	0.47	315	5

B.9.3.5 Acceptance of bait, granules or treated seeds

No testing is required since the formulated product BAS 119 33 H will be applied exclusively in spray treatments. Acceptance of bait, granules or treated seed are not applicable.

B.9.3.6 Supervised cage or field trials

According to Directive 91/414, CD 96/12, no further test is required since all TERs are favourable, and there is no evidence of a risk based on the tests performed with the active substance chloridazon.

B.9.3.7 Effects of secondary poisoning

The log P_{ow} of the active substance **chloridazon** was determined to be 1.2 (BASF DocID 1987/5075). Hence, a bioaccumulation study was not required and due to the low lipophilicity no risk of bioaccumulation is assumed.
In addition, chloridazon was rapidly and almost completely excreted via the urine and feaces by rats (BASF DocID 1991/10585) and lactating goats (BASF DocID 1992/5162). There was no indication of accumulation of chloridazon in tissues, organs or goat milk.

Therefore, it can be concluded that the application of BAS 119 33 H in beet crops does not give rise for concern of secondary poisoning by the active substance chloridazon.

Conclusion
The available data on the toxicity of the active substance chloridazon on terrestrial vertebrates others than birds and the Tier 1 and 2 risk assessment demonstrate an acceptable risk.
Under the highly conservative assumptions of a Tier I Assessment the TER_a for chloridazon is higher than the trigger of 10 set by Annex VI of Directive 91/414 EEC for a refined risk assessment. The TER_{lt} for chloridazon (for herbivorous mammals) is below the trigger of 5 and needs to be refined.
For herbivorous mammals a Tier II assessment based on an ecologically relevant NOAEL, BASF own residues and the species of concern results in a long-term TER, which is higher

than that in the Tier I assessment and also higher than the trigger of 5 set by Annex VI of Directive 91/414 EEC.

Two metabolites of chloridazon were found in sugar beets with > 10 % TRR (major metabolites). The glycoside metabolite A is metabolised in animals into the parent chloridazon and thus is covered by the toxicological data on chloridazon. Metabolite B is less toxic than chloridazon and thus is covered by the risk assessment for the parent compound. Also, in a metabolism study in lactating goats the applied radioactivity was rapidly excreted and there was no indication of an accumulation of metabolite B in goat tissues, organs and milk. The risk assessment for the parent molecule chloridazon would hence cover the potential risk from these major metabolites.

Due the low lipophilicity of the active substance chloridazon ($logP_{ow}$ < 1.2) it is concluded that there is no risk of bioaccumulation in food chains. In addition, chloridazon was rapidly and almost completely excreted from rats and lactating goats, and there was no indication of accumulation of chloridazon in tissues, organs or goat milk. It is thus concluded that the application of BAS 119 33 H in sugar beets does not give rise for concern of an accumulation of the active substance chloridazon in the food chain or for concern of secondary poisoning.

Therefore, it can be concluded that the application of the product BAS 119 33 H according to good agricultural practice will not adversely affect wild mammal populations under natural conditions.

B.9.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.4)

B.9.4.1 Acute toxicity (Annex II A 8.3.1, Annex III A 10.4)

B.9.4.1.1 Acute oral and contact toxicity of chloridazon technical (Annex II A; 8.3.1)

Title:	Effects of Reg. No. 13033 (chloridazon) on the Honeybee (*Apis mellifera L.*) in Laboratory trails BIE 2003-85
Author:	Sack, Dagmar (1994)
BASF RegDoc	1994/10090
Guidelines:	UK Working Dokument 7/3 of the United Kingdom Control of Pesticides Regulations, 1986
GLP	yes
Addendum No. 1	To study code P93-E137: Effect of Reg,No. 13 033 (common name: chloridazon) on the honeybee (*Apis mellifera L.*) in labory trails BIE 2003-86
Test design:	Test substance: chloridazon technical Reference substance: dimethoate technical Control variants: not described
Test procedure:	The tests were performed as multiple dose tests. The tested doses were 200, 150, 100 and 25 µg as/bee as well for the oral as the contact test. The

refence substance was also offered in 8 doses for the oral and contact test: 1.0; 0.5; 0.25; 0.1 and 0.05 µg/bee.

Results:

Chloridazon:	LD_{50}	oral (48 h):	>200	µg / bee
	LD_{50}	contact (48 h):	>200	µg / bee
Dimethoate:	LD_{50}	oral (48 h):	0,05	µg / bee
	LD_{50}	contact (48 h):	0,086	µg / bee

Control variants: no mortility after 48 hours

B.9.4.1.2 Acute oral and contact toxicity of formulated chloridazon to honeybees (Annex III A; 10.4)

Title: Effects of BAS 11933 H on the Honeybee (*Apis mellifera* L.) in Laboratory Trials.
BIE 2002-12
Author: Sack, Dagmar (1999)
BASF RegDoc 1999/11756
Guidelines: EPPO-guideline No.170 and OECD-guidelines for the Testing of Chemicals No.213 and No.214
GLP yes
Test design: Test substance: BAS 11933 H (nominal content 65 % chloridazon)
Reference substance: BAS 15211 J (nominal content 400 g/L dimethoate)
Control variants: sugar solution (for oral testing)
acetone; deionised water (for contact testing)
Test procedure: Oral and contact testing were performed as well as a limit test and as a mutiple dose test.
Limit test: dose: 200 µg/bee; 5 replicates with 10 bees each
Multiple dose test: 12.5; 25; 50; 100; 150 and 200 µg/ bee
3 replicates per dose with 10 bees each

Results:

BAS 11933 H	LD_{50}	oral (48 h):	>200	µg / bee
	LD_{50}	contact (48 h):	>200	µg / bee
BAS 15211 J	LD_{50}	oral (48 h):	0.29	µg / bee
	LD_{50}	contact (48 h):	0.36	µg / bee

Control variants: no or negligible mortality in all control variants after 48 hours

B.9.4.2 Bee brood feeding test (Annex II A 8.3.1.2)

Tests are not required as the test substance is not an IGR.

B.9.4.3 Residue test (Annex III A 10.4.2)

Tests are not required as the test substance is of low toxicity to honey bees.

B.9.4.4 Cage test (Annex III A 10.4.3)

Title:	Prüfung auf Bienengefährlichkeit für das Zulassungsverfahren – Zeltprüfung. Landwirtschaftskammer Westfalen-Lippe, Institut für Pflanzenschutz, Saatgutuntersuchung und Bienenkunde, Münster; Germany. BIE2003-85
Author:	Kock (1991)
Guideline:	BBA-guidelineVI, 23-1
GLP	no (but the test belonged to the official testing of plant protection products for registration in Germany.)
Test design:	Test substance: BAS 11933 H (nominal content 65 % chloridazon) + BAS 33705 H (16 % Phenmedipham) Reference substance: E 605 forte (500 g Parathion/ L) Control variants: tap water
Test procedure:	Cage size: 16 qm Test plant: flowering Phacelia Test concentration for the test substance: 3 % + 6 % in 200 L/ha Test colonies: small queenright colonies of 3 frames with all developmental stages of bees. Application was done during full bee flight in flowering Phacelia.
Results:	There was no harmful effect by the test substance to notice in both replicates.

B.9.4.5 Field test (Annex III A 10.4.4)

Tests are not required as the test substance is of low toxicity to honey bees.

B.9.4.6 Tunnel test (Annex III A 10.5.5)

Tests are not required as the test substance is of low toxicity to honey bees.

B.9.4.7 Risk assessment for honeybees

Risk assessment is done according to EPPO/Coe Risk Assessment Scheme:

Hazard Quotient = LD_{50}^{-1} x g as/ha.

The calculation is based on the highest amount of the active substance which is declared to be 2600 g as/ha.

Results:

Active substance (1.1.1.1)	HQ	oral (48 h):	13
	HQ	contact (48 h):	13
Formulation (1.1.1.2)	HQ	oral (48 h):	13
	HQ	contact (48 h):	13

All hazard quotients are clearly below the trigger of 50. This indicates, that there can be expected no risk for honeybees, when chloridazon-containing products are practically used.

B.9.5 Effects on other arthropod species (Annex IIA 8.3.2; Annex IIIA 10.5)

B.9.5.1 Acute toxicity (Annex II A 8.3.2; Annex III A 10.5.1)

B.9.5.1.1 Laboratory tests

◆ **Predatory mites (e.g. *Typhlodromus pyri*):**

Reference number: III A 10.5.1/1

Report: Ufer A., 1999(a); ANA 2002-13
Effect of BAS 119 33 H on the predatory mite *Typhlodromus pyr*i SCHEUTEN in a laboratory trial BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 43934; unpublished; BASF RegDoc# 1999/10461

Guidelines: Bakker F. et al (1992), Guidelines for testing the effects of pesticides on beneficials, Overmeer W.P.J. (1988), Laboratory method for testing side-effects of pesticides on the predacious mites *Typhlodromus pyri* and *Amblyseius potentillae* (Acari: Phytoseiidae), IOBC/WPRS XI/4/1988, IOBC/WPRS XV/3/1992

GLP: Yes

Material and methods
BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %) was applied to glass plates at nominal rates of 0.4 and 4.0 kg/ha at a spray application volume of approximately 200 L/ha. The control was treated with water. BAS 152 11 I (dimethoate, 400 g/L) at a rate of 15 mL/ha was used as a reference item. *Typhlodromus pyri* (protonymphs) were exposed in 5 units with 20 mites to the spray residues of the test item, reference item, and control, respectively. Mortality was assessed after 1, 3 and 7 days of exposure and reproduction after 14 days with the remaining adult mites.

Findings
Control mortality after 7 days was 5.0 %; the oviposition rate in the control was 7.8 eggs/ female. Statistically significant effects on the mortality and reproduction capacity of *T. pyri* were only observed for the highest application rate (t-test, $\alpha = 0.05$). During the 7-day egg laying period the number of offspring per female in the test item rates ranged between 8.1 and

4.4. The reference item 152 11 I (Dimethoate, 400 g/L) caused 100 % mortality of exposed mites after 7 days. The results are summarised below (Table B.9.5-1).

Table B.9.5-1: Effects on predatory mites (*Typhlodromus pyri*) exposed to BAS 119 33 H in a laboratory trial

Treatment	Rate [kg/ha] 1)	Mortality [%] 2)	Mortality corr. [%] 3)	Reproduction [eggs/female]	Effects on reproduction [%] 4)
Control	--	5.0	--	7.8	--
BAS 119 33 H	0.4	8.0	3.2	8.1	- 3.8
BAS 119 33 H	4.0	40.0 *	36.8	4.4 *	43.6
	Endpoints [kg/ha]				
LR/ER_{50}	~ 4.0				

1) Application rate in 200 L water/ha 2) Mortality: after 7 days of exposure to BAS 119 33 H on glass surface
3) Corrected mortality according to Schneider-Orelli (1947) 4) Values recalculated from original data
* = statistically significant differences compared to the control (t-test, $\alpha = 0.05$)

Valid: yes

Conclusion
The LR_{50} obtained under worst-case laboratory conditions for BAS 119 33 H on *Typhlodromus pyri* was around 4.0 kg/ha in 200 L water/ha. At this rate reproduction was reduced by 43.6 %. No effects on mortality or reproduction were observed at 0.4 kg/ha.

◆ **Parasitoids**

Reference number: III A 10.5.1/2

Report: Ufer A., 1999(b); ANA 2002-12
Effect of BAS 119 33 H on the parasitoid *Aphidius rhopalosiphi* in a laboratory trial BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 43935; unpublished; BASF RegDoc# 1999/10532

Guidelines: Mead-Briggs M. (1992): A laboratory method for evaluating the side-effects of pesticides on the cereal aphid parasitoid *Aphidius rhopalosiphi* (Destefani-Perez). Aspects of Applied Biology 31 pp. 179-189, Polgar L. (1988): Guideline for testing the effect of pesticides on *Aphidius rhopalosiphi* Hal. Hym. Aphidiidae. IOBC/WPRS Bulletin XI/4. Meeting Working Group Pesticides and Beneficial Organisms pp. 29-34, IOBC/WPRS XI/4/1988

GLP: Yes

Material and methods
BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %) was applied to glass plates at a nominal rate of 4.0 kg/ha at a spray application volume of approximately 200 L/ha. The control was treated with water. BAS 152 11 I (dimethoate, 400 g/L) at a rate of 0.3 mL/ha was used as a reference item. *Aphidius rhopalosiphi* (adults) were exposed in 3 units with 10 wasps to the spray residues of the test item and control, one unit for the reference item. Mortality was assessed at 2, 24 and 48 h after test initiation. For

the reproduction assessment 10 females per variant were individually confined over plots of untreated, aphid-infested wheat seedlings for 24 h and then removed. The number of parasitised aphid mummies was recorded after 13 days. Host: cereal aphids (*Rhopalosiphum padi*).

Findings
The test item BAS 119 33 H caused no mortality after 48 h, compared with no dead individuals in the control. No effects on reproduction were observed. The mean number of mummies produced per female was 20.6 in the control group and 22.1 in the test item group. These differences were statistically not significant (Table B.9.5-2). The reference item 152 11 I caused 100 % mortality of exposed wasps after 48 hours.

Table B.9.5-2: Effects on parasitoids (*Aphidius rhopalosiphi*) exposed to BAS 119 33 H in a laboratory trial

Treatment	Rate [kg/ha] 1)	Mortality [%] 2)	Reproduction [mummies/female] 3)	Effects on reproduction [%] 4)
Control	0.0	0.0	20.6	--
BAS 119 33 H	4.0	0.0 n.s.	22.1 n.s.	- 7.3
Endpoints [kg/ha]				
LR/ER_{50}	> 4.0			

1) Application rate in 200 L water/ha
2) Mortality: after 48 hours of exposure to BAS 119 33 H on glass surface
3) Reproduction: mean number of parasitised aphids/female
4) Recalculated from original data; negative values indicate an increase compared to the control
n.s. = not statistically significant when compared to the control (t-test, $\alpha = 0.05$)

Valid: yes

Conclusion
The LR_{50} obtained under worst-case laboratory conditions for BAS 119 33 H on the parasitic wasp *Aphidius rhopalosiphi* was LR_{50} > 4.0 kg in 200 L water/ha. No effects on reproduction were observed up to a rate equivalent to 4.0 kg BAS 119 33 H/ha in 200 L water/ha.

◆ **Foliage dwelling predators**

Reference number: III A 10.5.1/3

Report: Ufer A., 1998(a); ANA 2002-18
Effect of BAS 119 33 H on the green lacewing *Chrysoperla carnea* (Neuroptera: Chrysopidae) in a laboratory test
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 43930; unpublished; BASF RegDoc# 1998/11228

Guidelines: Vogt H. et al. (1985): Validation of beneficial testing: A joint initiative of the IOBC, BART, COMET & EPPO, Hassan S.A., Standard methods to test the side-effects of pesticides on natural enemies of insects and mites. Bull. OEPP 15 pp. 214-255 (1985)

GLP: Yes

Material and methods

BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %). Under laboratory conditions approximately 2 - 3 d old *Chrysoperla carnea* larvae; source: Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA), Darmstadt, Germany, (one replicate with 30 larvae each) were exposed to dried spray deposits of 6.0 kg/ha diluted in 400 L deionised water/ha on glass plates. Deionised water was used as a control treatment and BAS 152 11 I (dimethoate, 400 g/L), applied at a rate of 0.04 L/ha as reference treatment. The test reached from early larval instar (parental generation) until pupation, 9 weeks. Pupae were transferred to petridishes for development of adults. Mortality checks were carried out regularly until hatching of adult lacewings. In addition, for the control and the test substance treatment groups the reproduction performance, i.e. egg deposition and hatching rate, was determined.

Findings

The pre-imaginal mortality of *Chrysoperla carnea* exposed to BAS 119 33 H amounted to 13.33 %. In the control 6.67 % mortality was observed, this results in a corrected mortality of 7.14 %. In the test item treatment group the number of eggs per female per day was statistically significantly higher when compared to the control. The reproduction capacity as well as the hatching rates of test item and control variant were within the normal range of *Chrysoperla carnea*. The reference item BAS 152 11 I produced 100 % mortality of exposed lacewings.

The results are summarised below (Table B.9.5-3).

Table B.9.5-3: Effects on lacewings (*Chrysoperla carnea*) exposed to BAS 119 33 H in a laboratory trial

Treatment	Rate [kg/ha] 1)	Mortality [%] 2)	Mortality corrected [%] 3)	Reproduction [eggs/female/day]	Hatching rate [%]
Control	--	6.67	--	18.37	93.65
BAS 119 33 H	6.0	13.33	7.14	23.43 *	93.15
Endpoints [mg/L]					
LR/ER_{50}	> 6.0				

1) Application rate in 200 L deionised water/ha, dried residues
2) Mortality: percentage of individuals that did not reach maturity
3) Corrected mortality according to Schneider-Orelli (1947)
* = statistically significant when compared to the control (t-test, $\alpha = 0.05$)

Conclusion

The LR_{50} obtained under worst-case laboratory conditions of BAS 119 33 H was > 6.0 kg/ha. No adverse effects on mortality or reproduction of the foliage dwelling predator *Chrysoperla carnea* were observed up to an application rate of 6.0 kg BAS 119 33 H/ha in 400 L water/ha.

Valid: acceptable

B.9.5.2 Extended laboratory study

Not required.

◆ **Spiders**

Reference number: III A 10.5.1/4

Report: Schmitzer S., 1998; ANA 2002-15
Effects of BAS 119 33 H on the wolf spider *Pardosa spec.* (Araneae, Lycosidae) in the laboratory
Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany; project no. 3290065; unpublished;
BASF RegDoc# 1998/10554

Guidelines: Wehling A., Heimbach U. (1994): Auswirkungen von Pflanzenschutzmitteln auf Pardosa spec. als Vertreter der Familie Lycosidae (Araneae) im Laboratorium, Ring test group 1994 bis 1997

GLP: Yes

Material and methods
BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %); test species: Lycosid spiders (*Pardosa spp.: P. agrestris*, 29 spiders, *P. palustris*, 11 spiders, *P. prativaga*, 2 spiders, *P. amentata*, 2 spiders and subadults, 16 spiders), source: outdoor collected near Rossdorf, Germany. The spiders were exposed to direct application on inert quartz sand. Three variants (6.0 kg/ha test item, water treated control, 113.6 mL/ha thiodan EC 33 (33 % endosulfan) as reference item; all substances were applied in 400 L water/ha); 20 replicates per variant with 10 replicates containing 1 subadult or adult male and 10 replicates containing 1 subadult or adult female. After 0, 2, 4 and 6 hours and 1, 2, 3, 4, 7, 9, 11 and 14 days after application the number of living and dead individuals were assessed. The food consumption was assessed on day 1, 2, 3, 4, 7, 9, 11 and 14.

Findings
BAS 119 33 H caused no effect on mortality and feeding rate of wolf spiders. No adverse effect of BAS 119 33 H on food consumption occurred. No test item related behavioural abnormalities were observed Table B.9.5-4. The reference item thiodan caused a corrected mortality of 100 %.

Table B.9.5-4: Effects on lycosid spiders (*Pardosa* spp.) exposed to BAS 119 33 H in a laboratory trial

Treatment	Rate [kg/ha] [1)]	Mortality [%] [2)]	Reduction of feeding capacity [%]
Control	--	0.0	--
BAS 119 33 H	6.0	0.0	0
	Endpoint [kg/ha]		
LR/ER_{50}	> 6.0		

1) Application rate in 400 L water/ha
2) Mortality: mean of 10 replicates per sex and variant, i.e. 20 spiders/variant

Valid: yes

Conclusion
The LR_{50} obtained under worst-case laboratory conditions of BAS 119 33 H was LR_{50} > 6.0 kg/ha. BAS 119 33 H caused no adverse effects on mortality and food consumption of lycosid spiders of the genus *Pardosa* under worst-case laboratory conditions tested up to an application rate of 6.0 kg BAS 119 33 H/ha in 400 L water/ha.

◆ **Ground Dwelling Predators**

Reference number: III A 10.5.1/5

Report: Ufer A., 1998(b); ANA 2000-458
Effect of BAS 119 33 H on the rove beetle *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae) in a laboratory trial
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 49948, unpublished; BASF RegDoc# 1998/11359

Guidelines: IOBC/WPRS XV/3/1992

GLP: Yes

Material and Methods
Test item: BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %), test species: Rove beetle (*Aleochara bilineata*), adults 2 days old, source: in-house culture. Exposure of the beetles was reached via treated quartz sand; beetles were introduced into the test units immediately after treatment. Three variants, (test item at 6.0 L/ha, water treated control and dimethoate 400 g/L at 1.2 L/ha as reference item, all applied in 400 L water/ha), three replicates/variant; 10 pairs (female + male) of rove beetles/ replicate. The complete life cycle of beetles - parental generation, mating and oviposition of parental generation, hatching of F1 larvae, parasitation period until emergence of F1 adults - took place during the test. Assessment of reproduction was carried out by counting the number of beetles emerged from the parasitised fly pupae (*Delia antiqua*) starting approximately 28 days after application. Endpoint assessed was the reproduction efficiency of *Aleochara bilineata*.

Findings
The mean number of hatched beetles in the test item treated variant was 521. A mean of 34.2 % of the puparia in the test item variant was parasitised by *A. bilineata*. In the water treated control an average of 528 beetles hatched. This was 35.6 % of the available puparia in the control. Compared to the amount of hatched beetles in the control, the decrease of parasitism rate was 4 % in the treated variant (Table B.9.5-5). The reference item BAS 152 11 I produced a reduction of reproduction of 99.7 % compared to the control.

Table B.9.5-5: Effects on reproduction efficiency of rove beetles (*Aleochara bilineata*) exposed to BAS 119 33 H in a laboratory trial

Treatment	Rate [kg/ha] 1)	Parasitised pupae [%] 2)	Number of hatched beetles	Effects on reproduction [%] 3)
Control	--	35.6	528	--
BAS 119 33 H	6.0	34.2	521	4
		Endpoint [kg/ha]		
ER_{50}		> 6.0		

1) Application rate in 400 L water/ha
2) Reduction of reproduction efficiency: Decrease of number of offspring (beneficial capacity) compared to the control level
3) Values recalculated from original data

Valid: yes

Conclusion
The ER_{50} obtained under worst-case laboratory conditions of BAS 119 33 H was ER_{50} > 6.0 kg/ha. BAS 119 33 H caused no adverse effects on the reproduction rate of *Aleochara bilineata*, if applied at a rate of 6.0 kg BAS 119 33 H/ha in 400 L water/ha. The laboratory studies yielded sufficient data to exclude detrimental effects to non-target arthropods other than bees in both in-crop and off-crop areas. Hence, no extended lab tests or semi field tests are triggered.

B.9.5.2.1 Field tests

The laboratory studies yielded sufficient data to exclude detrimental effects to non-target arthropods other than bees in both in-crop and off-crop areas. Hence, no field test is indicated.

B.9.5.2.2 Metabolite testing

Arthropods may be exposed to metabolites in/on plants and to soils metabolites. Chloridazon is metabolised to the metabolites B and metabolite B-1 in aerobic soil. The active substance is of low toxicity and the respective risk assessment indicates acceptable risk. Therefore, tests with the metabolites are not needed.

B.9.5.3 Summary of toxicity data on arthropods other than bees

To assess the effect BAS 119 33 H on terrestrial arthropods other than bees five different arthropod taxa were tested in the laboratory (*Typhlodromus pyri, Aphidius rhopalosiphi, Chrysoperla carnea, Pardosa* sp. and *Aleochara bilineata*). These non-target arthropod species were chosen according to the recommendations of ESCORT II (Candolfi et al., 2001, see SANCO/10329/2002), representing different ecological groups. The tests cover laboratory trials with exposure on inert substrate.

The rate tested in the worst case laboratory studies was equivalent to the maximum single application rate of 4.0 kg product/ha for *Typhlodromus pyri* and *Aphidius rhopalosiphi*; the 1.5-fold maximum single application rate was applied for *Chrysoperla carnea*, *Aleochara bilineata* and *Pardosa* spec. The results of the studies are summarised in Table B.9.5-6.

Table B.9.5-6: Summary of effects of BAS 119 33 H on terrestrial arthropods in laboratory tests

Test species	Substrate	Stage	Rate [kg/ha] 1)	Effects lethal [%]	Effects sublethal [%] 2)
Predatory mites					
T. pyri	inert	Proto-nymph	0.4 4.0	3.2 36.8	- 3.8 43.6
			LR_{50} ~ 4.0 kg/ha		
Parasitoids					
A. rhopalosiphi	inert	adult	4.0	0	- 7.3
			LR_{50} > 4.0 kg/ha		
Foliage dwelling predators					
C. carnea	inert	larvae	6.0	7.14	no effect
			LR_{50} > 6.0 kg/ha		
Soil dwelling predators					
A. bilineata	inert	adult	6.0	--	4
			ER_{50} > 6.0 kg/ha		
Pardosa spp.	inert	Sub-adult	6.0	0	0
			LR_{50} > 6.0 kg/ha		

1) BAS 119 33 H
2) negative values indicate an increase in reproduction compared to the control

B.9.5.4 Risk assessment

The recommended use pattern for BAS 119 33 H includes one application per season in beets with application rates of 1 x 4.0 kg BAS 119 33 H/ha, corresponding to 2.6 kg/ha chloridazon.
The risk assessment is performed according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) for the performed standard tests on inert substrates (Tier I) based on the hazard quotients (HQ). Additionally, the risk assessment for off-crop scenario is performed according to the TER approach as applied at the German Federal Environmental Agency (Schulte et al., 1999).

The relevant exposure scenarios for these uses are depicted below (Table B.9.5-7) and were calculated considering the application rate of 4000 g/ha. Regarding off-crop concentrations for the TER approach a drift rate of 2.77 % in 1 m distance to the treated field and a vegetation distribution factor (VDF) of 5 was considered:

PEC off-crop = Application rate × drift / VDF.

Table B.9.5-7: Relevant exposure scenarios of BAS 119 33 H for in-crop and off-crop in arable crop according to Ganzelmeier (loading by drift using the 90th percentile for single application)

Arable crop	Number of applications	Drift [%]	1 × Rate [g/ha]
In-crop	1	100	4000
Off-crop, 1 m	1	2.77	22.2

B.9.5.4.1 Hazard quotients for in-field exposure

The "in-field" hazard quotient (HQ) is calculated by using the in-field exposure (maximum single application rate of 4000 g/ha BAS 421 12 F and the multiple application factor (MAF) of 1) and the LR_{50} derived from the worst-case laboratory study according to following formula:

$$\textbf{In-field HQ} = \frac{\text{Application rate} \times \text{MAF}}{LR_{50}}$$

Table B.9.5-8: Risk assessment using HQ (Tier 1) based on standard tests

Species	LR_{50} (g/ha BAS 119 33 H)	In-field HQ	Trigger
Aphidius rhopalosiphi	> 4000 g/ha	< 1.0	2
Typhlodromus pyri	4000 g/ha	1.0	2

The resulting in-field hazard quotient is below the proposed threshold value of 2 for non-target arthropods in-crop, indicating that the risk for non-target arthropods in-field is acceptable.

Other indicator species

In addition to the two general indicator species (*T. pyri* and *A. rhopalosiphi*) showing no unacceptable effects already in the Tier 1 risk assessment, studies are provided for 2 more species being relevant for a certain ecological compartment.

The representatives of soil dwelling species were exposed on inert substrate to the formulation BAS 119 33 H at test rates equivalent to the 1.5-fold of the maximum field application rate.

The effects on foliage dwelling insects cannot be assessed, since the test has to be checked for validity first.

Table B.9.5-9: Risk assessment based on standard tests with foliar and soil dwelling species

Ecological compartment	Species	Test application rate (g BAS 119 33 H/ha)	Effect	Trigger value for 1st Tier*
Soil dwelling predators	*Aleochara bilineata*	6000 g/ha	no effect on reproduction	30 %
	Pardosa spp	6000 g/ha	no effect on mortality and food consumption	30 %

* Trigger value for first tier data as laid down in Annex VI C point 2.5.2.4 Directive91/414/EEC

The data obtained indicate that no risk or unacceptable effects on non-target arthropods including soil dwelling predators will be anticipated for in-crop scenarios.

B.9.5.4.2 Risk assessment for off-field-exposure

Hazard quotients

The "Off-field" exposure is characterised by the application rate (MAF), the drift factor (DF) for 1 m according to SANCO/10329/2002 and the vegetation distribution factor (VDF 5) as

the VDF of 10 given by ESCORT 2 is considered unreliable (SANCO/10329/2002). Furthermore, a correction factor of 10 is considered.

$$\textbf{Off-field HQ} = \frac{\text{Application rate x MAF x (DF (0.0277/VDF 5) x CF (10)}}{LR_{50}}$$

Aphidius rhopalosiphi and *Typhlodromus pyri* representing the two required general indicator species were tested in worst-case laboratory studies on inert substrate. With the derived LR_{50} values following hazard quotients (HQ) values were calculated:

Table B.9.5-10: Risk assessment using HQ (Tier 1) based on standard tests

Species	LR_{50} (g/ha BAS 119 33 H)	Off-field HQ	Trigger
Aphidius rhopalosiphi	> 4000 g/ha	< 0.056	2
Typhlodromus pyri	4000 g/ha	0.056	2

By including the drift factor (DF = 0.0277) for 1 m and a correction factor (CF) of 10 the off-field HQ is below the proposed threshold value of 2. A potential hazard to non-target arthropods assuming the off-crop scenario can be excluded.

It can be concluded that in accordance with the calculated hazard quotients no risk or unacceptable effects on non-target arthropods will be anticipated for off-crop exposure scenarios.

B.9.5.4.3 Toxicity/exposure ratio (TER) approach for off-field exposure

The LR_{50} values of the standard toxicity tests are compared with the exposure concentration expected in 1 m distance from the field (Table B.9.5-9). All obtained toxicity exposure ratios are above the trigger of 10 indicating no need for extended studies and an acceptable risk for non-target arthropods off-crop.

Table B.9.5-11: Risk assessment using TER based on standard tests with foliar and soil dwelling species

Ecological compartment	Species	LR_{50} (BAS 119 33 H g /ha)	PEC 1 m distance (g/ha) *	TER	Trigger for 1st Tier*
Parasitoids	*Aphidius rhopalosiphi*	> 4000	22.2	> 180	10
Predatory mites	*Typhlodromus pyri*	4000	22.2	180	10
Foliar dwelling predators	*Chrysoperla carnea*	> 6000	22.2	> 270	10
Soil dwelling predators	*Aleochara bilineata*	> 6000	22.2	> 270	10
	Pardosa spp	> 6000	22.2	> 270	10

* PEC off-crop = Application rate × drift (2.77 %) / VDF (5).

The data obtained indicate that no risk or unacceptable effects on non-target insects including soil and foliar dwelling predators will be anticipated for off-crop exposure scenarios. No higher tier tests are required.

Conclusion

On account of the laboratory studies carried out and based on the respective assessment schemes, no risk or unacceptable effects from the use of BAS 119 33 H according to good agricultural practice will be anticipated for non-target arthropods other than bees assuming in-crop and off-crop exposure scenarios.

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.6.1)

B.9.6.1 Acute toxicity (Annex II A 8.4.1; Annex III A 10.6.1.1)

ACTIVE SUBSTANCE

Reference number: II A 8.4.1/1

Report: Luehrs U., 2001; ARW 2002-7
Acute toxicity (14 days) of BAS 119 H to the earthworm *Eisenia fetida* (SAVIGNY 1826) in artificial soil
Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany; project # 976021; unpublished
BASF RegDoc# 2001/1005995

Guidelines: OECD 207, ISO 11268-1

GLP: Yes

Material and methods
Test item chloridazon (BAS 119 H, Reg. No. 13033), batch N 198, purity: 93.5 %; specification Document J, test species earthworm *Eisenia fetida*, adult worms (with clitellum and weight 300 - 600 mg) less than one year old, source: IBACON, Rossdorf, Germany. Worms were exposed for 14 days in treated artificial soil (according to OECD 207) to concentrations of 198, 296, 444, 667 and 1000 mg as/kg soil dry weight, a water treated control and 2-chloroacetamide as reference item. The test item was mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil; 5 concentrations plus a control, four replicates for each concentration with 10 worms each. Initial evaluation of the test item in a range finding test. Assessment of worm mortality and behavioural effects after 7 and 14 days, measurement of weight change as sublethal parameter after 14 days.

Findings
Chloridazon caused no statistically significant mortality of the earthworms up to the highest test concentration (1000 mg as/kg soil dry weight). The test item had no negative impact on worm biomass. No other particular behavioural or morphological changes were observed (Table B.9.6-1).

Table B.9.6-1: Effect of chloridazon on earthworm (Eisenia fetida) mortality and biomass (14 d)

Concentration [mg as/kg soil dry weight]	Control	198	296	444	667	1000
Mortality [%]	0	0	0	0	2.5[1)]	0
Weight change [%]	-7.1	-7.0[1)]	-3.7[1)]	-4.9[1)]	-4.1[1)]	-5.8[1)]
Endpoints [mg as/kg]						
NOEC	1000					
LC_{50}	> 1000					
LC_{50} 95 % confidence limits	--					

1) no statistical significance (Fisher exact-test, ANOVA followed by Dunnett test, $\alpha = 0.05$)

Valid: yes

Conclusion
In a 14-d toxicity study with chloridazon to earthworms (*Eisenia fetida)* the LC_{50} was higher than 1000 mg as/kg soil dry weight. The NOEC (mortality, biomass) was determined to be 1000 mg as/kg soil dry weight, the highest concentration tested.

METABOLITES

Reference number: II A 8.4.1/2

Report: Dohmen G.P., 1991; ARW 97-00070
Effect of Reg. No. 14 456 on the mortality of the earthworm *Eisenia fetida* BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; report # P91-E037; unpublished;
BASF RegDoc# 1991/10504

Guidelines: OECD 207

GLP: Yes

Material and methods
Test item metabolite B of chloridazon (Reg. No. 14 456), batch L45/253, purity: 98.2 %, test species earthworm *Eisenia fetida*, from in-house culture, adult worms (with clitellum and weight > 250 mg) less than one year old. Worms were exposed for 14 days in treated artificial soil (according to OECD 207) to concentrations of 113, 204, 340, 634 and 1132 mg as/kg soil dry weight and a water treated control. The test item was mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil; 5 concentrations plus a control, four replicates for each concentration with 10 worms each. Initial evaluation of the test item in a range finding test. Assessment of worm mortality and behavioural effects after 7 and 14 days, measurement of weight change as sublethal parameter after 14 days.

Findings
Metabolite B of chloridazon caused no mortality of earthworms up to the highest test concentration (1132 mg/kg soil dry weight). The test item had no negative impact on worm biomass. There is a statistically significant increase in growth with higher concentrations up to a

maximum at about 650 mg/kg, perhaps explained in an enhanced bacterial activity. No other particular behavioural or morphological changes were observed. The results are summarised in Table B.9.6-2.

Table B.9.6-2: Effect of metabolite B of chloridazon on earthworm (*Eisenia fetida)* mortality and biomass (14 d)

Concentration [mg/kg soil dry weight]	Control	113	204	340	634	1132
Mortality [%]	0	0	0	0	0	0
Weight change [%]	-2.80	+0.34	+2.73	+5.56	+8.36	+4.81
Endpoints [mg/kg soil dry weight]						
NOEC	1132					
LC_{50}	> 1132					

Valid: yes

Conclusion
In a 14-d toxicity study with metabolite B of chloridazon to earthworms (*Eisenia fetida)* the LC_{50} was determined to be higher than 1132 mg/kg soil dry weight and the NOEC was 1132 mg/kg soil dry weight.

Reference number: II A 8.4.1/3

Report: Staab F., 2001; ARW 2003-152
Effect of BH 119 B-1 on the mortality of the earthworm *Eisenia fetida*
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany;
study code 52028; unpublished; BASF RegDoc# 2001/1005986

Guidelines: OECD 207

GLP: Yes

Material and methods
Test item: metabolite B-1 of chloridazon (Reg. No. 035 375), Lot No. 01658-42, purity: 99.9 %, test species earthworm *Eisenia fetida*, from in-house culture, adult worms (with clitellum and weight 250 mg - 600 mg), less than one year old. Worms were exposed for 14 days in treated artificial soil (according to OECD 207) to concentrations of 197.5, 296.3, 444.4, 666.7 and 1000 mg as/kg soil dry weight, a water treated control and 2-chloroacetanilide as reference item. The test item was mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil; 5 concentrations plus a control, four replicates for each concentration with 10 worms each. Initial evaluation of the test item in a range finding test. Assessment of worm mortality and behavioural effects after 7 and 14 days, measurement of weight change as sublethal parameter after 14 days.

Findings
Metabolite B-1 of chloridazon caused no mortality on earthworms up to the highest test concentration (1000 mg/kg soil dry weight). The test item had no significant effect on worm biomass. No other unusual behavioural or morphological changes were observed.
The results are summarised in Table B.9.6-3.

Table B.9.6-3: Effect of metabolite B-1 of chloridazon on earthworm (*Eisenia fetida)* mortality and biomass (14 d)

Concentration [mg/kg soil dry weight]	Control	197.5	296.3	444.4	666.7	1000
Mortality [%]	0.0	0.0	0.0	0.0	0.0	0.0
Weight change [%]	-6.30	-5.37	-3.02	-0.11	+2.54	-10.78
Endpoints [mg/kg soil dry weight]						
NOEC	1000					
LC_{50}	> 1000					

Valid: yes

Conclusion
In a 14-d toxicity study with metabolite B-1 of chloridazon to earthworms *(Eisenia fetida)* the LC_{50} was determined to be higher than 1000 mg/kg soil dry weight. The NOEC related to mortality and biomass was determined to be 1000 mg/kg soil dry weight. No effects on mortality and no adverse effects on biomass were observed.

FORMULATED PRODUCTS

Reference number: III A 10.6.1.1/1

Report: Staab F., 2001; ARW 2002-8
Effect of BAS 119 33 H on the mortality of the earthworm *Eisenia fetida* BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; study code 79557; unpublished; BASF Reg-Doc# 2001/1005985

Guidelines: OECD 207

GLP: Yes

Material and methods
Test item: BAS 119 33 H, batch no. 97-1, content of as: 65.4 % Reg. No. 13033 (nominal: 65 %), test species earthworm *Eisenia fetida*, from in-house culture, adult worms (with clitellum and weight 250 mg - 600 mg) less than one year old.
Worms were exposed for 14 days in treated artificial soil (according to OECD 207) to concentrations of 197.5, 296.3, 444.4, 666.7 and 1000 mg as/kg soil dry weight and a water treated control. The test item was mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil; 5 concentrations plus a control, four replicates for each concentration with 10 worms each. Initial evaluation of the

test item in a range finding test. Assessment of worm mortality and behavioural effects after 7 and 14 days, measurement of weight change as sublethal parameter after 14 days.

Findings
BAS 119 33 H caused no mortality on earthworms in any of the test items. No significant reduction of worm biomass was observed. The worms showed no unusual behavioural or morphological changes (Table B.9.6-4).

Table B.9.6-4: Effect of BAS 119 33 H on earthworm (*Eisenia fetida)* mortality and biomass (14 d)

Concentration [mg/kg soil dry weight]	Control	197.5	296.3	444.4	666.7	1000.0
Mortality [%]	2.5	0.0	0.0	0.0	0.0	0.0
Weight change [%]	-11.26	-12.61	-10.96	-6.93	-3.85	-11.91
Endpoints [mg/kg soil dry weight]						
NOEC	1000					
LC_{50}	> 1000					

Valid: yes

Conclusion
In a 14-d toxicity study with BAS 119 33 H to earthworms (*Eisenia fetida)* the LC_{50} was determined to be higher than 1000 mg BAS 119 33 H/kg soil dry weight. The NOEC related to mortality and biomass was determined to be 1000 mg BAS 119 33 H/kg soil dry weight.

B.9.6.2 Sublethal effects (Annex II A 8.4.2; Annex III A 10.6.1.2)

The results of the acute tests indicate that chloridazon and its metabolites B and B-1 are not acutely toxic to earthworms. TER values meet by far the Annex VI trigger of 10.

For the actives substance no investigation of sublethal effects was performed.

Metabolite B appeared to be more persistent in soils than the parent compound (parent: $DT_{50field}$-values 3 to 78.5 days (mean: 35 days); the respective $DT_{90field}$-values ranged from 35 to 214 days (mean: 104 days)) and is degraded with $DT_{50field}$-values ranging from 130 to 360 days. Further testing was triggered based on the new Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final, dated October 17 2002).

Metabolite B-1 was found in field studies only in minor amounts and only at a few samplings. This metabolite is regarded as not relevant in the terrestrial compartment. No additional study was needed.

METABOLITE(S)

Reference number: II A 8.4.2/01

Report: Wolf, A. (2004); ARW 2004-170
Effect of BH119-metabolite B on earthworm (*Eisenia fetida*) reproduction in a chronic test, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep., Study code 179839; unpublished, BASF RegDoc# 2004/1004432

Guidelines: ISO 11268-2: Soil quality – Effects of pollutants on earthworms (*Eisenia fetida*) – Part 2: Determination of effects on reproduction, 1998

Deviations: Test substrate with 5 % peat instead of 10 %

GLP: Yes (laboratory certified by Landesanstalt für Umweltschutz und Gewerbeaufsicht, Rheinland-Pfalz, Mainz)

Material and methods:

Test item:	BH 119-Metabolite B (Reg. No. 14456), Batch No. 41-216, purity: 99.8 %.
Test species:	Earthworm (*Eisenia fetida*) from in-house culture, adult worms (with clitellum and weight 300 mg - 600 mg), less than one year old.
Test design:	Different concentrations of the test item were mixed homogeneously into the soil before worms were placed on soil surface. 6 variants (4 test item concentrations, control, reference item); 4 replicates/variant with 10 worms each. Assessment of adult worm mortality and biomass was done after 28 days; offspring were maintained for additional 4 weeks; at the end of the test the number of surviving juveniles are counted to assess the reproduction rate.
Endpoints:	Mortality, weight change and number of juveniles
Reference item:	Benlate, 3.5 mg/kg substrate
Test rates:	0.6, 3.0, 6.0, 15.0 mg/kg soil dry weight.
Test conditions:	Artificial soil according to ISO 11268-2; pH 6.8 – 6.9; moisture about 60 % of maximimum WHC, temperature 20 °C – 21 °C; light/dark 16:8 hours
Statistics:	Descriptive statistics, ANOVA followed by Dunnett test (Toxstat ver. 3.5).

Findings:
BH 119-metabolite B caused no mortality on earthworms up to the highest test concentration of 15.0 mg/kg soil dry weight. The test item had no significant effects on worm biomass and reproduction rate. The reference item caused 78.74 % reduction of the reproduction.

The results are summarised in Table B.9.6-5.

Table B.9.6-5: Effect of BH 119-metabolite B on earthworm (*Eisenia fetida)* reproduction (56 d)

BH 119-Metabolite B [mg/kg substrate]	Control	0.6	3.0	6.0	15.0	Reference
Adult mortality (day 28) [%]	0	0	0	0	0	5.0
Weight gain [%]	+25.86	+22.20 n.s.	+32.33 n.s.	+29.14 n.s.	+29.97 n.s.	+26.97 n.s.
Number of juveniles/replicate	127.0	136.75 n.s.	111.75 n.s.	122.0 n.s.	111.5 n.s.	27.00*
Reproduction in percent of control (day 56) [%]	-	107.68 n.s. .0	87.99 n.s.	96.06 n.s.	87.80 n.s.	21.26*
Amount of food added [g]	34	34	34	34	34	34
Endpoints	**mg/kg substrate**					
NOEC	**15.0**					

n.s. = No statistically significant differences compared to the control (Dunnett-test for body weight and reproduction data; $\alpha = 0.05$)
* = significant difference

Valid: Yes

Conclusion:
In a 56-day reproduction study on earthworms (*Eisenia fetida*) with BH 119-Metabolite B the NOEC was determined to be 15.0 mg/kg soil dry weight, the highest concentration tested.

Comment of the RMS:
The notifier did not investigate sublethal effects on earthworm since only one application of the herbicide per season is recommended.
The total rate of 2.6 kg as/ha can be splitted and applied up to three times post-emergence up the BBCH 19. Due to the relatively short time interval between the respective applications it is assumed that they can be taken as one application and an investigation of sublethal effects on earthworms is not required.

B.9.6.3 Field study (Annex IIA 10.6.1.3)

According to Directive 91/414 EEC a field study is required, where TER_{lt} is < 5.

The active substance is considered relatively persistent in soil with $DT_{50field}$-values ranging from 3 to 78.5 days (mean: 35 days); the respective $DT_{90field}$-values ranged from 35 to 214 days (mean: 104 days) (see Table B.8.1-33).

Metabolite B appeared to be more persistent in soils than the parent compound and degraded with $DT_{50field}$-values ranging from 130 to 360 days (see Table B.8.1-34). Further testing was triggered only based on the new Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final, dated October 17, 2002). A reproduction test was therefore submitted.

Metabolite B-1 was found in field studies only in minor amounts and only at a few samplings. This metabolite is regarded as not relevant in the terrestrial compartment. No additional study was needed.

Residue content in earthworms is not required to be determined since chloridazon and its metabolite have no bioaccumulation potential (logPow < 3).

B.9.6.4 Summary of toxicity data on earthworms

Data summary and evaluation is based on studies performed with the active substance chloridazon and its metabolites B and B-1.

The toxicity of **chloridazon** and its soil **metabolites B** and **B-1** as well as the formulation have been tested on earthworms in 14-day toxicity studies with up to 1132 mg/kg substrate and are summarised in Table B.9.6-6.

Chloridazon and the formulated product BAS 119 33 H exhibited no intrinsic toxicity to earthworms (LC_{50} = >1000 mg as/kg; NOEC = 1000 mg as/kg, less biomass decrease than control). The soil metabolites B and B-1 were practically non-toxic to earthworms with LC_{50}-values of > 1132 mg/kg and >1000 mg/kg and NOEC-values of 1132 mg/kg and 1000 mg/kg substrate, respectively.

Table B.9.6-6: Summary of effects of chloridazon, its metabolites B and B-1 and formulation on earthworms

Test species	Test system	Toxicity [mg/kg soil dry weight]	
		LC_{50}	NOEC/NOAEC
Chloridazon			
Eisenia fetida	14-d toxicity test	> 1000	1000
Metabolite B			
Eisenia. fetida	14-d toxicity test	> 1132	1132
	56-d reproduction	-	15
Metabolite B-1			
Eisenia fetida	14-d toxicity test	> 1000	1000
BAS 119 33 H			
Eisenia fetida	14-d toxicity test	> 1000	1000

B.9.6.5 Risk assessment

For the standard risk assessment, the **acute toxicity** of the active substance is compared with the initial predicted environmental concentration ($PEC_{soil, ini}$) for chloridazon and its metabolites, assuming a worst-case scenario with one application at a rate of 2.6 kg as/ha chloridazon (pre-emergence scenario; no crop interception). This is equivalent to the maximum single application rate resulting from the use pattern of BAS 119 33 H. For calculation of the PEC_{soil} see chapter B 8.3.

Table B.9.6-7: Acute TER-values for earthworms exposed to residues of chloridazon and its metabolites in soil

Test species	Adjusted toxicity [mg as/kg substrate]	PEC_{ini} [1] [mg/kg soil]	TER_a	Trigger TER
Chloridazon				
E. fetida	> 1000	3.467	> 288	10
Metabolite B				
E. fetida	> 1132	0.600	> 1887	10
Metabolite B-1				
E. fetida	> 1000	0.172	> 5814	10
Chloridazon recalculated from BAS 119 33 H				
E. fetida	> 650	3.458 [2]	> 188	10

1) Calculation based on sugar beet scenario with 1 x 4.0 kg BAS 119 33 H/ha corresponding to 2.6 kg/ha chloridazon, see Document M-III, chapter 9.1 (BASF DocID 2003/1001029).
2) PEC was recalculated from the product. PEC-calculation based on sugar beet scenario with 1 x 4.0 kg BAS 119 33 H/ha (containing 650 g/kg chloridazon) see chapter B 8.3.

The acute TER-value for the active substance **chloridazon** is clearly higher than the trigger value laid down the Annex IV of the Directive 91/414/EEC.

Since the two **metabolites of chloridazon** did not exhibit intrinsic acute toxicity to earthworms, the calculation of acute TER values for the metabolites (metabolite B and metabolite B-1) resulted in TER values > 1887 and > 5814 and also meet the 91/414 EEC Annex VI trigger of 10.

The acute TER-value for the active substance chloridazon as contained in the **formulation BAS 119 33 H** (0 % interception) is above the trigger of the 91/414 EEC Annex VI.

Table B.9.6-8: Long-term TER-values for earthworms exposed to residues of metabolite B in soil

Test species	Adjusted toxicity [mg as/kg substrate]	PEC_{ini} [1] [mg/kg soil]	TER_{lt}	Trigger TER
Metabolite B				
E. fetida	15	0.600	25	5

1) Calculation based on sugar beet scenario with 1 x 4.0 kg BAS 119 33 H/ha corresponding to 2.6 kg/ha chloridazon, see Document M-III, chapter 9.1 (BASF DocID 2003/1001029).

The long-term TER-value for the metabolite B is clearly higher than the trigger value laid down in the Annex IV of the Directive 91/414/EEC.

Conclusion

The risk assessment for earthworms used PEC-calculations based on the realistic exposure scenario in sugar beets (1 x 4.0 kg BAS 119 33 H/ha, 0 % interception). The acute and long-term TER values for chloridazon and the metabolites B and B-1 as well as for the lead formulation BAS 119 33 H are above the 91/414 EEC Annex VI trigger values of 10 or 5 indicating no potential risk to earthworms.

B.9.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

ACTIVE SUBSTANCE

No data submitted.

METABOLITES

No data submitted.

FORMULATED PRODUCTS

No data submitted.

B.9.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)

B.9.8.1 Laboratory testing

Studies were performed with a representative formulation containing chloridazon. The formulation BAS 119 33 H is a herbicidal product, which contains the active substance chloridazon (BAS 119 H) with a nominal content of 650 g/kg.

The recommended use pattern for BAS 119 33 H comprises one application per season in beets pre-emergence and up to three applications post-emergence (BBCH 14). In any case, the maximum rate of chloridazon applied per hectare and year is 2.6 kg active substance, i.e. 4.0 kg/ha formulated product.

Reference number: III A 10.7.1/1

Report: Hamm R.T., 1988(a); BMF 2002-4
Effect of Pyramin WG (BAS 119 33 H) on the nitrification
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF RegDoc# 1988/10050

Guidelines: BBA VI 1-1

GLP: Yes

Material and methods

Test item: BAS 119 33 H, batch no. V-H 1988 (APE/CF), content of active substance: 65 % Reg. No. 13 033.

Test species:	Biologically active agricultural soils: 1) loamy sand soil, 2) loam soil.
Test design:	NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process were determined by using calibrated ion-sensitive electrodes and the Orion expandable ion-analyser 901, respectively, over a time period of 28 days.
Endpoints:	Effect on NO_3-nitrogen production after 28 days of exposure.
Reference item:	Nitrapyrin
Test concentrations:	Control, 4.0 mg BAS 119 33 H/kg (corresponding to an application rate of 3.0 kg BAS 119 33 H/ha dry soil) and 40 mg per kg soil (corresponding to an application rate of 30 kg BAS 119 33 H/ha dry soil; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3); 3 replicates per concentration. Reference item: 0.5 mg/kg dry soil.
Test conditions:	Soil moisture: 52 % of its water holding capacity in case of the loamy sand and 47.5 % in case of the loam. Soil samples were incubated at 21 °C ± 1 °C while stored in plastic bottles. Sampling scheme: 0, 7, 14, 21 and 28 days after treatment.
Statistics:	Descriptive statistics.

Findings

The single application rate (4.0 mg/kg dry soil) caused no observable effect on NO_3 -nitrogen production in both soils. The ten-fold rate (40 mg/kg dry soil) caused a slight inhibition in NO_3 -nitrogen production in the loamy sand soil. In the loam soil the ten-fold application rate caused slight stimulation of the nitrification followed by a slightly decreased N-transformation rate of –12 % deviation from the control after 28 days (Table B.9.8-1).

Table B.9.8-1: Effect on nitrogen transformation in two soils exposed to BAS 119 33 H (day 28)

Soil	% Deviation from the control [1)]	
	4.0 mg BAS 119 33 H per kg dry soil	40 mg BAS 119 33 H per kg dry soil
Loamy sand soil	+3.0	-3.0
Loam soil	-3.0	-12.0

1) - = inhibition; + = stimulation

The reference item nitrapyrin caused 76 % inhibition in nitrification in the loamy sand soil and 2 % inhibition in the loam soil.

Valid: yes

Conclusion

BAS 119 33 H caused no adverse effects on nitrogen transformation (measured as NO_3-N production) in two soils at single and ten-fold application rates tested up to concentrations of 40 mg BAS 119 33 H/kg, corresponding to a field application rate of 30 kg BAS 119 33 H/ha. According to the evaluation proposal given in OECD 216, from the results it may be concluded, that BAS 119 33 H has no long-term influence on nitrogen transformation in soils.

Reference number: III A 10.7.1/2

Report: Hamm R.T., 1988(b); BMF 2002-5
Effect of Pyramin WG (BAS 119 33 H) on soil respiration
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF RegDoc# 1988/10051

Guidelines: BBA VI 1-1

GLP: Yes

Material and methods

Test item: BAS 119 33 H, batch no. V-H 1988 (APE/CF), content of active substance; 65 % Reg. No. 13 033.

Test species: Biologically active agricultural soils: 1) loamy sand soil; 2) loam soil.

Test design: Determination of carbon-transformation in soil after addition of glucose. Comparison of test item treated soil with a non-treated soil. 4 replicates per treatment and concentration. A Sapromat B12 was used to measure the O_2 consumption over a period of maximum 12 hours at different sampling intervals. Sampling scheme: 0, 14 and 28 days after treatment.

Endpoints: Effects on O_2 consumption after 28 days of exposure.

Test concentrations: Control, 4.0 mg BAS 119 33 H/kg (corresponding to an application rate of 3.0 kg BAS 119 33 H/ha dry soil) and 40 mg BAS 119 33 H/kg (corresponding to an application rate of 30 kg BAS 119 33 H/ha dry soil). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.

Test conditions: Soil moisture: 40 % (loamy sand soil) to 55 % (loam soil) of its water holding capacity. Soil samples were incubated at 20 °C ± 2 °C while stored in plastic bottles.

Statistics: Descriptive statistics.

Findings

BAS 119 33 H caused a slight stimulation at the 10-fold application rate (40 mg/kg dry soil) of + 5.3 % of the carbon transformation in the loamy sand soil after 28 days. In the loam soil a slight decreased respiration was observed at the 10-fold application rate. The slightly reduced or enhanced carbon transformation rates of the treated soil samples do not represent significant differences as compared to the control data (Table B.9.8-2).

Table B.9.8-2: Effect on carbon transformation in two soils exposed to BAS 119 33 H (day 28)

Soil	% Deviation from the control [1)]	
	4.0 mg BAS 119 33 H per kg dry soil	40 mg BAS 119 33 H per kg dry soil
Loamy sand soil	+5.3	+5.3
Loam soil	-1.0	-4.9

1) - = inhibition; + = stimulation

Valid: yes

Conclusion
Based on the results of this study BAS 119 33 H caused no adverse effects on the carbon transformation (measured as oxygen consumption) at single and 10-fold application rates in loamy sand soil and loam soil tested up to a concentration of 40 mg BAS 119 33 H/kg, corresponding to a field application rate of 30 kg BAS 119 33 H/ha.

According to the evaluation proposal given in OECD 217, from the results it may be concluded, that BAS 119 33 H has no long-term influence on carbon-transformation in soils.

Additional studies were performed with potential soil metabolites.

Reference number: II A 8.5/1

Report: Gerhardt R., 1991(b); BMF 2003-69
Effect of Reg. No. 14 456 on the nitrogen turnover in the soil
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF DocID 1991/10442

Guidelines: BBA VI 1-1

GLP: Yes

Reference number: II A 8.5/2

Report: Gerhardt R., 1991(c); BMF 2003-70
Addendum to laboratory study code P91-E036: Effect of Reg. No. 14 456 on the nitrogen turnover in the soil
BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF DocID 1991/10986

Guidelines: BBA VI 1-1

GLP: Yes

Material and methods
Test item: Metabolite B of chloridazon (Reg. No. 14 456), charge L45/253, purity: 98.2 %.
Test species: Biologically active agricultural soils: 1) loamy sand soil, 2) sandy loam soil.
Test design: Determination of the N-transformation (NO_3-nitrogen production) in soil amended with horn meal (concentration in soil 0.2 % and 0.071 %, trials of control and test item amended with 0.2 % and 0.071 %, reference item amended with 0.2 %). Comparison of test item treated soil with a non-treated soil and a reference item treated soil. 3 replicates per treatment and concentration. NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process was determined by using an ammonia-electrode and a nitrate-electrode, respectively. Sampling scheme: 0, 14 and 28

	days after treatment, aliquots were withdrawn and subjected to the measurement.
Endpoints:	Effect on nitrate formation after 28 days of exposure.
Test concentrations:	Control, 1.71 mg/kg metabolite B of chloridazon (corresponding to an application rate of 1.28 kg/ha metabolite B of chloridazon) and 8.53 mg/kg metabolite B of chloridazon (corresponding to an application rate of 6.40 kg/ha Metabolite B of chloridazon) and reference item. The reference item was applied at a rate of 6.33 µL/kg dry soil. Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
Reference item:	N-SERVE 24 E (nitrapyrin [2-chloro-6-(trichloromethyl)pyridine] 21.9 %).
Test conditions:	Soil moisture: 45 % (loamy sand soil) to 45 % (sandy loam soil) of its water holding capacity. Soil samples were incubated at 20 °C ± 2 °C while stored in glass bottles.
Statistics:	Descriptive statistics.

Findings

The test item caused practically no effects in the sandy loam soil at both application rates. After 14 days an inhibition of the nitrogen-transformation in the loamy sand soil could be observed, especially for the higher application rate (8.53 mg/kg metabolite B of chloridazon) amended with 0.2 % horn meal. The slightly reduced or enhanced nitrate values of the treated soil samples observed at almost all sampling dates do not represent significant differences as compared to the control data. The results are summarised in Table B.9.8-3.

Table B.9.8-3: Effect on N-transformation in two soils exposed to metabolite B of chloridazon (day 28)

Soil	% Deviation from the control [1)]	
	1.71 mg/kg dry soil	8.53 mg/kg dry soil
Loamy sand soil (0.2 % horn meal)	+0.1	-1.8
Loamy sand soil (0.071 % horn meal)	-7.0	-8.2
Sandy loam soil (0.2 % horn meal)	-1.0	+3.4
Sandy loam soil (0.071 % horn meal)	+4.9	+3.7

1) - = inhibition; + = stimulation

The reference item N-SERVE 24 E in both soils produced the expected level of effect (86.1 % and 45 % inhibition).

Valid: yes

Conclusion

Based on the results of this study metabolite B of chloridazon caused no adverse effects on the nitrogen-transformation (measured as NO_3-nitrogen production) in two field soils tested at concentrations equivalent to field application rates of 1.28 kg (50 % of active substance) and 6.40 kg/ha.

According to the evaluation proposal given in OECD 216, from the results it may be concluded, that metabolite B of chloridazon has no long-term influence on nitrogen-transformation in soils.

Reference number: II A 8.5/3

Report: Gerhardt R., 1991(a); BMF 2003-71
Effect of Reg. No. 14456 on soil respiration BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished;
BASF DocID 1991/10441

Guidelines: BBA VI 1-1

GLP: Yes

Material and methods

Test item: Metabolite B of chloridazon (Reg. No. 14 456), charge L45/253, purity: 98.2 %.

Test species: Biologically active agricultural soils: loamy sand and sandy loam soil.

Test design: Determination of O_2-consumption in soil after addition of glucose. Comparison of test item treated soil with a non-treated and a toxic standard treated soil. 4 replicates per treatment and concentration. A Sapromat B12 was used to measure the O_2-consumption over a period of 20 hours at different sampling intervals. Sampling scheme: 0, 7, 14, 21 and 28 days after treatment, aliquots were withdrawn and subjected to the measurement.

Endpoints: Effect on O_2-consumption after 28 days of exposure.

Test concentrations: Control, 1.71 mg/kg metabolite B of chloridazon (corresponding to an application rate of 1.28 kg/ha) and 8.53 mg/kg metabolite B of chloridazon (corresponding to an application rate of 6.40 kg/ha).
The reference item was applied at a rate of 0.8 and 20 µg/kg dry soil.
Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.

Reference item: "Aretit flüssig"

Test conditions: Soil moisture: 50 % (loamy sand) to 47 % (sandy loam) of its water holding capacity. Soil samples were incubated at 20 °C ± 2 °C while stored in plastic bottles.

Statistics: Descriptive statistics.

Findings

No adverse influences of metabolite B of chloridazon on carbon transformation could be observed at both application rates in both soils after 28 days. No or only negligible deviations from the control of +3.5 % (loamy sand), +2.9 % (sandy loam), - 2.6 % (loamy sand) and + 2.9 % (sandy loam) were measured in the 1.71 and 8.53 mg/kg dry soil test item concentrations, respectively (Table B.9.8-4).

Table B.9.8-4: C-transformation in soil exposed to metabolite B of chloridazon (day 28)

Soil	% Deviation from the control [1)]	
	1.71 mg/kg dry soil	8.53 mg/kg dry soil
Loamy sand soil	+3.5	-2.6

Soil	% Deviation from the control [1)]	
	1.71 mg/kg dry soil	8.53 mg/kg dry soil
Sandy loam soil	+2.9	+2.9

1) - = inhibition

In a separate study the reference item caused a significant inhibition of the soil respiration with 41.1 % in loamy sand soil and 30.0 % in the sandy loam soil.

Valid: yes

Conclusion
Based on the results of this study, metabolite B of chloridazon caused no adverse effects on the C-transformation (measured as oxygen consumption) in two field soils tested at concentrations equivalent to field application rates of 1.28 kg/ha (50 % of active substance) and 6.40 kg/ha.

According to the evaluation proposal given in OECD 217, from the results it may be concluded, that metabolite B of chloridazon has no long-term influence on carbon-transformation in soils.

Reference number: II A 8.5/4

Report: Krieg W., 2001; BMF 2003-72
Effect of BH 119-B1 on soil micro-organisms: Carbon transformation test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany; unpublished; BASF DocID 2001/1005969

Guidelines: OECD 217

GLP: Yes

Material and methods

Test item: Metabolite B-1 of chloridazon (Reg. No. 035375), batch no. 01196-259 (PCP04974), purity: 99.7 %.

Test species: Biologically active agricultural soil: silty sand soil.

Test design: Determination of O_2-consumption in soil after addition of glucose. Comparison of test item treated soil with a non-treated and a toxic standard treated soil. 4 replicates per treatment and concentration. A BSB digi (Fa. Johanna Otto) was used to measure the O_2 consumption over a period of 20 hours at different sampling intervals. Sampling scheme: 0, 7, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the measurement.

Endpoints: Effect on O_2 consumption after 28 days of exposure.

Test concentrations: Control, 0.35 mg/kg metabolite B-1 of chloridazon (corresponding to an application rate of 0.26 kg/ha) and 1.75 mg/kg metabolite B-1 of chloridazon (corresponding to an application rate of 1.3 kg/ha).
The reference item was applied at a rate of 30 mg/kg dry soil. Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.

Reference item: DINOTERB
Test conditions: Soil moisture: 45 % of its water holding capacity. Soil samples were incubated at 20 °C ± 2 °C while stored in glass bottles.
Statistics: Descriptive statistics.

Findings
No adverse influences of Metabolite B-1 of chloridazon on carbon transformation could be observed at the single and five-fold application rate after 28 days. No or only negligible deviations from the control of 0 % (single) and -6.41 % (five-fold) were measured (Table B.9.8-5).

Table B.9.8-5: C-transformation in soil exposed to metabolite B-1 of chloridazon (day 28)

Soil	% Deviation from the control [1)]	
	0.35 mg/kg dry soil	1.75 mg/kg dry soil
Silty sand soil	0	-6.41

1) - = inhibition

In a separate study the reference item caused a significant inhibition of the soil respiration with 35.85 % in loamy sand soil (01/145/00).

Valid: yes

Conclusion
Based on the results of this study, metabolite B-1 of chloridazon caused no adverse effects on the C-transformation (measured as oxygen consumption) in the field soil tested at concentrations equivalent to field application rates of 0.26 kg/ha (10 % of active substance) and 1.3 kg/ha.

According to the evaluation proposal given in OECD 217, from the results it may be concluded that metabolite B-1 of chloridazon has no long-term influence on carbon-transformation in soils.

B.9.8.2 Summary of results and risk assessment

Laboratory studies on the influence of BAS 119 33 H on non-target soil micro-organisms, i.e. nitrogen transformation and carbon transformation, tested in two field soils, did not exhibit adverse effects at test concentrations of 3 and 30 kg BAS 119 33 H/ha (i.e.: 2.6 kg as/ha. and 26 kg as/ha corresponding to 75 % of the max. yearly recommended application rate of 4.0 kg/ha and its 7.5-fold rate.
All deviations compared to the control within the test period of 28 days were < 25 %. It is therefore concluded that the use of BAS 119 33 H according to good agricultural practice will not adversely affect ecosystem functions driven by soil micro-organisms.

Table B.9.8-6: Summary of effects of BAS 119 33 H on soil micro-organisms (day 28)

Test system/ soil type	Application rate [kg/ha]	Result [%] of control	Reference
C-transformation			

Test system/ soil type	Application rate [kg/ha]	Result [%] of control	Reference
Loamy sand	3.0	+5.3	Hamm 1988/10051
	30.0	+5.3	
Loam	3.0	-1.0	
	30.0	-4.9	
N-transformation			
Loamy sand	3.0	+3.0	Hamm 1988/10050
	30.0	-3.0	
Loam	3.0	-3.0	
	30.0	-12.0	

Furthermore, the soil metabolites of BAS 119 H, i.e. metabolite B and metabolite B-1, have been tested at concentrations, which reflect the maximum transformation rates of the active substance into the respective metabolite in the soil, i.e. 50 % (metabolite B, no molecular correction factor) and 10 % (metabolite B-1, no molecular correction factor) on the basis of the maximum single field application rate of 2.6 kg as/ha.
The results show that the tested soil metabolites also have no adverse effects on soil micro-organisms and their physiological activities. The deviations compared to the control within the test period of 28 days are by far < 25 %. The results are summarised in Table B.9.8-7.

Table B.9.8-7: Summary of effects of metabolite B and metabolite B-1 of chloridazon on soil micro-organisms

Test system/	Application rate		Result	Reference
	[mg/kg]	[kg/ha]	[%] deviation from control [1)]	
Metabolite B				
N-transformation				
Loamy sand soil (0.2 % horn meal)	1.71	1.28	+0.1	Gerhardt 1991/10442 Gerhardt 1991/10986
	8.53	6.40	-1.8	
Loamy sand soil (0.071 % horn meal)	1.71	1.28	-7.0	
	8.53	6.40	-8.2	
Sandy loam soil (0.2 % horn meal)	1.71	1.28	-1.0	
	8.53	6.40	+3.4	
Sandy loam soil (0.071 % horn meal)	1.71	1.28	+4.9	
	8.53	6.40	+3.7	
C-transformation				
Loamy sand soil	1.71	1.28	+3.5	Gerhardt 1991/10441
	8.53	6.40	-2.6	
Sandy loam soil	1.71	1.28	+2.9	
	8.53	6.40	+2.9	
Metabolite B-1				
C-transformation				
Silty sand soil	0.35	0.26	0	Krieg 2001/1005969
	1.75	1.3	-6.41	

1) - = inhibition; + = stimulation

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6)

B.9.9.1 Toxicity to plants

The formulation BAS 119 33 H is a herbicidal product that contains the active substance chloridazon (BAS 119 H) with a nominal content of 650 g/kg. The herbicidal effects of chloridazon are primarily due to its inhibition of the photosynthetic electron transport through binding to the D1-protein of photosystem II.
The herbicide is effective against a wide spectrum of dicotyledonous weeds and annual blue grass as well as wind bent grass. The systemic herbicide is rapidly absorbed by the roots and after post-emergence application also by shoots and leaves. The compound shows acropetal and basipetal translocation. When applied pre-emergence, chloridazon uptake via roots and shoots is influenced by soil moisture, temperature and slightly by the relative humidity.

The recommended use pattern for BAS 119 33 H comprises one application per season in beets pre-emergence and up to three applications post-emergence. The compound can also be worked into the soil prior to sowing. Pre-emergence application is most effective if there is enough soil moisture for the distribution of the active substance into the soil. After spraying on dry soil surfaces the highest herbicidal activity occurs after the next rainfall.
In any case, the maximum rate of chloridazon applied per hectare and year is 2.6 kg active substance, i.e. 4.0 kg/ha formulated product.

The notifier submitted two studies with 6 different plant species each regarding the effects on terrestrial non-target plants (III A 10.8/1 and /2). They belong to six different plant families, and comprise four dicotyledonous and two monocotyledonous plant species. The tests were done with the formulated product and application of the compound via spraying, as off-crop plants would be exposed to that.

Additionally, the RMS has access to summary reports about plant toxicity studies with the active substance and metabolites as well as to one study with the product. The notifier had performed all studies. The data were retrieved from the internal database of the German Federal Environmental Agency and are presented at the end of the chapter.

Submitted by the notifier

FORMULATED PRODUCT

Reference number: III A 10.8/1

Report: Frank P., 2000(a); PFL 2002-4
BAS 119 33 H: A toxicity test to determine the effects of the test item on seedling emergence of terrestrial plants
Staatliche Lehr- und Forschungsanstalt, Neustadt, Germany; study code 71161; unpublished. BASF RegDoc# 2000/1017181

Guidelines: OECD 208, EEC 91/414

GLP: Yes

Material and methods

Test item BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13933 (nominal: 65 %), test species: oilseed rape (*Brassica napus*), pea (*Pisum sativum*), sunflower (*Helianthus annus*), flax (*Linum usitatissimum*), oats (*Avena sativa*), onion (*Allium cepa*).
BAS 119 33 H was tested under greenhouse conditions in a dose-response design at concentrations of 188, 375, 750, 1500, 3000 and 6000 g/ha and a water treated control (corresponding to 123, 245, 491, 981, 1962 and 3924 g as/ha or 0.16, 0.33, 0.66, 1.31, 2.62 and 5.23 mg as/kg soil (depth 5 cm, bulk density 1.5 g/mL). Five replicates/variant were run with 1 pot/replicate, 4 - 7 seeds per pot (species dependent); BAS 119 33 H was applied pre-emergence using a laboratory spray cabin with a water rate of 200 L/ha. Following the application the plants were cultivated for 21 days in the greenhouse. Assessments for seedling emergence and phytotoxicity (e.g. scorch, stunting, deformations) were done 7, 14 and 21 days after application (DAA); plant height and fresh plant weight were determined 21 DAA.

Findings

Slight damages were observed only at the both highest rates (3000 g/ha and 6000 g/ha BAS 119 33 H) tested on oilseed rape. No other adverse effects of BAS 119 33 H on the test plants were found. The results are summarised in Table B.9.9-1 and Table B.9.9-2.

Table B.9.9-1: Effects of BAS 119 33 H on plant biomass and condition (visible damage) 21 days after application

Rate [g/ha]	*Brassica napus*	*Pisum sativum*	*Helianthus annus*	*Linum usitatissimum*	*Allium cepa*	*Avena sativa*
Plant weight [% of control]						
Control	100	100	100	100	100	100
187.5	97	98	93	90	107	104
375	100	111	97	87	100	99
750	102	132	90	84	114	100
1500	84	99	91	102	100	104
3000	75	107	91	93	107	106
6000	92	102	85	85	79	100
Mean visible damage [% damage compared to control]						
Control	0	0	0	0	0	0
187.5	0	0	0	0	0	0
375	0	0	0	0	0	0
750	4	0	0	0	0	0
1500	0	0	0	0	0	0
3000	4	0	0	0	0	0
6000	9	0	0	0	0	0

Table B.9.9-2: NOER, ER_{25} and ER_{50} of BAS 119 33 H pre-emergence applications on terrestrial plants 21 days after application*

Plant species	*Brassica napus*	*Pisum sativum*	*Helianthus annus*	*Linum usitatissimum*	*Allium cepa*	*Avena sativa*
	Phytotoxicity (visual damages) [g/ha] (max. application rate 4000 g/ha)					
NOER	1500	6000	6000	6000	6000	6000
	Plant height (shoots above ground) [g/ha]					
NOER	6000	6000	6000	6000	3000	6000

ER_{25}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000
ER_{50}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000
	Plant weight (shoots above ground) [g/ha]					
NOER	6000	6000	6000	6000	6000	6000
ER_{25}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000
ER_{50}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000

* (1500 g/ha corresponding to 981, 6000 g/ha to 3924 g as/ha or to 1.31 and 5.23 mg as/kg soil, respectively (depth 5 cm, bulk density 1.5 g/mL)

Valid: yes

Conclusion
Based on these results conducted under greenhouse conditions it can be concluded that pre-emergence applications by means of spraying BAS 119 33 H up to rates of 6000 g/ha will not result in reduced seedling emergence of tested plant species.

Reference number: III A 10.8/2

Report: Frank P., 2000(b); PFL 2002-5
BAS 119 33 H: A toxicity test to determine the effects of the test item on vegetative vigour of terrestrial plants
Staatliche Lehr- und Forschungsanstalt, Neustadt, Germany; study code 71163; unpublished, BASF RegDoc# 2000/1017201

Guidelines: OECD 208, EEC 91/414

GLP: Yes

Material and methods
Test item BAS 119 33 H, batch no. 97-1, content of active substance: 65.4 % Reg. No. 13033 (nominal: 65 %), test species: oilseed rape (*Brassica napus*), pea (*Pisum sativum*), sunflower (*Helianthus annus*), flax (*Linum usitatissimum*), oats (*Avena sativa*), onion (*Allium cepa*).
BAS 119 33 H was tested under greenhouse conditions in a dose-response design at concentrations of 188, 375, 750, 1500, 3000 and 6000 g/ha and a water treated control (corresponding to 123, 245, 491, 981, 1962 and 3924 g as/ha). Six replicates/variant were run with 1 pot/replicate, 3-5 plants per pot (species dependent).
BAS 119 33 H was applied post-emergence (growth stage BBCH 12–14, except sunflower with growth stage BBCH 14-15) using a laboratory spray cabin with a water volume of 200 L/ha. Following the application the plants were cultivated for 21 days. Assessment for phytotoxicity (e.g. scorch, stunting, deformations) was done approx. 7, 14 and 21 days after application (DAA). Shoot fresh weight and plant height were determined at study termination, 21 DAA.

Findings
Visual damages were observed for rates ≥ 375 g/ha BAS 119 33 H tested on oilseed rape and for the both highest rates (3000 g/ha BAS 119 33 H and 6000 g/ha BAS 119 33 H) tested on sunflower. The ER_{25} and ER_{50} values for plant height and plant fresh weight could only be calculated for oilseed rape, as all other species showed less than 50 % damage. The results are summarised in Table B.9.9-3. Effects on plant height were generally less pronounced than

effects on plant weight, apart from oat for which the lowest NOEC of 375 g/ha was determined for plant height.

Table B.9.9-3: Effect of BAS 119 33 H on plant biomass and condition (visible damage) 21 days after application in the vegetative vigour test

Plant species	*Brassica napus*	*Pisum sativum*	*Helianthus annus*	*Linum usitatissimum*	*Avena sativa*	*Allium cepa*
Plant weight [% of control]						
Control	100	100	100	100	100	100
187.5	98	95	133	75	89 *	97
375	98	79	111	81	100	94
750	95	128	132	80	89	86
1500	91	103	156	80	97	85
3000	74 *	119	122	62 *	90	83
6000	38 *	85	136	68 *	81 *	64 *
Mean visible damage [% damage compared to control]						
Control	0	0	0	0	0	0
187.5	0	0	0	0	0	0
375	3	0	0	0	0	0
750	14	0	0	0	0	0
1500	19	0	0	0	0	0
3000	40	0	8	0	0	0
6000	72	0	20	0	0	0

* statistically significant difference compared to the control (Dunnett test, $\alpha = 0.05$)

Table B.9.9-4: NOER, ER_{25} and ER_{50} of BAS 119 33 H post-emergence applications on terrestrial plants 21 days after application in the vegetative vigour test

Plant species	*Oilseed rape*	*Pea*	*Sunflower*	*Flax*	*Oats*	*Onion*
	Phytotoxicity (visual damages) [g/ha] (max. application rate 4000 g/ha)					
NOER	187.5	6000	1500	6000	6000	6000
	Plant height (shoots above ground) [g/ha]					
NOER	6000	6000	6000	6000	6000	6000
ER_{25}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000
ER_{50}	> 6000	> 6000	> 6000	> 6000	> 6000	> 6000
	Plant weight (shoots above ground) [g/ha]					
NOER	1500	6000	6000	1500	6000	3000
ER_{25}	2894	> 6000	> 6000	1500 > EC > 3000	> 6000	3000 > EC > 6000
ER_{50}	4781	> 6000	> 6000	> 6000	> 6000	> 6000

Valid: yes

Conclusion

Based on the results of the study it can be concluded that post-emergence applications of BAS 119 33 H by spraying caused no adverse effects on plant weight of sunflower, pea and oats. The most sensitive plant species was oilseed rape with an ER_{50} for plant biomass of 4781 g/ha BAS 119 33 H and a NOEC of 187.5 g/ha for phytotoxicity.

Overall conclusion of RMS:

Application of BAS 1109 33 H via spraying on soil and plant surfaces is of low toxicity to the tested plants and resulted in ER_{50} for plant biomass > 6000 g/ha (spraying on soil) and between 4781 and > 6000 g/ha (spraying on plants), respectively. Oilseed rape was the most sensitive species in both test systems with highest susceptibility observed after post-emergence spraying. The NOER for plant weight was found to be equivalent to 3924 g as/ha or 981 g as/ha, respectively.

For the risk assessment of the monograph the results of the terrestrial plant growth test performed with spray application in accordance with the intended use will be used.

B.9.9.2 Summary of results and risk assessment

The effects of BAS 119 33 H on terrestrial non-target plants are summarised in Table B.9.9-5.

Table B.9.9-5: Summary of effects of BAS 119 33 H on terrestrial non-target plants

Test species	Test system	NOER plant weight [g/ha]	ER_{50} plant weight [g/ha]	ER_{50} plant weight [g as/ha]
Application using spraying on soil				
Oilseed rape	Seedling emergence	6000	> 6000	> 3924
Pea	Seedling emergence	6000	> 6000	> 3924
Sunflower	Seedling emergence	6000	> 6000	> 3924
Flax	Seedling emergence	6000	> 6000	> 3924
Onion	Seedling emergence	6000	> 6000	> 3924
Oats	Seedling emergence	6000	> 6000	> 3924
Application using spraying on plants				
Oilseed rape	Vegetative vigour	1500	4781	3127
Pea	Vegetative vigour	6000	> 6000	> 3924
Sunflower	Vegetative vigour	6000	> 6000	> 3924
Flax	Vegetative vigour	1500	> 6000	> 3924
Oats	Vegetative vigour	6000	> 6000	> 3924
Onion	Vegetative vigour	3000	> 6000	> 3924
Application via incorporation into the soil				
		EC_{10} plant weight [µg as/kg]	EC_{50} plant weight [µg as/kg]	ER_{50} plant weight [g as/ha]
Barley	Plant growth	160.6	670.9	384
Oats	Plant growth	133.6	406.4	232.6
Corn	Plant growth	478.3	4747	2717
Oilseed rape	Plant growth	75.1	133.3	76.3
Sugar beet	Plant growth	166.2	681.4	390.1
Pea	Plant growth	>2585	>4542	>2600

For the exposure of terrestrial non-target plants via spray drift the PEC at soil surface can be calculated based on the standard spray drift rates determined by Ganzelmeier for 1 m and 5 m distance to the treated area. Concerning the exposure of seedlings, however, it has to be considered that in the off-crop area soil will be exposed only to a part of the drifted product because of interception with vegetation. Thus the PEC for soil has to be corrected by a factor of interception. Since for off-crop areas no data for the degree of interception are available, these data have to be taken from studies with crops (e.g. Becker et al., 1999). Based on the assumption that at time of BAS 119 33 H applications off-crop vegetation is similar to a barley crop at growth stage BBCH 14, an interception of 40 % can be assumed, i.e. only 60 % of the spray drift reaches the soil in off-crop areas. Furthermore, assuming a distribution of the

product or the active substance within a 5 cm soil layer, respective soil concentrations were calculated considering a bulk density of 1.5 kg/L.
The results of the PEC calculations are given below.

Table B.9.9-6: PEC values of BAS 119 33 H for the exposure of terrestrial non-target plants

Maximum application rate of BAS 119 33 H [g/ha]	4000.0 (2616 g as/ha)	
Distance from treated field	1 m	5 m
Spray drift rate [%]	2.77	0.57
PEC vegetation [g/ha] [1)]	110.8 (72.5 g as/ha)	22.8 (14.9 g as/ha)
Factor of interception [%]	60 % on soil	60 % on soil
PEC soil surface [g/ha], off-crop	66.5 (43.5 g as/ha)	13.6 (8.95 as/ha)
PEC soil [mg/kg soil, 5 cm depth], off-crop	0.073 mg as/kg soil	0.012 mg as/kg soil

Based on these PEC values the following TER values are calculated for terrestrial non-target plants based on the results of the most sensitive test, the vegetative vigour test (Table B.9.9-7).

Table B.9.9-7: Toxicity, PEC and TER values of BAS 119 33 H for vegetative vigour of terrestrial non-target plants, exposure via spray drift

Test species	Toxicity (ER_{50}) [g/ha]	PEC vegetation, 1 m [1)] [g/ha]	TER (Trigger = 10 [2)])
Oilseed rape	4781	110.8	53
Pea	> 6000	110.8	> 54
Sunflower	> 6000	110.8	> 54
Flax	> 6000	110.8	> 54
Oats	> 6000	110.8	> 54
Onion	> 6000	110.8	> 54

[1)] at maximum application rate of 4000 g/ha
[2)] trigger = 10 due to 6 test species

These calculated TER values are a basis for a risk assessment. It has to be stressed that each risk assessment for non-target plants should be based on the following considerations:

The survival of the plant species has to be guaranteed. Thus, the production of plant biomass is more adequate as a criterion for a risk evaluation than visual damages, as e.g. leaf curl, which can be tolerated by terrestrial plants, and which are without impact for the plant population. Biomass production of the plant population is adequate to seedling emergence, since seedling emergence is a premise for conservation of the non-target plants. Therefore, effects on seedling emergence should be considered in a risk assessment, too.
Because of their higher accuracy and lower uncertainty, ER_{50} values give a better basis for a risk assessment than NOER or ER_{25} values. Though the ER_{50} values are based on a non-lethal endpoint (plant biomass), for which it is known that a 50 % reduction in an early stage can be largely compensated by individual plants as well as the plant population, they are an indication for potential hazard for non-target plant species. In contrary, because of the non-lethal endpoint, the ER values consider already a factor of uncertainty.

In the studies submitted by the notifier no effects on seedling emergence were observed for BAS 119 33 H applied via spraying on soil. ER_{50} values in the seedling emergence test were all > 6000 g/ha BAS 119 33 H, which is above the maximum application rate of 4000 g/ha.

Some effects were observed on vegetative vigour of terrestrial plants. The most sensitive species tested was oilseed rape after spray application with a calculated TER value of > 50 based on plant weight.
The obtained TER values in these studies are all above the TER of 5 of the Guidance Document on Terrestrial Ecotoxicity (SANCO/10329/2002).

Conclusions
To assess the risk of non-target plants outside the treated area the effects observed in the standard plants of the OECD guideline after application of BAS 119 33 H by spraying on soil surface or plants were used.

Based on reasons given in this risk assessment it can be concluded that the risk for populations of terrestrial non-target plants is acceptable if BAS 119 33 H is applied at rates up to 4.0 kg BAS 119 33 H/ha according to good agricultural practice.

Comments of RMS:
The RMS has access to summary reports about plant toxicity studies with the active substance and metabolites as well as to one study with the product. The studies were performed by the notifier. The data were retrieved from the internal database of the German Federal Environmental Agency and are presented below.
These results can only be treated as additional information about the effects on non-crop plants and cannot be used in the risk assessment because an evaluation of the validity of the test is not possible (Otto, 1992) or the exposure to the herbicide is not in accordance with the relevant exposure route (spray drift) for off-crop plants.

Studies amended by RMS for further information:

ACTIVE SUBSTANCE and METABOLITES

No studies with the active substance were submitted but summarised results of tests with chloridazon and its metabolites B and B-1 are available (Otto, 1992; BASF Reg.Doc. #92/12627, 20.02.1992). Chloridazon and the metabolites B and B-1 were tested under greenhouse conditions on seedling emergence of non-target plants, mostly non-crop species, at concentrations of 0.25, 0.5, 1.0 and 2.0 kg as/ha. Test species were *Zea mays*, *Solanum nigrum*, *Lamium amplexicaule*, *Veronica spec.*, *Beta vulgaris*, *Chenopodium album*, *Polygonum persicaria* and *Sinapis alba*. The results are summarised in the following table.

Table B.9.9-8: Seedling emergence (% effects) of terrestrial plants exposed to chloridazon and metabolites

Test substance	Test rate (kg as/ha)	*Zea mays*	*Solanum nigrum*	*Lamium amplexicaule*	*Veronica spec*	*Beta vulgaris*	*Chenopodium album*	*Polygonum persicaria*	*Sinapis alba*
Chloridazon	2.0	0	85	85	98	10[x]	70	75	60
	1.0	0	65	50	90	10[x]	20	10	30
	0.5	0	30	15	75	0	0	10	10
	0.25	0	20	10	75	0	0	10	0
Metabolite B	2.0	0	0	0	15[x]	0	0	0	0
	1.0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	0	0	0	0
	0.25	0	0	0	0	0	0	0	0
Metabolite B-1	2.0	0	0	0	15[x]	0	0	0	0
	1.0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	0	0	0	0
	0.25	0	0	0	0	0	0	0	0

x = slight depression of growth

The metabolites showed no herbicidal activity compared to the parent compound up to 2000 g as/ha. *Veronica spec.* appeared to be the most sensitive species for chloridazon with 75 % effect at the lowest concentration of 250 g as/ha.

Reference number: Amended by the RMS

Report: Schmidt, O., 2001; PFL2004-148
Bioassay zur Ermittlung von EC_{10}-(NOEL) und EC_{50}-Werten für BAS 119 33 H (Pyramin DF) bei ausgewählten Nachbaukulturen
BASF AG, Forschung Pflanzenschutz, Germany, data report APR/RH 20010316SDT; unpublished
BASF RegDoc# 2001/1006003

Guidelines: EPPO PP1/207 (1): Einfluß auf Folgekulturen. Biologische Bundesanstalt für Land- und Forstwirtschaft. Mai 2000
Pestemer, W. and Pucelik-Günther, P. (1997): Standardised bioassay for the determination of ED_{10}- (NOEL) and ED_{50}-values for herbicides and selected following crops in soil (Berichte der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 29)

GLP: No

Material and methods
Test item BAS 119 33 H (65 %, WG), batch no. 17-7393; test species: sweet corn (*Zea mays*), winter barley (*Hordeum vulgare*), sugar beet (*Beta vulgaris*), oilseed rape (*Brassica napus*), oat (*Avena sativa*), pea (*Pisum sativum*).
BAS 119 33 H was tested under greenhouse conditions in a dose-response design at concentrations of 0.0013, 0.0025, 0.0051, 0.0102, 0.0203, 0.0406, 0.0813, 0.163, 0.325, 0.65, 1.3 and 2.6 kg as/ha in 400 L water/ha and a water treated control. The highest test concentration corresponds to the maximum application rate. In two trials the test item was incorporated into loamy sand and the seedlings were distributed to 10 plants/pot after emergence in treated soil

(six replicates for each test variant). Assessments for herbicidal injuries were done by visual scoring and measuring of the fresh weight at test termination on day 22, and the selectivity indices were determined.

Findings
The application of BAS 119 33 H caused herbicidal injuries for all tested species, with different values depending on applied dose and species. The results are summarised in the following table.

Table B.9.9-9: Effects of BAS 119 33 H on plant biomass 22 days after application

Plant species	*Barley*	*Oats*	*Corn*	*Oilseed Rape*	*Sugar beet*	*Pea*
Plant fresh weight [g as/ha] (max. application rate 2600 g as/ha)						
ER_{10}	91.9	76.5	273.8	42.9	95.1	>1479
ER_{50}	384.0	232.6	2717	76.3	390.1	>2600
Plant fresh weight [ppb resp. µg as/kg soil] (max. application rate equivalent to 3490 µg as/kg soil)						
EC_{10}	160.6	133.6	478.3	75.1	166.2	>2585
EC_{50}	670.9	406.4	4746.6	133.3	681.4	>4542

Valid : yes

Conclusion
The oilseed rape (*Brassica napus*) was the most sensitive species with an EC_{50} for fresh weight of 133.3 µg as/kg soil and an EC_{10} of 75.1 µg as/kg soil or regarding the application rate with an ER_{50} and ER_{10} of 76.3 and 42.9 g as/ha, respectively.
At the highest application rate of 2600 g/ha plant fresh weight of four out of six plants was reduced by more than 50 %. Therefore, there is an indication on a potential risk for non-target plants exposed to the herbicide incorporated into soil.
The amended seedling emergence test (BASF Reg.Doc. #92/12627, 20.02.1992) confirms the high susceptibility of non-crop plants to BAS 119 33 H.

However, contrary to the submitted studies where the product was applied by spraying onto the soil surface or to plants, in the amended study the test substance was incorporated into the soil. Thus, the seeds and the early seedlings were directly exposed to BAS 119 33 H right from the start of the test and during the first stages of development. This can result in a higher susceptibility of the plants compared to spray application on soil and plant surfaces, as observed in the tests submitted by the notifier.

Since for BAS 119 33 H spray drift has to be assumed as the relevant source of exposure of terrestrial non-target plants, a distribution of the active substance into the soil after deposition is of no relevance for the risk assessment.

B.9.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)

In the laboratory study on inhibition of oxygen consumption by activated sludge (II A 8.7, B 8.15.1) the NOEC was found to be 500 mg as/L indicating a low risk for disturbance of sewage treatment processes. It is expected that the small chloridazon water concentrations cannot affect water treatment procedures. Therefore, no data regarding the impact of chloridazon on water treatment procedures have been generated.

Comment of RMS:
Acceptable.

B.9.11 References relied on

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner[1]
AIIA-8.1	Blomquist, D. and Johannson, O.C.	1995	Trade-offs in nest site selection in coastal population of lapwings *Vanellus vanellus*. Ibis, 137, 1995, 550-558 not GLP,published AVS2004-332	N	-
AIIA-8.1	Milsom, T.P., Holditch, R.S. and Rochard, J.B.A.	1985	Diurnal use of an airfield and adjacent agricultural habitats by lapwings *Vanellus vanellus*. Journal of Applied Ecology, 22, 1985, 313-326 not GLP, published AVS2004-333	N	-
AIIA-8.1.1; AIIIA-10.1	Munk, R. et al.	1990	Avian single-dose oral LD_{50} of Reg.Nr. 13 033; 95 % (= test compound No. 88/174-1) to the bobwhite quail (*Colinus virginianus*). BASF 1990/0296 GLP, unpublished AVS2003-168	N	BAS
AIIA-8.1.2; AIIIA-10.1	Munk, R. et al.	1990	Avian dietary LC_{50} test of Reg.Nr. 13 033; 95 % (= test substance 88/174-1) in the mallard duck (*Anas platyrhynchos* L.). BASF 1990/0298 GLP, unpublished AVS2003-170	N	BAS
AIIA-8.1.2; AIIIA-10.1	Munk, R. et al.	1990	Avian dietary LC_{50} test of Reg.Nr. 13 033; 95 % (= test substance No. 88/174-1) in the bobwhite quail (*Colinus virginianus*). BASF 1990/0297 GLP, unpublished AVS2003-169	N	BAS
AIIA-8.1.2	Pinek, M. and Kamieniarz, R.	2000	Habitat use by the partridge *Perdix perdix* during the breeding season in the diversified agricultural landscape of western Poland. Acta Ornithologica (Warsaw), 35, 2000, 183-189 not GLP, published AVS2004-302	N	-

[1] Only notifier listed

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner[1]
AIIA-8.1.2	Zörner, H.	1989	Feldhase *Lepus europaeus* (Pallas). Stubbe, M. (Ed.). Buch der Hege. Haarwild. Deut. Landwirtschaftsverlag, Berlin, 1, 1989, 286-321 not GLP, published AVS2004-303	N	-
AIIA-8.1.3	Buxton, J.M., Crocker, D.R. and Pascual, J.A.	1998	Birds and farming: Information on risk assessment. Contract PN0919, Milestone Report, 1998 CSL Proj. No. M37 not GLP, published AVS2004-296	N	-
AIIA-8.1.3	Dwenger, R.	1991	Das Rebhuhn (*Perdix perdix*). A. Ziemsen Verlag; Glutz von Blotzheim, 1991 not GLP, published AVS2004-297	N	-
AIIA-8.1.3	Glänzer, U., Havelka, P. and Thieme, K.	1993	Rebhuhn-Forschung in Baden-Württemberg mit Schwerpunkt in Strohgäu bei Ludwigsburg. Beihefte zu den Veröffentlichungen für Naturschutz und Landschaftspflege in Baden-Württemberg, 70, 1993, 1-108 not GLP, published AVS2004-298	N	-
AIIA-8.1.3	Kaiser, W.	1998	Grey partridge (*Perdix perdix*) survival in relation to habitat quality. Gibier Faune Sauvage, 15, 1998, 157-162 not GLP, published AVS2004-299	N	-
AIIA-8.1.3	Marboutin, E. and Aebischer, N.J.	1996	Does harvesting arable crops influence the behaviour of the European hare *Lepus europaeus*? Wildl. Biol., 2, 1996, 83-91 not GLP, published AVS2004-300	N	-
AIIA-8.1.3	Middleton, A.D. and Chitty, H.	1987	The food of adult partridges, *Perdix perdix* and *Alectoris rufa*, in Great Britain. Jornal of Animal Ecology, 6, 1987, 322-336 not GLP, published AVS2004-301	N	-
AIIA-8.1.3; AIIA-10.1	Zok, S.	2000	Report: Reg. Nr. 13033 - 1-generation reproduction study on the bobwhite quail (*Colinus virginianus*) by administration in the diet. BASF 2000/1018810 GLP, unpublished AVS2001-160	Y	BAS

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AIIA-8.2	Jatzek, H.-J.	1989	Determination of the longterm effects of chloridazon tech.Reg. No. 13 033 N143 on the parthenogenetic reproduction rate of the waterflea *Daphnia magna* STRAUS. 1989/10058 GLP, unpublished WAT2004-785	N	BAS
AIIA-8.2.1	Munk, R. and Kirsch, P.	1990	Report on the study of the acute toxicity. Chloridazon-B-metabolite/Reg. No. 14 456. Rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792). BASF 1990/0315 GLP, unpublished WAT2003-452	N	BAS
AIIA-8.2.1; AIIIA-10.2	Munk, R. and Kirsch, P.	1990	Report on the study of the acute toxicity. Reg.Nr. 13 033. Bluegill (*Lepomis macrochirus* RAF.). BASF 1990/0186 GLP, unpublished WAT2003-451	N	BAS
AIIA-8.2.1	Munk R. and Kirsch, P.	1990	Report on the study of the acute toxicity. Reg.Nr. 13 033. Rainbow trout (*Salmo gairdneri* RICH.). BASF 1990/0187 GLP, unpublished WAT2003-450	N	BAS
AIIA-8.2.1; AIIIA-10.2	Zok, S.	1999	Metabolite B-1 - Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792) in a static system (96 hours). BASF 1999/11845 GLP, unpublished WAT2003-454	Y	BAS
AIIA-8.2.2	Jatzek, H.-J.	1989	Bestimmung der Langzeitwirkung von Chloridazon techn. Reg.-Nr. 13033 N 143 auf die pathogenetische Reproduktionsrate des Wasserflohs *Daphnia magna* Straus. 03/0537/89-1890537 not GLP, unpublished WAT1999-333	N	BAS
AIIA-8.2.1	Munk, R. and Kirsch, P.	1989	Sublethal toxic effects on rainbow trout (*Salmo gairdneri* RICH.) of Reg.Nr. 13 033; isomer reduced (chloridazon techn.). BASF 1989/10059 GLP, unpublished WAT2003-453	N	BAS

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AIIA-8.2.3	Daum, A.	2002	Determination of the n-octanol/water partition-coefficient of Reg. No. 35 375 (BAS 119 H metabolite B1). BASF 2002/1010433 GLP, unpublished WAT2003-455	Y	BAS
AIIA-8.2.3	Redeker, J.	1989	Determination of the octanol/water-partition coefficient of LAB 14456. BASF 1989/10166 GLP, unpublished WAT2003-456	N	BAS
AIIA-8.2.4; AIIIA-10.2	Elendt-Schneider, B.	1990	Determination of the acute toxicity of chloridazon-metabolite B (PS. Nr. 14 456) to the water flea *Daphnia magna* STRAUS. BASF 1991/10120 GLP, unpublished WAT1999-328	N	BAS
AIIA-8.2.4; AIIIA-10.2	Jatzek, H.-J.	1999	Determination of the acute effect of BH 119-B1 on the swimming ability of the water flea *Daphnia magna* STRAUS according to OECD 202 and GLP, EN 45001 and ISO 9002. BASF 1999/10560 GLP, unpublished WAT2003-457	Y	BAS
AIIA-8.2.4	Jatzek , H.-J.	1990	Determination of the acute toxicity of chloridazon techn. Reg.-Nr. 13033 to the waterflea *Daphnia magna* Straus. BASF 1990/10074 GLP, unpublished WAT2001-546	N	BAS
AIIA-8.2.5	Dohmen, G.P.	1994	Effect of BAS 119 H on the reproduction of *Daphnia magna* STRAUS in a chronic toxicity test. BASF 1994/10205 GLP, unpublished WAT2003-459	Y	BAS
AIIA-8.2.6; AIIIA-10.2.1	Dohmen, G.P.	1992	Effect of Reg. No. 13033 on the Growth of the Green Alga *Ankistrodesmus bibraianus*. BASF 1992/11796 ! 3383 ! P91-E058 GLP, unpublished WAT2001-545	N	BAS

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AIIA-8.2.6; AIIIA-10.2	Jatzek, H.-J.	2002	Reg. No. 14456 (metabolite of BAS 119 H, chloridazon) - Determination of the inhibitory effect on the cell multiplication of unicellular green algae. BASF 2002/1006171 GLP, unpublished WAT2003-458	Y	BAS
AIIA-8.2.6; AIIIA-10.2	Kubitza, J.	1999	Effect of BAS 119 H on the Growth of the Blue-Green Alga *Anabaena flos-aquae*. BASF 1999/10036 GLP, unpublished WAT2001-544	Y	BAS
AIIA-8.2.6	Reuschenbach, P.	1999	Determination of the inhibitory effect of BH 119-BI on the cell multiplication of unicellular green algae according to OECD 201 and GLP, EN 45001 and ISO 9002 BASF 1999/10544 ! 99/0080/60/1 GLP, unpublished WAT2003-460	Y	BAS
AIIA-8.2.8; AIIIA-10.2	Dohmen, G.P.	2000	Effect of BAS 119 H on the Growth of *Lemna gibba* in a seven day static toxicity test. BASF 2000/1011448 GLP, unpublished WAT2001-543	Y	BAS
AIIA-8.3.1.1	Sack, D.	1994	Effect of Reg. No. 13 033 (chloridazon) on the honeybee (*Apis mellifera* L.) in laboratory trials. 1994/10090 GLP, unpublished BIE2003-85	Y	BAS
AIIA-8.3.1.1	Sack , D.	1997	Addendum No. 1 to study code P93-E137: Effect of Reg. No. 13 033 (common name: Chloridazon) on the honeybee (*Apis mellifera* L.) in laboratory trials. 1997/10943 GLP, unpublished BIE2003-86	Y	BAS
AIIA-8.3.2; AIIIA-10.5	Schulte, C., Füll, C. and Kühnen, U.	1999	Bewertungskriterien des Umweltbundsamtes: Auswirkungen von Pflanzenschutzmitteln auf terrestrische Arthropoden (Assessment critica of the Federal Environmental Agency: Effects of plant protection products on terrestrial arthropods). UWSF-Z. Umweltchem. Ökotox, 11, 5, 1999, 261-266 not GLP, published ANA2004-372	N	-

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AIIA-8.3.2; AIIIA-10.5.1	Ufer, A.	1999	Effect of BAS 119 33 H on the Predatory Mite *Typhlodromus Pyri* Scheuten in a laboratory trial. BASF 1999/10461 GLP, unpublished ANA2002-13	Y	BAS
AIIA-8.4.1	Dohmen, G. P.	1991	Effect of Reg. No. 14456 on the mortality of the earthworm *Eisenia fetida*. BASF 1991/10504 GLP, unpublished ARW97-00070	N	BAS
AIIA-8.4.1	Lührs, U.	2001	Acute toxicity (14 days) of BAS 119 H to the earthworm *Eisenia fetida* (Savigny 1826) in artificial soil. BASF 2001/1005995 GLP, unpublished ARW2002-7	Y	BAS
AIIA-8.4.1; AIIIA-10.6	Staab, F.	2001	Effect of BH 119 B-s on the mortality of the earthworm *Eisenia fetida*. BASF 2001/1005986 GLP, unpublished ARW2003-152	Y	BAS
AIIA-8.4.1; AIIIA-10.6.1.1	Wolf, A.	2004	Effect of BH 119-metabolite B on earthworm (*Eisenia fetida*) reproduction in a chronic toxicity test. 2004/1004432 GLP, unpublished ARW2004-170	Y	BAS
AIIA-8.5	Gerhardt, R.	1991	Effect of Reg. No. 14456 on soil respiration. BASF 1991/10441 GLP, unpublished BMF2003-71	N	BAS
AIIA-8.5; AIIIA-10.7	Gerhardt, R.	1991	Addendum to laboratory study code P91-E036: Effect of Reg. No. 14 456 on the nitrogen tur-nover in the soil. BASF 1991/10986 GLP, unpublished BMF2003-70	N	BAS
AIIA-8.5; AIIIA-10.7	Gerhardt, R.	1991	Effect of Reg. No. 14 456 on the nitrogen tur-nover in the soil. BASF 1991/10442 GLP, unpublished BMF2003-69	N	BAS

Annex point/ reference number	Author(s)	Year	Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BBA registration number	Data protection claimed Y/N	Owner[1]
AIIA-8.5; AIIIA-10.7; AIIIA-10.7.1	Hamm, R.T.	1988	Effect of Pyramin WG (BAS 119 33 H) on soil respiration. BASF 1988/10051 GLP, unpublished BMF2002-5	N	BAS
AIIA-8.5; AIIIA-10.7; AIIIA-10.7.1	Hamm, R.T.	1988	Effect of Pyramin WG (BAS 119 33 H) on the nitrifikation. BASF 1988/10050 GLP, unpublished BMF2002-4	N	BAS
AIIA-8.5; AIIIA-10.7	Krieg, W.	2001	Effect of BH 119-B1 on soil micro-organisms: Carbon transformation test. BASF 2001/1005969 GLP, unpublished BMF2003-72	Y	BAS
AIIA-8.6; AIIIA-10.8	Frank, P.	2000	BAS 119 33 H: A toxicity test to determine the effects of the item on vegetative vigour of terrestrial plants. BASF 2000/1017201 GLP, unpublished PFL2002-5	Y	BAS
AIIA-8.6; AIIIA-10.8	Frank, P.	2000	BAS 119 33 H: A toxicity test to determine the effects of the item on seedling emergence of terrestrial plants. BASF 2000/1017181 GLP, unpublished PFL2002-4	Y	BAS
AIIA-8.6	Otto, S.	1992	Prüfung von Chloridazon / Metabolit B / Metabolit B-I im Vorauflaufverfahren (Gewächshaus); 20.02.92/cb 257. 1992/12627 not GLP, unpublished PFL2003-168	Y	BAS
AIIA-8.6	Schmidt, O.	2001	Bioassay zur Ermittlung von EC_{10}- (NOEL) und EC_{50}-Werten für BAS 119 33 H (Pyramin DF) bei ausgewählten Nachbaukulturen. 2001/1006003 GLP, unpublished PFL2004-148	Y	BAS
AIIIA-10.7	Dressel, J.	2003	Estimation of the dissipation time of BAS 119 H (chloridazon) in sugar beet shoots according to first order kinetics. 2003/1005440 not GLP, unpublished AVS2004-295	Y	BAS

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AIIIA-10.2.1	Dohmen, G.P.	2000	Effect of BAS 119 33 H on the immobility of *Daphnia magna* STRAUS in a 48 hour static, acute toxicity test. BASF 2000/1011469 GLP, unpublished WAT2003-468	Y	BAS
AIIIA-10.2.1	Kubitza, J.	1000	Effect of BAS 119 33 H on the Growth of the Green Alga *Pseudokirchneriella subcapitata*. BASF 2000/1011468 GLP, unpublished WAT2001-548	Y	BAS
AIIIA-10.2.1	Zok, S.	2002	BAS 119 33 H - Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss*) in a static system over 96 hours. BASF 2002/1008601 GLP, unpublished WAT2003-223	Y	BAS
AIIIA-10.4; AIIIA-10.4.1	Sack, D.	1999	Effect of BAS 11933 H on the Honeybee (*Apis mellifera* L.) in Laboratory Trials. 1999/11756 GLP, unpublished BIE2002-12	Y	BAS
AIIIA-10.5.1	Schmitzer, S.	1998	Effect of BAS 119 33 H on the Wolf Spider *Pardosa spec*. (Araneae, Lycosidae) in the laboratory. BASF 1998/10554 GLP, unpublished ANA2002-15	Y	BAS
AIIIA-10.5.1	Ufer, A.	1998	Effect of BAS 119 33 H on the Green Lacewing *Chrysoperla Carnea* (Neuroptera: Chrysopidae) in a laboratory test. BASF 1998/11228 GLP, unpublished ANA2002-18	Y	BAS
AIIIA-10.5.1	Ufer, A.	1999	Effect of BAS 119 33 H on the parasitoid *Aphidius Rhopalosiphi* in a laboratory trial. BASF 1999/10532 GLP, unpublished ANA2002-12	Y	BAS
AIIIA-10.5.1	Ufer, A.	1998	Effect of BAS 119 33 H on the rove beetle *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae) in a laboratory trial. BASF 1998/11359 GLP, unpublished ANA2000-458	Y	BAS

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AIIIA-10.6.1.1	Staab, F.	2001	Effect of BAS 119 33 H on the mortality of the earthworm *Eisenia fetida*. BASF 2001/1005985 GLP, unpublished ARW2002-8	Y	BAS
AIIIA-10.8	Becker, F.A. et al.	1999	Quelle: BVL. Nachrichtenb. Deut. Pflanzenschutzd., 51, 9, 1999, 237-242 not GLP, published PFL2004-145	N	-
AIIIA-10.8	Dressel, J.	2003	Estimation of the dissipation time of BAS 119 H (chloridazon) in sugar beet shoots according to first order kinetics. 2003/1005440 not GLP, unpublished PFL2004-110	Y	BAS
AIIIA-10.8	Schulz, H.	1999	Testing of the residues behaviour of BAS 536 06 H in sugar beets under field conditions in Italy 1996 - Fresenius chem. und biolog. Laboratorien, study 0. FI-96/03644-00. 1999/10348 GLP, unpublished AVS2004-294	Y	BAS

Codes of owner

BAS: BASF Aktiengesellschaft