

List of end points  
Rapporteur Member State

Month and year

Active Substance (Name)

Sweden	May 2006 Updated December 2006	Difenoconazole
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# Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

## Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡

Function (e.g. fungicide)

Difenoconazole

Fungicide

Rapporteur Member State

Co-rapporteur Member State

Sweden

Not assigned

## Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡

Chemical name (CA) ‡

CIPAC No ‡

CAS No ‡

EC No (EINECS or ELINCS) ‡

FAO Specification (including year of publication) ‡

Minimum purity of the active substance as manufactured ‡

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

Molecular formula ‡

Molecular mass ‡

Structural formula ‡

1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-[1,2,4] triazole

1-[[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole

Not allocated

119446-68-3

Not allocated

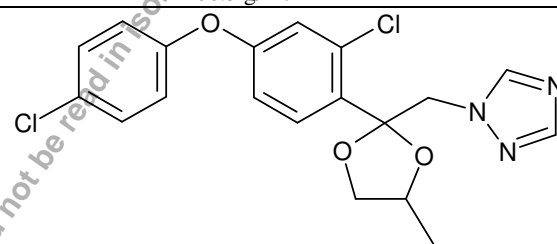
No FAO specification available.

940 g/kg

Difenoconazole as manufactured does not contain any relevant impurities.

C<sub>19</sub>H<sub>17</sub>Cl<sub>2</sub>N<sub>3</sub>O<sub>3</sub>

406.3 g/mol



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# Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

## Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	82.0-83.0°C (99.3%)
Boiling point (state purity) ‡	Not relevant at atmospheric pressure as decomposition occurs. 100.8°C at 3.7 mPa (99.3%)
Temperature of decomposition (state purity)	Decomposition starts at about 337°C (99.3%)
Appearance (state purity) ‡	<u>Technical material</u> : Off-white powder with a slightly sweetish odour, purity not stated. <u>Purified material</u> : White fine odourless crystalline powder, purity 99.3 %
Vapour pressure (state temperature, state purity) ‡	$3.32 \times 10^{-8}$ Pa at 25°C (99.0%)
Henry's law constant ‡	$9.0 \times 10^{-7}$ Pa m <sup>3</sup> mol <sup>-1</sup>
Solubility in water (state temperature, state purity and pH) ‡	15 mg/l $\pm$ 1.3 mg/l at pH 7.2 and 25 °C No pH effect is anticipated at environmentally relevant pH
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 25°C in g/L (94.6%): acetone: >500 g/l dichloromethane: >500 g/l ethyl acetate: >500 g/l hexane: 3.0 g/l methanol: >500 g/l octanol: 110 g/l toluene >500 g/l
Surface tension ‡ (state concentration and temperature, state purity)	62.8 mN/m at 20°C (90 % saturated solution)(94.6%)
Partition co-efficient ‡ (state temperature, pH and purity)	log P <sub>OW</sub> = 4.36 $\pm$ 0.02 at 25 °C and a pH of approx. 8 (99.3%) No pH effect is anticipated at environmentally relevant pH.
Dissociation constant (state purity) ‡	pK <sub>a1</sub> = 1.07 $\pm$ 0.18 for the corresponding acid (i.e the neutral species is predominantly present at pH > 1.1) (99.3%)
UV/VIS absorption (max.) incl. $\epsilon$ ‡ (state purity, pH)	$\lambda_{\max}$ [nm] Neutral media: 215 235 275  $\lambda_{\max}$ [nm] Acidic media: 215 235 275  $\lambda_{\max}$ [nm] Alkaline media: 220 235 275 No absorption maxima between 300 nm and 700 nm at any pH.
Flammability ‡ (state purity)	Flammability: Not highly flammable Auto-flammability: No self-ignition below the melting point Flash-point: Not applicable since the melting point is > 40 °C
Explosive properties ‡ (state purity)	Not explosive (91.8%)
Oxidising properties ‡ (state purity)	Not oxidising (91.8%)

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## Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

## Summary of representative uses evaluated (Difenoconazole)\*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pome fruit	EU (N/S)	Score A7402T	F	<i>Podospheara leucotricha</i> <i>Venturia inaequalis</i>	EC	250 g/l	High vol spray or mist blower	Spray programme beginning at flowering (BBCH 61)	1-4	10-14	0.00375	500 1500	0.01875 0.05625	28	EU(N)
											0.0075	500 1000	0.0375 0.0750	14	EU (S)
Carrot	EU (N/S)	Score A7402T	F	<i>Alternaria dauci</i> <i>Erysiphe heraclei</i>	EC	250 g/l	High vol spray	BBCH 42/43	1-3	14	-	100 500	0.125	14	
Wheat	EU (N/S)	Dividend A9142G	F	<i>Fusarium spp.</i> <i>Tilletia spp.</i>	FS	30 g/l	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	-	0.005 0.012	-	kgas/ha rate depends on seeding rate
Barley	EU (N/S)	Dividend A9142G	F	<i>Pyrenophthora graminea</i>	FS	30 g/l	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	-	0.005 0.012	-	kgas/ha rate depends on seeding rate
Triticale	EU (N/S)	Dividend A9142G	F	<i>Fusarium spp.</i> <i>Tilletia spp.</i>	FS	30 g/l	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	-	0.005 0.012	-	kgas/ha rate depends on seeding rate
Rye	EU (N/S)	Dividend A9142G	F	<i>Fusarium spp.</i> <i>Urocystis occulata</i>	FS	30 g/l	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	-	0.005 0.012	-	kgas/ha rate depends on seeding rate

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Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Oats	EU (N/S)	Dividend A9142G	F	<i>Ustilago avenae</i> <i>Pyrenophora avenae</i> <i>Cochliobolus sativum</i> <i>Fusarium culmorum</i> <i>Gibberella avenacea</i> <i>Pythium ultimum</i>	FS	30 g/l	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	-	0.005 0.012	-	kgas/ha rate depends on seeding rate

\*For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).  
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)  
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)  
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds  
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989  
(f) All abbreviations used must be explained  
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).**  
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
(k) Indicate the minimum and maximum number of application possible under practical conditions of use  
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha  
(m) PHI - minimum pre-harvest interval

**List of end points**

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**Methods of Analysis****Methods of Analysis****Analytical methods for the active substance (Annex IIA, point 4.1)**

Technical as (analytical technique)	GC-FID
Impurities in technical as (analytical technique)	Confidential information, see Annex C
Plant protection product (analytical technique)	HPLC-UV (Dividend) and GC-FID (Score)

**Analytical methods for residues (Annex IIA, point 4.2)****Residue definitions for monitoring purposes**

Food of plant origin	Difenoconazole
Food of animal origin	Difenoconazole + CGA 205375
Soil	Difenoconazole + CGA 205375 (metabolite: final decision on inclusion in the definition of the residue pending additional data expected mid-2006)
Water surface	Difenoconazole
drinking/ground	Difenoconazole
Air	Difenoconazole

**Monitoring/Enforcement methods**

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS; 0.02 – 0.05 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Difenoconazole and CGA 205375: HPLC-MS/MS; 0.01 mg/kg
Soil (analytical technique and LOQ)	Difenoconazole and CGA 205375: HPLC-MS/MS; 0.01 mg/kg
Water (analytical technique and LOQ)	GC-ECD; 0.05 (drinking) – 0.1 (surface)
Air (analytical technique and LOQ)	HPLC-MS/MS; 0.99 ng/L
Body fluids and tissues (analytical technique and LOQ)	Not relevant

**Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)**

Active substance	RMS/peer review proposal
	None

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## Mammalian toxicology

### Impact on Human and Animal Health

#### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	About 80 - 90% based on the biliary (73- 76%), urinary (14 - 9%) excretion observed in bile duct cannulated rats within 48 hours. Lower absorption rates at higher dose levels.
Distribution ‡	Initially highest residues in fat, liver, brown fat, Harderian gland, adrenal gland and stomach. At 168 hours, residues above the plasma concentration only detected in fat.
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid and extensive (> 92%) within 48 hours mainly via faeces (>77%) and in urine (>12%). Entero hepatic recirculation demonstrated.
Metabolism in animals ‡	Extensively metabolised, approximately 68% of the dose recovered in faeces as metabolites hydroxyl-CGA-205375, hydroxyl-CGA-169374 and CGA-205375. 1, 2, 4- triazole determined to represent <10% in male rats.
Toxicologically relevant compounds ‡ (animals and plants)	Pending: genotoxicity studies of plant metabolites 1, 2, 4- triazole (CGA 131013) and triazole lactic acid (CGA 205369) are in progress.
Toxicologically relevant compounds ‡ (environment)	None

#### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral ‡	1453 mg kg <sup>-1</sup>	R22
Rat LD <sub>50</sub> dermal ‡	>2010 mg kg <sup>-1</sup>	
Rat LC <sub>50</sub> inhalation ‡	>3300 mg/m <sup>3</sup>	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non- irritant	
Skin sensitisation ‡	Non-sensitiser	

#### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: liver/Reduced body weight, heart and carcass weight Reduced food and water consumption Dog: cataract formation	
Relevant oral NOAEL ‡	90-day toxicity (rat): 20/21 (M/F) mg kg <sup>-1</sup> day <sup>-1</sup> 28 week (dog): 31/35 mg kg <sup>-1</sup> day <sup>-1</sup>	
Relevant dermal NOAEL ‡	28-day toxicity (rat): 1 000 mg kg <sup>-1</sup> day <sup>-1</sup>	
Relevant inhalation NOAEL ‡	N/E	N/R

#### Genotoxicity ‡ (Annex IIA, point 5.4)

Substance is unlikely to be genotoxic. Increases in chromosomal aberrations were reported in CHO cells treated <i>in vitro</i> with difenoconazole, but only at high concentrations inducing cytotoxicity and they were not clearly reproducible either between repeat examinations of the same slides, between experiments or across studies.	
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#### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat: reduced body weight gain and reduced absolute body weight Mouse: liver/reduced body weight gain	
Relevant NOAEL ‡	2-year combined chronic toxicity/oncogenicity in rat: 1.0/1.3 (M/F) mg kg <sup>-1</sup> day <sup>-1</sup> 18 months oncogenicity study in mice: 4.7/ 5.6 (M/F) mg kg <sup>-1</sup> day <sup>-1</sup>	
Carcinogenicity ‡	In view of the lack of genotoxicity and the finding of liver adenomas/carcinomas only in mice and only at concentrations at which toxicity was observed, the substance is considered not likely to pose a	

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#### Mammalian toxicology

carcinogenic risk to humans.	
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#### Reproductive toxicity (Annex IIA, point 5.6)

##### Reproduction toxicity

Reproduction target / critical effect ‡

Retarded body weight gain, reduced absolute pup body weights	
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Relevant parental NOAEL ‡

250 ppm $\equiv$ 17.3 mg kg <sup>-1</sup> day <sup>-1</sup>	
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Relevant reproductive NOAEL ‡

>2500 ppm $\equiv$ 178.0 mg kg <sup>-1</sup> day <sup>-1</sup> for the reproductive parameters analysed.	
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Relevant offspring NOAEL ‡

250 ppm $\equiv$ 17.3 mg kg <sup>-1</sup> day <sup>-1</sup>	
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##### Developmental toxicity

Developmental target / critical effect ‡

Reduced body weight gain/reduced food consumption (rat, rabbit)	
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Relevant maternal NOAEL ‡

25 mg kg <sup>-1</sup> day <sup>-1</sup>	
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Relevant developmental NOAEL ‡

25 mg kg <sup>-1</sup> day <sup>-1</sup>	
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#### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡

No data available	N/R
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Repeated neurotoxicity ‡

No data available	N/R
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Delayed neurotoxicity ‡

No data available	N/R
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#### Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡

Supplementary study on enzyme induction performed concluding that difenoconazole is a reversible barbiturate-type inducer of metabolising enzymes in the mouse liver.
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Studies performed on metabolites or impurities ‡

The major metabolites found in the mammalian metabolism of difenoconazole (CGA 205374, CGA 205375 and CGA 189138) were further investigated regarding the acute oral toxicity and the ability to induce mutations in bacteria. The results raise no concern. Relevant studies on plant metabolites, including studies of toxicokinetics, acute oral toxicity and genotoxicity, were submitted for triazole alanine (CGA 131013) and triazole acetic acid (CGA 205369). The results raise no concern. Genotoxicity studies of 1, 2, 4-triazole and triazole lactic acid are in progress and RMS suggests to include these in an addendum to the DAR.
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#### Medical data ‡ (Annex IIA, point 5.9)

No detrimental effects on health in manufacturing personnel.
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#### Summary (Annex IIA, point 5.10)

ADI ‡

Value	Study	Safety factor
0.01 mg kg <sup>-1</sup> day <sup>-1</sup>	2-year combined chronic toxicity/ oncogenicity in rat	100

AOEL ‡

0.20 mg kg <sup>-1</sup> day <sup>-1</sup>	90-day rat	100
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ARfD ‡

0.20 mg kg <sup>-1</sup> day <sup>-1</sup>	90-day rat	100
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#### Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (SCORE® 250 EC (A 7402 G, EC) (23.2% w/w)

1.4% undiluted solution, 4.6% diluted spray solution. Rat <i>in vivo</i> and comparative <i>in vitro</i> human/rat skin.
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#### Exposure scenarios (Annex IIIA, point 7.2)

Operator

<b>SCORE® 250 EC (A-7402 T)</b> <b>Use in pome fruit, 1L bottle. Vehicle mounted airblast sprayer. No PPE</b>
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#### Mammalian toxicology

Northern EU: application rate 56.25 g a.i./ha, 500 L water/ha:  
UK POEM: 0.013 mg/kg bw (6.5% of AOEL);  
German Model: 0.0044 mg/kg bw (2.2% of AOEL)  
Southern EU: application rate 75 g a.i./ha, 500 L water/ha:  
UK POEM: 0.018 mg/kg bw (8.8% of AOEL)  
German Model: 0.0058mg/kg bw (2.9% of AOEL)  
**Use in pome fruit, 1L bottle. Hand held application. No PPE**  
Northern EU: application rate 56.25 g a.i./ha, 500 L water/ha:  
UK POEM: 0.12 mg/kg bw (60% of AOEL);  
German Model: 0.0048mg/kg bw (2.4% of AOEL)  
Southern EU: application rate 75 g a.i./ha, 500 L water/ha:  
UK POEM: 0.13 mg/kg bw (65% of AOEL)  
German Model: 0.0063 mg/kg bw (3.2% of AOEL)  
**Use in carrots, 1L bottle. Vehicle mounted boom sprayer.**  
**Application rate 125 g a.i./ha, 100 L water/ha. No PPE**  
UK POEM: 0.056 mg/kg bw (28% of AOEL)  
German Model: 0.0054 mg/kg bw (2.7% of AOEL)  
**DIVIDEND®030 FS (A-9142 G)**  
Estimated exposure calculated by the notifier using the SEEDTROPEX model. **No PPE.**  
<11% of AOEL

#### Workers

**SCORE® 250 EC (A-7402 T)**  
EURO POEM model used for calculations. **No PPE**  
**Pome fruit**  
Northern EU: application rate 56.25 g a.i./ha  
0.016 mg/kg bw (8% of AOEL)  
Southern EU: application rate 75 g a.i./ha  
0.021 mg/kg bw (10% of AOEL)  
**Carrot**  
application rate 125 g a.i./ha  
0.19 mg/kg bw (10% of AOEL)  
**DIVIDEND®030 FS (A-9142 G)**  
Estimated exposure calculated by the notifier using the SEEDTROPEX model.  
2.5% of AOEL

#### Bystanders

**SCORE® 250 EC (A-7402 T)**: <1% of AOEL  
**DIVIDEND®030 FS (A-9142 G)**: considered to be of no risk (no calculations performed).

#### Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Substance classified (name)	RMS/peer review proposal
	Xn; R22

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## Residues

### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	- Cereals, seed treatment (BBCH 00). - Root vegetables (carrot), foliar treatment (BBCH 42/43) - Fruits (pome fruit), foliar treatment (BBCH 61)
Rotational crops	Leafy vegetables (lettuce, spinach), root vegetables (carrot, sugarbeet, turnip), cereals (spring and winter wheat, maize), oilseeds (mustard)
Metabolism in rotational crops similar to metabolism in primary crops	Yes, in part. Two metabolites were observed: triazole alanine (CGA-131013) and triazole acetic acid (CGA-142856). No residues of parent difenoconazole were found. A new metabolite was observed, CGA-205369 (triazole lactic acid).
Processed commodities	Difenoconazole is stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation (95.6 to 98.6% of the applied radioactivity consisted of parent difenoconazole).
Residue pattern in processed commodities similar to residue pattern in raw commodities	Yes, in part. Unprocessed apple = 0.023 mg/kg <sup>a</sup> Raw juice = <0.02 mg/kg <sup>a</sup> (TF=<0.9) Wet pomace = 0.1 mg/kg <sup>a</sup> (TF=4.5) <sup>a</sup> mean value of 3 studies.
Plant residue definition for monitoring	Parent Difenoconazole
Plant residue definition for risk assessment	Parent Difenoconazole
Conversion factor (monitoring to risk assessment)	None

### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Ruminant (goat), poultry (hen)
Time needed to reach plateau concentration in milk and eggs	48 hours in milk: [phenyl- <sup>14</sup> C] difenoconazole 144 hours in milk: [triazole- <sup>14</sup> C] difenoconazole 168 hours in egg yolk: [phenyl- <sup>14</sup> C] and [triazole- <sup>14</sup> C] 120 hours in eggs white: [triazole- <sup>14</sup> C] difenoconazole
Animal residue definition for monitoring	Parent difenoconazole + metabolite CGA-205375 (1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-[1,2,4]triazol-1-yl-ethanol)
Animal residue definition for risk assessment	Parent Difenoconazole
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes

### Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Maximum residues of difenoconazole in human food commodities of succeeding crops (lettuce, carrot, spinach) grown in rotation after cereals and carrots are not expected to exceed 0.01 mg/kg. In one of four available studies, conducted with [triazole- <sup>14</sup> C] difenoconazole, high residues of difenoconazole equivalents/kg were found in mature maize and mature wheat grain (0.211 and 0.341 mg difenoconazole equivalents/kg, respectively). The majority of the TRR consisted of the metabolite CGA-131013 (triazole alanine; 44-66.2% TRR), CGA-142856 (triazole acetic acid; 25.9% TRR) and CGA-205369 (triazole lactic acid; 9.7%TRR) (see Table B.7.9.2-2, section B.7)
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### Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

Potato, tomato, cotton (cottonseed oil), wheat (straw, forage and grain): stable at <-20 °C for at least 24 months. Lettuce (head), soybean (beans), wheat forage, banana: stable at <-20 °C for at least 12 months. Animal commodities (eggs, milk, beef liver, poultry breast): stable at <-20 °C for at least 12 months.
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### Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: Yes <sup>a</sup>	Poultry: No <sup>b</sup>	Pig: no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			

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#### Residues

Muscle  
Liver  
Kidney  
Fat  
Milk  
Eggs

Residue levels in feeding studies (dose level: mg/kg)		
Mean (max) mg/kg		
*	N/R	N/R
*	N/R	N/R
*	N/R	N/R
*	N/R	N/R
*	N/R	N/R
*	N/R	N/R

\*Dietary burden based on representative crops not carried out, as this is not representative of the true dietary burden based on all registered crops. Calculation of the actual dietary burden and proposals for MRLs in products of animal origin will be included in the EU MRL submission.

<sup>a</sup>A new feeding study has recently been conducted. The samples have been analysed for parent difenoconazole and the metabolite CGA-205375 using updated analytical methods. Additionally, the level of 1, 2, 4-triazole in the samples has also been determined. The estimated completion of the final report for the study is mid-2006. The RMS suggests that this study could be included in an Addendum.

<sup>b</sup>The transfer of residues of difenoconazole from poultry into tissues and eggs has been investigated in a new study. The level of 1, 2, 4-triazole in the tissues and eggs after feeding of difenoconazole has also being determined. The samples have been analysed and the final report is currently being written. The estimated completion of the final report for the study is mid-2006. The RMS suggests that this study could be included in an Addendum.

N/R=Not required

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## Residues

### Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL estimated from trials according to the intended use	STMR (b)
	State region (N or S or both) where use is intended. In case of import tolerance state country (code).	Report actual individual results of supervised residue trials which are in line with intended use (see also Guidance Document Appendix B)	State deficiency in residue trials, results of trials with higher use rate giving similar results, proposed extrapolations and other information which supports your decision (see also Guidance Document Appendix D) etc.	MRL - 1 (R <sub>max</sub> )	MRL - 2 (R <sub>ber</sub> ) <sup>4</sup>
Wheat Grain	Northern and Southern Europe	14 trials: PHI = N/A, 4 x <0.01, 10 x 0.02 mg/kg		0.03	0.04 0.02
Pome Fruit	Northern and Southern Europe	11 trials: PHI = 14, 0.04, 0.05, 0.07, 0.08, 0.10, 0.11, 0.13, 0.14, 0.15, 0.16, 0.28 mg/kg	MRL calculation is based on 11 trials conducted in the Southern region.	0.31	0.30 0.11
Carrot	Northern and Southern Europe	16 trials: PHI = 14, <0.02, 5 x 0.02, 2 x 0.03, 0.04, 0.05, 2 x 0.07, 2 x 0.11, 0.12, 0.13 mg/kg		0.16	0.20 0.04

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

<sup>3</sup> MRL proposal derived from supervised residue trials according to Guidance Document Appendix I. When the MRL is estimated at the LOD this should be annotated by an asterisk after the number.

<sup>4</sup> STMR value from results of supervised residue trials for MRL setting.

MRL - 1: MRL calculated according to Method I (Doc. 7039/VI/95 EN 22/7/1997, Appendix I, Calculation of maximum residue levels and safety intervals).

MRL - 2: MRL calculated according to Method II (Doc. 7039/VI/95 EN 22/7/1997, Appendix I, Calculation of maximum residue levels and safety intervals).

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Residues

### Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw/day
TMDI (% ADI)	4.0% (WHO European diet – adult, 60 kg bw)
TMDI (% ADI) according to national (to be specified) diets	13.6% (German model – girl, 13.5 kg bw) 9.9% (UK model – adult, 70.1 kg bw) 12.1% (UK model – child, 43.6 kg bw) 53.2% (UK model – toddler, 14.5 kg bw) 38.7% (UK model – infant, 8.7 kg bw)
IEDI (%ADI)	1.8% (WHO European diet – adult, 60 kg bw) 5.8% (German model – girl, 13.5 kg bw) 4.0% (UK model – adult, 70.1 kg bw) 5.1% (UK model – child, 43.6 kg bw) 20% (UK model – toddler, 14.5 kg bw) 14.6% (UK model – infant, 8.7 kg bw)
NEDI (specify diet) (% ADI)	Not calculated (TMDI < 100%)
Factors included in IEDI and NEDI	N/A
ARfD	0.20 mg/kg
IESTI	--
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Current WHO methodology and UK acute consumption data: Max 8.4 % (apples in toddlers)
Factors included in NESTI	Highest residue (HR), Transfer factor

<sup>5</sup> To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted diets.

### Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Apple – washed fruit	1	0.71	
Apple – wet pomace	1	3.5	
Apple – dry pomace	1	15.6	
Apple – juice (before/after pasteurisation)	1	0.02/0.02	
Apple - puree	1	0.14	
Apple – wet pomace	3	6.5	
Apple – juice (before pasteurisation)	3	<0.9	

### Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Cereal grain	0.02* mg/kg
Carrot	0.2 mg/kg
Pome fruit	0.3 mg/kg

When the MRL is proposed at the LOD this should be annotated by an asterisk after the number.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Mineralization after 100 days ‡	1.6-2.1% after 90/120 d [ <sup>14</sup> C-triazole]-label (n=2) 3.7-19.3% after 90/100/120 d [ <sup>14</sup> C-chlorophenyl]-label (n=6)
Non-extractable residues after 100 days ‡	21.8-36.6% after 90/120 d [ <sup>14</sup> C-triazole]-label (n=2) 17.4-33.7% after 90/100/120 d [ <sup>14</sup> C-chlorophenyl]-label (n=6)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	CGA 205375: max. 4.4-9.7% after 56-120 d [ <sup>14</sup> C-triazole] and [ <sup>14</sup> C-chlorophenyl] labels (n=7) CGA 71019: max. 20.6-23.4% after 190/271 d [ <sup>14</sup> C-triazole]-label (n=2)

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

Anaerobic degradation ‡	
Mineralization after 100 days	0.1% after 110 d [ <sup>14</sup> C-triazole]-label (n=1)
Non-extractable residues after 100 days	11.6% after 110 d [ <sup>14</sup> C-triazole]-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

#### Laboratory studies ‡

Difenoconazole	Aerobic conditions						
Soil type	g/ha <sup>1</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) <sup>3</sup> 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
loam	141	7.2	20 / 40	104 / 345	64	0.999	SFO
loam	143	7.2	20 / 40	118 / 392	72	0.998	SFO
sand	75	5.0	20 / 40	123 / 409	105	0.913	SFO
silt loam	750	7.2	20 / 60	456 <sup>2</sup> / >>273 <sup>2</sup>	-	0.892	SFO
silt loam	750	7.2	30 / 60	175 <sup>2</sup> / >>178 <sup>2</sup>	-	0.977	SFO
silt loam	750	7.2	20 / 30	709 <sup>2</sup> / >>281 <sup>2</sup>	-	0.855	SFO
silt loam	750	7.2	20 / 60	345 <sup>2</sup> / >>281 <sup>2</sup>	-	0.973	SFO
silt loam	750	7.2	10 / 60	602 <sup>2</sup> / >>281 <sup>2</sup>	-	0.952	SFO
silt loam	75	7.2	20 / 60	83 / 277	58	0.950	SFO
loam	128	7.2	20 / 30	136 <sup>2</sup> / 452 <sup>2</sup>	-	0.986	SFO
loam	128	7.2	10 / 60	338 <sup>2</sup> / >1000 <sup>2</sup>	-	0.993	SFO
loam	12.8	7.2	20 / 60	53 / 175	37	0.995	SFO
loam sterile	128	7.2	20 / 60	>1000 <sup>2</sup> / >1000 <sup>2</sup>	-	-	-
sandy loam	193	7.4	20 / 40	149 / 496	100	0.977	SFO
sandy loam/loamy sand	193	7.5	20 / 40	186 / 617	133	0.939	SFO
silty clay loam	193	6.7	20 / 40	187 / 620	107	0.972	SFO
Geometric mean				117 / 388	79		
Median				120 / 400	86		

1 Test concentration re-calculated into corresponding g a.s./ha dose for comparison with the representative uses. Rate of degradation of difenoconazole appeared to be decreased at high test concentrations. Results from studies carried out at test concentration corresponding to 750 g a.s./ha were therefore not included in the mean/median since this rate exceeds the maximum treatment rate recommended.

2 Values not included in the mean/median because they were obtained from high test concentrations or from 10/30°C, dry moisture or sterile conditions.

3 In case the same soil was tested under standard conditions, the variations in temperature and moisture were not considered for mean/median values of normalised data.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

CGA 71019		Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
sandy loam	6.4	20 / 40	6.3 / 21	-	4.3	0.75	SFO
loamy sand	5.8	20 / 40	9.9 / 33	-	7.6	0.81	SFO
silt loam	6.7	20 / 40	12 / 41	-	7.5	0.95	SFO
Geometric mean			9.1 / 30.5		6.3		
Median			9.9 / 33		7.5		

CGA 205375		Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
sandy loam	7.4	20 / 40	93 / 309	-	63	0.980	SFO
sandy loam/loamy sand	7.5	20 / 40	83 / 275	-	60	0.995	SFO
silt loam	5.8	20 / 40	152 / 504	-	92	0.996	SFO
Geometric mean			106 / 350		70		
Median			93 / 309		63		

## Field studies ‡

Difenoconazole									
Soil type (indicate if bare or cropped soil was used).	Location	g/ha <sup>1</sup>	pH	Depth (cm) <sup>2</sup>	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	St. (r <sup>2</sup> )	DT <sub>50</sub> (d) Norm. 20°C	Method of calculation
silt loam bare	Germany	>>250	7.4	0-20	160	532	0.853	-	SFO
silt loam bare	Germany	500	6.6	0-20	22	72	0.963	-	SFO
loamy sand bare	Germany	500	6.2	0-20	57	189	0.817	-	SFO
silt loam bare	Germany	500	6.8	0-20	64	211	0.885	-	SFO
loamy sand bare	Germany	500	5.6	0-30	63	211	0.766	-	SFO
sandy loam bare	Germany	750	6.0	0-20	265	879	0.752	-	SFO
silt loam bare	Germany	750	6.0	0-20	241	802	0.652	-	SFO
silt loam bare	Germany	750	5.7	0-20	116	384	0.810	-	SFO
clay loam bare	Switzerland	125	7.3	0-10	83	277	0.934	-	SFO
clay bare	UK	375	7.6	0-10	156 <sup>2</sup>	519 <sup>2</sup>	0.844	-	SFO
clay bare	UK	125	7.6	0-10	227 <sup>2</sup>	755 <sup>2</sup>	0.827	-	SFO
sandy loam bare	Spain	800	-	0-10	54 <sup>2</sup>	178 <sup>2</sup>	0.777	-	SFO
sandy loam bare	Spain	150	-	0-10	38 <sup>2</sup>	128 <sup>2</sup>	0.937	-	SFO
sandy clay bare	UK	375	8.2	0-10	133 <sup>2</sup>	442 <sup>2</sup>	0.840	-	SFO
loam asparagus	Italy	6x125	-	0-30	181 <sup>2</sup>	602 <sup>2</sup>	0.750	-	SFO
clay treated seed	Canada	40	7.7	0-10	87 <sup>2</sup>	289 <sup>2</sup>	0.741	-	SFO
clay loam treated seed	Canada	37	6.6	0-10	28 <sup>2</sup>	92 <sup>2</sup>	0.895	-	SFO
clay treated seed	Canada	36	8.3	0-10	76 <sup>2</sup>	254 <sup>2</sup>	0.902	-	SFO
clay loam treated seed	Canada	36	6.1	0-10	34 <sup>2</sup>	114 <sup>2</sup>	0.821	-	SFO
Geometric mean					92	307			
Median					83	277			

<sup>1</sup> Treatment rate (g a.s./ha) used in studies.

<sup>2</sup> Indicates depth considered, however, residues possible to quantify were sometimes only found in the top soil horizon.

<sup>3</sup> Values not included in the mean/median because studies were only considered to be of supplementary nature, or because study was performed on treated seeds.

## pH dependence ‡

(yes /no) (if yes type of dependence)

Soil accumulation and plateau concentration ‡

No

No accumulation observed after up to 10 years use.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

### Laboratory studies ‡

Difenoconazole	Anaerobic conditions						
Soil type	g/ha <sup>1</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
loam	128	7.2	20 / flooded	stable	-	-	-
Geometric mean/median				-	-	-	-

<sup>1</sup> Test concentration re-calculated into corresponding g a.s./ha dose for comparison with the representative uses.

CGA 71019	Anaerobic conditions						
Soil type	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
silt loam	7.3	20 / flooded	81 / 268	-	-	0.972	SFO
Geometric mean/median			-	-	-	-	-

CGA 205375	Anaerobic conditions						
Soil type	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
sandy loam/loamy sand	7.5	20 / flooded	213 / 706	-	-	0.986	SFO
Geometric mean/median			-	-	-	-	-

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

Difenoconazole ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
sand	0.36	7.9	-	-	12.8	3870	0.74
sandy loam	1.98	7.8	-	-	63.0	3520	0.76
silt loam	1.74	6.5	-	-	54.8	3470	0.85
silty clay loam	0.67	6.9	-	-	47.2	7730	0.91
clay	2.79	5.9	-	-	97.8	3470	0.89
sand	0.52	6.5	-	-	2.1	400	0.80
silt loam	0.58	7.5	-	-	35.0	5660	0.88
sandy loam	0.58	8.5	-	-	11.5	1960	0.94
Arithmetic mean					40	3760	0.85
Median					41	3495	0.87
pH dependence, Yes or No			No				

CGA 71019 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
silty clay	0.70	8.8	-	-	0.83	120	0.90
clay loam	1.74	6.9	-	-	0.75	43	0.83
silty clay loam	0.70	7.0	-	-	0.72	104	0.92
sandy loam	0.81	6.9	-	-	0.72	89	1.02
Arithmetic mean					0.75	89	0.91
Median					0.74	82	0.91
pH dependence (yes or no)			No				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

CGA 205375 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
loamy sand	2.17	5.7	-	-	118	5440	0.81
silty clay loam	1.16	6.6	-	-	45.5	3920	0.76
clay	2.63	6.7	-	-	44.1	1680	0.76
sandy loam	1.17	6.8	-	-	22.6	1930	0.72
loam	1.22	7.6	-	-	23.6	1930	0.77
Arithmetic mean					51	2980	0.76
Median					44	1930	0.76
pH dependence (yes or no)				No			

## Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	<p>Elution: 200 mm Time period: 2 d</p> <p>Difenoconazole did not move out of the zone of application in any of four soils tested. Study used only to support results from adsorption/desorption tests.</p>
Aged residues leaching ‡	Not submitted, not required

Lysimeter/ field leaching studies ‡	Not submitted, not required
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## PEC (soil) (Annex IIIA, point 9.1.3)

Difenoconazole	DT <sub>50</sub> (d): 246 days
Method of calculation	Kinetics: SFO Field or Lab: 90 %-ile of DT <sub>50</sub> s from field studies (n=9).
Application data	<p>Crop: Seed treatment; Spray on apples; Spray on carrots Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm<sup>3</sup> % plant interception: Seed treatment: no interception; Apples: 65% Carrots: 80% Number of applications: 1 (seed treatment); 4 (apples); 3 (carrots) Interval (d): 7 d (apples); 14 d (carrots) Application rates: 12.3 g a.s./ha (seed treatment); 4 x 75 g a.s./ha (apples); 3 x 125 g a.s./ha (carrots)</p>

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
<u>Difenoconazole</u>				
<u>Seed treatment</u>				
Initial	0.016		-	
Short term				
24h	0.016	0.016	-	-
2d	0.016	0.016	-	-
4d	0.016	0.016	-	-
Long term				
7d	0.016	0.016	-	-
28d	0.015	0.016	-	-
50d	0.014	0.015	-	-
100d	0.012	0.014	-	-

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

PEC <sub>(s)</sub> (mg/kg) <u>Difenoconazole</u> <u>Apples</u>		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.035		0.136	
Short term	24h	-	-	0.136	0.136
	2d	-	-	0.135	0.136
	4d	-	-	0.134	0.135
Long term	7d	-	-	0.133	0.135
	28d	-	-	0.126	0.131
	50d	-	-	0.118	0.127
	100d	-	-	0.103	0.118
Plateau concentration		0.076 mg/kg after 7 yr (lower part of "saw-teeth" curve)			

PEC <sub>(s)</sub> (mg/kg) <u>Difenoconazole</u> <u>Carrots</u>		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.033		0.096	
Short term	24h	-	-	0.096	0.096
	2d	-	-	0.096	0.096
	4d	-	-	0.095	0.096
Long term	7d	-	-	0.094	0.095
	28d	-	-	0.089	0.092
	50d	-	-	0.084	0.090
	100d	-	-	0.072	0.084

## CGA 71019

Method of calculation

Initial PECs=  
Max parent PECs x Max. metabolite in soil x Mol. Wt fraction.  
where:  
Max. parent PECs: 0.016 mg/kg (seed treatment);  
0.136 mg/kg (apples); 0.096 mg/kg (carrots)  
Max. CGA 71019 in soil: 23%  
Molecular weight fraction: 0.170.

Application data

Use of difenoconazole as Seed treatment; Spray in apples;  
Spray in carrots.

PEC <sub>(s)</sub> (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
<u>Seed treatment</u>					
Initial		0.0006		-	
<u>Apples</u>					
Initial				0.0053	
<u>Carrots</u>					
Initial		-		0.0038	

**List of end points**

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

**Fate and behaviour in the environment**
CGA 205375

Method of calculation

Initial PECs=  
Max parent PECs x Max. metabolite in soil x Mol. Wt fraction.  
where:  
Max. parent PECs: 0.016 mg/kg (seed treatment);  
0.136 mg/kg (apples); 0.096 mg/kg (carrots)  
Max. CGA 205375 in soil: 10%  
Molecular weight fraction: 0.862.

Application data

Use of difenoconazole as Seed treatment; Spray in apples;  
Spray in carrots.

PEC<sub>(s)</sub>  
(mg/kg)

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
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Seed treatment

Initial	0.0014	-	
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Apples

Initial	-	0.012	
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Carrots

Initial	-	0.0083	
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**Route and rate of degradation in water (Annex IIA, point 7.2.1)**

Hydrolytic degradation of the active substance and metabolites &gt; 10 % ‡

Difenoconazole: No degradation observed at pH 5, 7 and 9 (25°C, 30 days)

CGA 71019: No degradation observed at pH 5, 7 and 9 (25°C, 30 days)

CGA 205375: No degradation observed at pH 4, 7 and 9 (50°C, 5 days)

Photolytic degradation of active substance and metabolites above 10 % ‡

Difenoconazole: Stable (<10% transformation over 15 days, continuous irradiation)

CGA 205375: Stable (<10% transformation over 15 days, continuous irradiation)

Quantum yield of direct phototransformation in water at λ &gt; 290 nm

0.0155.  
Predicted half-lives were between 12 and >10000 years at 52°N latitude depending on season.

CGA 205375: 0.0266.  
Predicted half-lives were between 14 and >10000 years at 52°N latitude depending on season.

Readily biodegradable ‡  
(yes/no)

No

**Degradation in water / sediment**

Difenoconazole	<p>Distribution of total radioactivity in Pond/River systems (20°C): Max. in water 88/80% day 0. Decreased to 20/32% by day 3 and to &lt;10% by day 7/14. Distribution of Difenoconazole in Pond/River systems (8°C): Max. in water 83/87% day 0. Decreased to 15/36% by day 3 and to 2.3/12% by day 14. Max. in sediment 99.8/96.5% day 42.</p> <p>Metabolites identified (20°C, <sup>14</sup>C-chlorophenyl label): CGA 205375 max. 4.9% in pond system (days 32 and 127), max. 11.6-11.4% in river system (days 90-183).</p>									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys. Degradation	St. (r <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> water Dissipation	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Pond	-	6.9	20	ca 324/>1000	0.998	1.0 / 3.3	0.987	-		SFO
River	-	7.2	20	ca 307/>1000	0.999	2.0 / 6.6	0.968	-		SFO
Pond	-	7.2	8	DT <sub>50</sub> ca 3 y <sup>1</sup>	-	1.0 / 3.4	0.991	-		SFO
River	-	7.2	8	DT <sub>50</sub> ca 2 y <sup>1</sup>	-	0.8 / 6.2	0.999	-		SFO
Geometric mean				315 / >1000		1.1 / 4.6		-		

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

1 DT<sub>50</sub> values related to degradation in whole systems obtained at 8°C were not included in mean value.

CGA 205375	Distribution of CGA 205375 in Pond/River systems: Max. in water 97/96% day 0. Decreased to <10% by day 7/14. Max. in sediment 91/87% day 62/28.  Metabolites identified ( <sup>14</sup> C-triazole label): CGA 71019 max. 3.2% in pond system (day 148), max. 14.1% in river system (day 148).									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys. Degradation	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water Dissipation	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Pond	7.97	7.09	20	ca 630/>1000	0.765	1.4 / 4.7	0.958	-	-	SFO
River	8.1	7.46	20	ca 301/>1000	0.932	3.1 / 10.2	0.985	-	-	SFO
Geometric mean				ca 435/>1000		2.1 / 6.9				

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Parent; Pond, 20°	-	6.9	3.0 % (183 d) <sup>1</sup>	-	13.9 % (183 d) <sup>1</sup>
Parent; River, 20°	-	7.2	3.9 % (183 d) <sup>1</sup>	-	8.7 % (183 d) <sup>1</sup>
Parent; Pond, 8°	-	7.2	1.9 % (183 d) <sup>1</sup>	-	11.4 % (183 d) <sup>1</sup>
Parent; River, 8°	-	7.2	2.9 % (183 d) <sup>1</sup>	-	9.8 % (183 d) <sup>1</sup>
CGA 205375; Pond	7.97	7.09	0.5 % (148 d) <sup>2</sup>	-	8.2 % (148 d) <sup>2</sup>
CGA 205375; River	8.1	7.46	0.4 % (148 d) <sup>2</sup>	-	13.0 % (148 d) <sup>2</sup>

<sup>1</sup> <sup>14</sup>C-Chlorophenyl radiolabel

<sup>2</sup> <sup>14</sup>C-triazole radiolabel

## PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

### Difenoconazole

Parameters used in FOCUSsw step 1 and 2

Parameters used in FOCUSsw step 3

Parameters used in FOCUSsw step 4

Risk mitigation applied in FOCUSsw step 4

Application rate

Molecular weight (g/mol): 406 Water solubility (mg/L): 15 K <sub>OC</sub> (mL/g): 3759.4 (mean value) DT <sub>50</sub> soil (d): 86 (arithmetic mean of normalised lab values; after RMS's evaluation instead representing the median value) DT <sub>50</sub> water/sediment system (d): 315.5 (mean value) DT <sub>50</sub> water (d): 315.5 (mean value, degradation whole system) DT <sub>50</sub> sediment (d): 315.5 (mean value, degradation whole system) Crop interception (%): 0 (seed treatment); 70 (apples and carrots) "No drift" option used for seed treatment scenario (Steps 1-2).
Version control no.'s of FOCUS software: SWASH 1.1; Drift calculator 1.1; PRZM_SW 1.1.1; MACRO 4.4.2; TOXSWA 1.1.1 Vapour pressure: 0 (worst case) 1/n: 0.8 (mean value) Other parameters set to the same value as in Steps 1 and 2.
Version control no.'s of FOCUS software: As in Step 3 except TOXSWA ver. 2.2.1 Other parameters set to the same value as in Steps 3.
Buffers of 14 m and 20 m used for apples to reduce spray drift. Vegetative buffer strip of 5 m used for carrots to reduce spray drift and run-off (run-off reduction 50%).
Seed treatment (Steps 1 and 2): 12.3 g a.s./ha Apples (Steps 1-4): 4 x 75 g a.s./ha (7 d interval) Carrots (Steps 1-4): 3 x 125 g a.s./ha (at Steps 3 and 4 scenario R2 also 6 x 125 g a.s./ha was simulated to account for 2 annual crops grown) (14 d interval) Application window for 1st treatment, Step 3: 1 March-18 April (apples); 2 March-15 June (carrots) Application window for 1st treatment, Step 4: 1 March-6 April (apples); 2 March-3 June (carrots)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

Difenoconazole FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment	0	0.693		26.0	
Apples	0	32.4		722	
Carrots	0	24.2		801	

Difenoconazole FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment					
N EU autumn planting	0	0.336		12.6	
Apples S EU, spring	0	4.23		128	
Carrots S EU, spring	0	2.73		96.5	

Difenoconazole FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
Apples						
D3	Ditch	0	1.789		3.875	
		7		0.326		3.686
		21		0.206		3.259
		28		0.191		3.111
D4	Pond	0	0.241		3.937	
		7		0.219		3.937
		21		0.193		3.934
		28		0.185		3.932
D4	Stream	0	1.677		0.255	
		7		0.018		0.242
		21		0.015		0.219
		28		0.015		0.209
D5	Pond	0	0.240		4.033	
		7		0.219		4.033
		21		0.192		4.031
		28		0.185		4.029
D5	Stream	0	1.806		0.287	
		7		0.020		0.271
		21		0.019		0.244
		28		0.014		0.232
R1	Pond	0	0.227		3.723	
		7		0.205		3.723
		21		0.179		3.718
		28		0.172		3.714
R1	Stream	0	1.372		0.718	
		7		0.034		0.695
		21		0.029		0.652
		28		0.023		0.634
R2	Stream	0	1.819		1.568	
		7		0.026		1.548
		21		0.022		1.510
		28		0.019		1.492
R3	Stream	0	1.943		1.849	
		7		0.130		1.740
		21		0.103		1.557
		28		0.096		1.489
R4	Stream	0	1.380		1.761	
		7		0.093		1.690

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

Difenoconazole FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		21		0.040		1.571
		28		0.036		1.522

Difenoconazole FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
Carrots						
D3	Ditch	0	0.573		0.979	
		7		0.093		0.937
		21		0.059		0.840
		28		0.044		0.800
D6	Ditch	0	0.570		0.428	
		7		0.076		0.410
		21		0.026		0.374
		28		0.026		0.362
R1	Pond	0	0.082		3.908	
		7		0.076		3.892
		21		0.068		3.854
		28		0.066		3.818
R1	Stream	0	0.376		23.00	
		7		0.057		22.86
		21		0.030		22.59
		28		0.025		22.49
R2, 1st crop	Stream	0	0.504		62.88	
		7		0.015		62.54
		21		0.007		61.09
		28		0.006		60.84
R2, 2nd crop	Stream	0	0.504		146.6	
		7		0.022		145.3
		21		0.014		143.1
		28		0.012		142.8
R3	Stream	0	0.530		7.356	
		7		0.050		7.314
		21		0.030		7.249
		28		0.025		7.234
R4	Stream	0	0.713		18.15	
		7		0.190		17.85
		21		0.088		17.45
		28		0.085		17.19

Difenoconazole FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
Apples, 14 m buffer						
D3	Ditch	0	0.326		0.777	
D4	Pond	0	0.101		1.74	
D4	Stream	0	0.351		0.056	
D5	Pond	0	0.101		<b>1.78</b>	
D5	Stream	0	0.378		0.062	
R1	Pond	0	0.095		1.68	
R1	Stream	0	0.287		0.508	
R2	Stream	0	0.381		1.51	
R3	Stream	0	0.407		0.769	
R4	Stream	0	<b>0.444</b>		1.52	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

Difenoconazole FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
Apples, 20 m buffer						
D3	Ditch	0	0.325		0.515	
D4	Pond	0	0.064		1.14	
D4	Stream	0	0.183		0.030	
D5	Pond	0	0.064		1.16	
D5	Stream	0	0.197		0.033	
R1	Pond	0	0.067		1.26	
R1	Stream	0	0.230		0.478	
R2	Stream	0	0.198		<b>1.50</b>	
R3	Stream	0	0.292		0.623	
R4	Stream	0	<b>0.444</b>		1.49	

Difenoconazole FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
Carrots, 5 m buffer						
D3	Ditch	0	0.151		0.273	
D6	Ditch	0	0.150		0.123	
R1	Pond	0	0.044		2.20	
R1	Stream	0	0.162		11.7	
R2, 1st crop	Stream	0	0.180		32.0	
R2, 2nd crop	Stream	0	0.180		<b>74.1</b>	
R3	Stream	0	0.206		3.73	
R4	Stream	0	<b>0.392</b>		9.24	

## CGA 71019

Parameters used in FOCUSsw step 1 and 2

Molecular weight (g/mol): 69
Water solubility (mg/L): 730
Soil or water metabolite: Both
K <sub>OC</sub> (mL/g): 89 (mean value)
DT <sub>50</sub> soil (d): 6.45 (arithmetic mean of normalised lab values)
DT <sub>50</sub> water/sediment system (d): 1000 (worst case assumption)
DT <sub>50</sub> water (d): 1000 (worst case assumption)
DT <sub>50</sub> sediment (d): 1000 (worst case assumption)
Simulated together with parent compound:
Crop interception (%): 0 (seed treatment); 70 (apples and carrots)
"No drift" option used for seed treatment scenario.
Max. occurrence observed (%):
Water/Sediment: 9.6 (worst case assumption calc. by RMS)
Soil: 23.4
Seed treatment: 12.3 g a.s./ha
Apples: 4 x 75 g a.s./ha (7 d interval)
Carrots: 3 x 125 g a.s./ha (14 d interval)

Application rate

CGA 71019 FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment	0	0.148		0.132	
Apples	0	3.76		3.11	
Carrots	0	4.43		3.89	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

CGA71019 FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment N EU autumn planting	0	0.0482		0.0429	
Apples S EU, spring	0	0.272		0.237	
Carrots S EU, spring	0	0.176		0.155	

### CGA 205375

Parameters used in FOCUSsw step 1 and 2

Molecular weight (g/mol): 350  
 Water solubility (mg/L): 100 (assumed value)  
 Soil or water metabolite: Both  
 K<sub>OC</sub> (mL/g): 2979.4 (mean value)  
 DT<sub>50</sub> soil (d): 71.5 (arithmetic mean of normalised lab values)  
 DT<sub>50</sub> water/sediment system (d): 465.5 (arithmetic mean)  
 DT<sub>50</sub> water (d): 465.5 (mean value, degradation whole system)  
 DT<sub>50</sub> sediment (d): 465.5 (mean value, degradation whole system)  
 Simulated together with parent compound:  
 Crop interception (%): 0 (seed treatment); 70 (apples and carrots)  
 "No drift" option used for seed treatment scenario.  
 Max. occurrence observed (%):  
 Water/Sediment: 11.6  
 Soil: 9.7  
 Seed treatment: 12.3 g a.s./ha  
 Apples: 4 x 75 g a.s./ha (7 d interval)  
 Carrots: 3 x 125 g a.s./ha (14 d interval)

Application rate

CGA 205375 FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment	0	0.0679		2.02	
Apples	0	3.20		57.8	
Carrots	0	2.38		62.6	

CGA205375 FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Seed treatment N EU autumn planting	0	0.0327		0.973	
Apples S EU, spring	0	0.457		11.0	
Carrots S EU, spring	0	0.274		7.61	

### PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

Model used: FOCUS PEARL 2.2.2  
 Scenarios: Difenoconazole and the metabolites CGA71019 and CGA 205375 were simulated in separate model runs.  
 For use in apples all 9 FOCUS scenarios were run. For use in carrots Châteaudun, Hamburg, Kremsmünster, Porto and Thiva were run with two annual crops assumed, and Jokioinen was run with one annual crop assumed.  
 The results from the simulations in apples and carrots are considered to cover also the use of difenoconazole in seed treatment.  
 Crops: Apples and carrots.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

## Application rate

<p>Difenoconazole: DT<sub>50</sub> soil (d): 86.0 (arithmetic mean of normalised lab values; after RMS's evaluation instead representing the median value) Koc (mL/g): 3759.4 (mean value) 1/n: 0.8 (mean value)</p> <p>CGA 71019: DT<sub>50</sub> soil (d): 6.45 (arithmetic mean of normalised lab values) Koc (mL/g): 89 (mean value) 1/n: 0.9 (mean value)</p> <p>CGA 205375: DT<sub>50</sub> soil (d): 71.5 (arithmetic mean of normalised lab values) Koc (mL/g): 2979.4 (mean value) 1/n: 0.8 (mean value)</p>
<p>Difenoconazole: Application rate: 4 x 75 g a.s./ha, 7 d interval (apples); 3 x 125 g a.s./ha or 6 x 125 g a.s./ha, 14 d interval (carrots) No. of applications: 4 (apples); 3 (carrots, Jokioninen) 6 (carrots, remaining scenarios) Time of application: BBCH 61 (apples); BBCH 42-43 (carrots) Application window for 1st treatment: 22 March - 17 May (apples); 10-19 April (carrots) Crop interception (%): 65 (apples); 70 (carrots)</p> <p>CGA 71019: Application rate: 4 x 2.98 g a.s./ha, 7 d interval (apples); 3 x 4.97 g a.s./ha or 6 x 4.97 g a.s./ha, 14 d interval (carrots) (calc. as appl. rate parent x max. metabolite in soil (23.4%) x mol. wt fraction (69/406)). Other parameters as for parent.</p> <p>CGA 205375: Application rate: 4 x 6.07 g a.s./ha, 7 d interval (apples); 3 x 10.12 g a.s./ha or 6 x 10.12 g a.s./ha, 14 d interval (carrots) (calc. as appl. rate parent x max. metabolite in soil (9.4%) x mol. wt fraction (350/406)). Other parameters as for parent.</p>

PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

PELMOI / Apples	Scenario	Difenoconazole (µg/L)	Metabolites (µg/L)	
			CGA 71019	CGA 205375
	Chateaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

PELMOI / Carrots	Scenario	Difenoconazole (µg/L)	Metabolites (µg/L)	
			CGA 71019	CGA 205375
	Chateaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen <sup>1</sup>	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

<sup>1</sup> One carrot crop per season assumed; in the other scenarios two annual carrot crops assumed.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Fate and behaviour in the environment

### Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not submitted, not required
Quantum yield of direct phototransformation	Difenoconazole: 0.0155 (in water) CGA 205375: 0.0266 (in water)
Photochemical oxidative degradation in air ‡	DT <sub>50</sub> 5 hours derived by the Atkinson method (AOP 1.85). OH (12 h) concentration assumed: $1.5 \times 10^6$ radicals/cm <sup>3</sup> .
Volatilisation ‡	Volatilisation from soil: <0.05% after 24 hours (measured as % <sup>14</sup> C in absorption trap). Volatilisation from plants and soil: <9% after 24 hours (measured as % loss).
Metabolites	None identified.

### PEC (air)

Method of calculation	Expert judgement based on vapour pressure, Henry's Law constant and experimental data on volatilisation.
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### PEC<sub>(a)</sub>

Maximum concentration	Expected to be negligible.
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### Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: CGA 71019 and CGA 205375 Surface water: CGA 71019 and CGA 205375 Sediment: CGA 205375 Groundwater: None Air: None
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### Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not submitted, not required
Surface water (indicate location and type of study)	Not submitted, not required
Ground water (indicate location and type of study)	Not submitted, not required
Air (indicate location and type of study)	Not submitted, not required

### Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Not readily biodegradable. Log Pow 4.4. R53.
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‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

### Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
<b>Birds ‡</b>				
<i>Japanese quail</i>	difenoconazole	Acute	LD50 >2000	-
	metabolite CGA131013	Acute	no data	-
<i>Mallard duck</i>	difenoconazole	Short-term	5 d LC <sub>50</sub> >349	5 d LC <sub>50</sub> >5000
<i>Mallard duck</i>	metabolite CGA131013	Short term	5 d LC <sub>50</sub> >1342	5 d LC <sub>50</sub> >5000
<i>Bobwhite quail</i>	difenoconazole	Long-term	NOEL 9.75	NOEL 100
	metabolite CGA131013	Long-term	no data	-
<b>Mammals ‡</b>				
<i>Rat</i>	difenoconazole	Acute	LD <sub>50</sub> >1453	-
	DIVIDEND 030FS	Acute	LD <sub>50</sub> >3000	-
	SCORE 250EC	Acute	LD <sub>50</sub> >3000	-
	metabolite CGA 131013	Acute	LD <sub>50</sub> >5000	-
<i>Rat</i>	difenoconazole	Long-term	NOAEL 17.3	-
	metabolite CGA 131013	Long-term	NOAEL 100	-
<b>Additional higher tier studies ‡</b>				
no further data				

### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

#### Seed treatment to cereals, 60 mg/kg seed

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
<b>Tier 1 (Birds)</b>				
granivorous bird, a.i.	Acute	22.8	>88	10
granivorous bird, metabolite		8.66	>230	10
medium herbivorous bird, a.i.		22.8	>44	10
medium herbiv. bird, metabolite		17.5	110	10
small herbivorous bird, a.i.		63.6	31.4	10
small herbivorous bird, metabolite		24.4	82	10
granivorous bird, a.i.	Short-term	22.8	15	10
granivorous bird, metabolite		8.66	155	10
medium herbivorous bird, a.i.		22.8	15	10
medium herbiv. bird, metabolite		8.74	154	10
small herbivorous bird, a.i.		31.8	11	10
small herbivorous bird, metabolite		12.2	110	10
granivorous bird, a.i.	Long-term	7.60	1.3	5
granivorous bird, metabolite		2.89	3.4	5
medium herbivorous bird, a.i.		3.88	1.3	5
medium herbiv. bird, metabolite		2.97	3.3	5
small herbivorous bird, a.i.		10.8	0.91	5
small herbivorous bird, metabolite		4.14	2.4	5
fish-eating bird, a.i.		0.046	210	5
earthworm-eating bird, a.i.		0.059	160	5
exposure via drinking water		<<0.001	>20000	5
<b>Higher tier refinement (Birds)</b>				
granivorous bird, a.i.*	Long-term	1.89	5.1	5
granivorous bird, metabolite*		0.72	13	5
medium herbivorous bird, a.i.**		0.093	105	5
medium herbiv. bird, metabolite**		0.034	287	5
small herbivorous bird, a.i.**		0.13	75	5
small herbiv. bird, metabolite**		0.049	200	5

\*refinement based on measured residues of difenoconazole in shoots emerging from treated seeds

\*\*refinement based on measured data on dissipation of difenoconazole from treated seeds and diet composition of skylark in April (Green, 1978).

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

<b>Tier 1 (Mammals)</b>				
granivorous mammal, a.i.	Acute	13.8	105	10
granivorous mammal, metabolite		5.24	954	10
small herbivorous mammal*, a.i.		83.4	17.4	10
small herbiv. mammal*, metab.		31.7	158	10
granivorous mammal, a.i.	Long-term	4.54	<b>3.8</b>	5
granivorous mammal, metabolite		1.73	58	5
small herbivorous mammal*, a.i.		14.2	<b>1.2</b>	5
small herbiv. mammal*, metab.		5.39	19	5
medium herbivorous mammal*, a.i.		2.86	6.1	5
medium herbiv. mammal*, metab.		1.09	92	5
fish-eating mammal, a.i.		0.029	604	5
earthworm-eating mammal, a.i.		0.076	229	5
exposure via drinking water		<<0.001	>200000	5
<b>Higher tier refinement (Mammals)</b>				
granivorous mammal, a.i.	Long-term	2.57	6.7	5
small herbivorous mammal*, a.i.		0.17	102	5
medium herbivorous mammal*, a.i.		0.034	509	5

\* in higher tier refinement a medium sized herbivore was used, since small herbivorous mammals (default used in the first tier assessment) would avoid open areas with no or little vegetation cover.

**Pome fruit, 4 applications of 75 g as/ha, 7 days interval (Southern EU), covers also pome fruit, 4 applications of 56.25 g as/ha, 7 days interval (Northern EU).**

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
<b>Tier 1 (Birds)</b>				
insectivorous bird	Acute	4.06	493	10
insectivorous bird	Short-term	2.26	154	10
insectivorous bird	Long-term	2.26	<b>4.3</b>	5
fish-eating bird, a.i.		0.29	25	5
earthworm-eating bird, a.i.		0.46	20	5
exposure via drinking water		0.022	442	5
<b>Higher tier refinement (Birds)</b>				
insectivorous bird*	Long-term	1.38	7.1	5
<b>Tier 1 (Mammals)</b>				
herbivorous mammal, a.i.	Acute	9.57	152	10
herbivorous mammal, metabolite		3.64	1374	10
herbivorous mammal, a.i.	Long-term	8.33	<b>2.1</b>	5
herbivorous mammal, metabolite		3.17	32	5
fish-eating mammal, a.i.		0.18	98	5
earthworm-eating mammal, a.i.		0.64	27	5
exposure via drinking water		<0.01	>5000	5
<b>Tier 2 refinement (Mammals)</b>				
herbivorous mammal, a.i. (Southern EU, 4x75 g as/ha)**	Long-term	4.89	<b>3.5</b>	5
<b>Tier 3 refinement (Mammals)</b>				
herbivorous mammal, a.i. (Southern EU, 4x75 g as/ha)***	Long-term	2.89	6.0	5

\*refinement for insectivorous birds based on PT 0.61.

\*\*refinement for mammals based on interception values from FOCUSgw.

\*\*\*refinement for mammals based on interception values from FOCUSgw and diet composition data for field vole.

**Carrots, 3 applications of 125 g as/ha, 14 days interval**

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
<b>Tier 1 (Birds)</b>				
medium sized herbiv. bird, a.i.	Acute	10.7	>186	10
medium sized herbiv. bird, metab.		4.08	>490	10
insectivorous bird		6.76	>296	10
medium sized herbiv. bird, a.i.	Short-term	5.70	61	10
medium sized herbiv. bird, metab.		2.17	>618	10
insectivorous bird		3.77	93	10
medium sized herbiv. bird, a.i.	Long-term	3.65	<b>2.7</b>	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Indicator species/Category <sup>2</sup>	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger <sup>3</sup>
medium sized herbiv. bird, metab.		1.15	8.5	5
insectivorous bird		3.77	2.6	5
fish-eating bird, a.i.		0.18	53	5
earthworm-eating bird, a.i.		0.33	30	5
exposure via drinking water		<0.02	>400	5
<b>Higher tier refinement (Birds)</b>				
medium sized herbiv. bird, a.i.*	Long-term	1.47	6.6	5
insectivorous bird*		1.88	5.2	5
<b>Tier 1 (Mammals)</b>				
herbivorous mammal, a.i.	Acute	3.96	367	10
herbivorous mammal, metabolite		1.50	3333	10
herbivorous mammal, a.i.	Long-term	1.2	14	5
herbivorous mammal, metabolite		0.46	217	5
fish-eating mammal, a.i.		0.11	152	5
earthworm-eating mammal, a.i.		0.44	39	5
exposure via drinking water		<0.01	>5000	5

\*refinement for birds based on PT 0.5.

## Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup> (mg as/L)
<b>Laboratory tests ‡</b>				
<b>Fish</b>				
Rainbow trout	difenoconazole	96 hr (flow-through)	Mortality, EC <sub>50</sub>	1.1 (0.98-1.1)
Fathead minnow	difenoconazole	34 d (flow-through)	Larval weight NOEC	<b>0.0076</b>
Rainbow trout	DIVIDEND 030FS	96 hr (static)	Mortality, EC <sub>50</sub>	0.70 (0.43 – 1.2)
Rainbow trout	SCORE 250EC	96 hr (static)	Mortality, EC <sub>50</sub>	<b>0.65</b> (0.56 – 1.1)
Rainbow trout	SCORE 250EC	21 d (semi-static)	Growth NOEC	0.15 (mm)
Rainbow trout	Metab. CGA 71019	96 hr (static)	Mortality, EC <sub>50</sub>	498 (378 – 657)
Rainbow trout	CGA 205375	96 hr (static)	Mortality, EC <sub>50</sub>	0.74 (0.58 – 0.95)
Rainbow trout	CGA 71019	28 d (static-renewal)	Behaviour effects, NOEC	3.2
<b>Aquatic invertebrate</b>				
Daphnia magna.	difenoconazole	48 h (static)	Mortality, EC <sub>50</sub>	0.77 (0.59 – 0.95)
Mysidopsis bahia	difenoconazole	96 h (flow-through)	Mortality, EC <sub>50</sub>	<b>0.15</b> (0.11 – 0.22)
Crassostrea virginica	difenoconazole	96 h (flow-through)	Shell deposition, EC <sub>50</sub>	>0.30
Daphnia magna.	difenoconazole	21 d (flow-through)	Reproduction, NOEC	<b>0.0056</b> (mm)
Daphnia magna.	DIVIDEND 030FS	48 h (static)	Mortality, EC <sub>50</sub>	0.43 (0.3 – 0.6)
	SCORE 250EC	48 h (static)	Mortality, EC <sub>50</sub>	0.62 – 1.38
Daphnia magna	Metab. CGA 71019	48 h (static)	Mortality, EC <sub>50</sub>	>100
Daphnia magna.	CGA 205375	48 h (static)	Mortality, EC <sub>50</sub>	1.4 (1.2 – 1.7)
<b>Sediment dwelling organisms</b>				
Chironomus riparius	difenoconazole	28 d (static)	NOEC via water	0.015
Chironomus riparius	SCORE 250EC	28 d (static)	NOEC via water	0.075
Chironomus riparius	CGA 205375	28 d (static)	NOEC via water	0.4
Chironomus riparius	CGA 205375	28 d (static)	NOEC via sediment	10 mg/kg dw
<b>Algae</b>				
Scenedesmus subspicatus	difenoconazole	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub>	0.032 (0.026 – 0.039)
Pseudokirchneriella subspicata	DIVIDEND 030FS	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	1.8 (1.3 – 2.6) >3.0 (2-8 - >3.0)
Scenedesmus subspicatus	SCORE 250EC	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	0.29 (0.22 – 0.60) 0.96 (0.62 – 1.75)
Selenastrum capricornutum	Metab. CGA 71019	96 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	13 (11 – 15) >31

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup> (mg as/L)
<i>Selenastrum capricornutum</i>	CGA 205375	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	1.2 (1.2 – 1.3) 3.1 (3.0 – 3.2)
<b>Higher plant</b>				
No reliable data, not required.				
<b>Microcosm or mesocosm tests</b>				
Not required.				

<sup>1</sup> indicate whether based on nominal (<sub>nom</sub>) or mean measured concentrations (<sub>mm</sub>). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

## Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

## FOCUS Step1

## Seed treatment to cereals, 60 mg/kg seed

Test substance	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub>	TER	Annex VI Trigger <sup>1</sup>
SCORE 250EC	Rainbow trout	0.65	Acute	0.00069	942	100
difenoconazole	Fathead minnow (ELS)	0.0076	Chronic	0.00069	11	10
difenoconazole	<i>Mysidopsis bahia</i>	0.15	Acute	0.00069	217	100
difenoconazole	<i>Daphnia magna</i>	0.0056	Chronic	0.00069	<b>8.1</b>	10
difenoconazole	<i>Scenedesmus subspicatus</i>	0.032	Chronic	0.00069	46	10
difenoconazole	<i>Chironomus riparius</i>	0.015 (water)	Chronic	0.00069	22	10
CGA 71019	Rainbow trout	498	Acute	0.00015	3320000	100
CGA 71019	Rainbow trout	3.2	Chronic	0.00015	21333	10
CGA 71019	<i>Daphnia magna</i>	>100	Acute	0.00015	666667	100
CGA 71019	Aquatic invertebrates	-	Chronic	0.00015	-	10
CGA 71019	<i>Pseudokirchneriella subcapitata</i>	13	Chronic	0.00015	86667	10
CGA 205375	Rainbow trout	0.74	Acute	0.000068	10882	100
CGA 205375	Fish	-	Chronic	0.000068	-	10
CGA 205375	<i>Daphnia magna</i>	1.4	Acute	0.000068	20588	100
CGA 205375	<i>Chironomus riparius</i>	0.4 (water)	Chronic	0.000068	5882	10
CGA 205375	<i>Pseudokirchneriella subcapitata</i>	1.2	Chronic	0.000068	17647	10

Pome fruit Southern EU, 4 x 75 g as/ha, 7 days interval between treatments (covers also pome fruit in Northern EU, 4 x 56.25 g as/ha, 7 days interval between treatments).

Test substance	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub>	TER	Annex VI Trigger <sup>1</sup>
SCORE 250EC	Rainbow trout	0.65	Acute	0.032	<b>20</b>	100
difenoconazole	Fathead minnow (ELS)	0.0076	Chronic	0.032	<b>0.2</b>	10
difenoconazole	<i>Mysidopsis bahia</i>	0.15	Acute	0.032	<b>4.7</b>	100
difenoconazole	<i>Daphnia magna</i>	0.0056	Chronic	0.032	<b>0.2</b>	10
difenoconazole	<i>Scenedesmus subspicatus</i>	0.032	Chronic	0.032	<b>1.0</b>	10
difenoconazole	<i>Chironomus riparius</i>	0.015	Chronic	0.032	<b>0.5</b>	10
CGA 71019	Rainbow trout	498	Acute	0.0038	131053	100
CGA 71019	Rainbow trout	3.2	Chronic	0.0038	842	10
CGA 71019	<i>Daphnia magna</i>	>100	Acute	0.0038	26316	100
CGA 71019	Aquatic invertebrates	-	Chronic	0.0038	-	10
CGA 71019	<i>Pseudokirchneriella subcapitata</i>	13	Chronic	0.0038	3421	10
CGA 205375	Rainbow trout	0.74	Acute	0.0032	231	100
CGA 205375	Fish	-	Chronic	0.0032	-	10
CGA 205375	<i>Daphnia magna</i>	1.4	Acute	0.0032	438	100
CGA 205375	<i>Chironomus riparius</i>	0.4	Chronic	0.0032	125	10
CGA 205375	<i>Pseudokirchneriella subcapitata</i>	1.2	Chronic	0.0032	375	10
CGA 205375	Sediment organisms	0.4	Chronic	0.0032	125	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Carrots, 3 x 125 g as/ha, 14 days interval between treatments.

Test substance	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub> (mg/L)	TER	Annex VI Trigger <sup>1</sup>
SCORE 250EC	Rainbow trout	0.65	Acute	0.024	<b>27</b>	100
difenoconazole	Fathead minnow (ELS)	0.0076	Chronic	0.024	<b>0.32</b>	10
difenoconazole	<i>Mysidopsis bahia</i>	0.15	Acute	0.024	<b>6.3</b>	100
difenoconazole	<i>Daphnia magna</i>	0.0056	Chronic	0.024	<b>0.23</b>	10
difenoconazole	<i>Scenedesmus subspicatus</i>	0.032	Chronic	0.024	<b>1.3</b>	10
difenoconazole	<i>Chironomus riparius</i>	0.015	Chronic	0.024	<b>0.63</b>	10
CGA 71019	Rainbow trout	498	Acute	0.0044	113182	100
CGA 71019	Rainbow trout	3.2	Chronic	0.0044	727	10
CGA 71019	<i>Daphnia magna</i>	>100	Acute	0.0044	22727	100
CGA 71019	Aquatic invertebrates	-	Chronic	0.0044	-	10
CGA 71019	<i>Pseudokirchneriella subcapitata</i>	13	Chronic	0.0044	2955	10
CGA 205375	Rainbow trout	0.74	Acute	0.0024	308	100
CGA 205375	Fish	-	Chronic	0.0024	-	10
CGA 205375	<i>Daphnia magna</i>	1.4	Acute	0.0024	583	100
CGA 205375	<i>Chironomus riparius</i>	0.4	Chronic	0.0024	167	10
CGA 205375	<i>Pseudokirchneriella subcapitata</i>	1.2	Chronic	0.0024	500	10
CGA 205375	Sediment organisms	0.4	Chronic	0.0024	167	10

## FOCUS Step 2

Seed treatment of wheat, 60 mg as/kg seed, autumn, Northern Europe (worst case, covers also spring application in Northern and Southern EU).

Test substance	N/S	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub> (mg/L)	TER	Annex VI Trigger <sup>1</sup>
difenoconazole	N	<i>Daphnia magna</i>	0.0056	Chronic	0.00034	16	10

Pome fruit Southern EU, 4 x 75 g as/ha, 7 days interval between treatments (covers also pome fruit in Northern EU, 4 x 56.25 g as/ha, 7 days interval between treatments).

Test substance	N/S	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub> (mg/L)	TER	Annex VI Trigger <sup>1</sup>
SCORE 250EC	S	Rainbow trout	0.65	Acute	0.0042	155	100
difenoconazole	S	Fathead minnow (ELS)	0.0076	Chronic	0.0042	<b>1.8</b>	10
difenoconazole	S	<i>Mysidopsis bahia</i>	0.15	Acute	0.0042	<b>36</b>	100
difenoconazole	S	<i>Daphnia magna</i>	0.0056	Chronic	0.0042	<b>1.3</b>	10
difenoconazole	S	<i>Scenedesmus subspicatus</i>	0.032	Chronic	0.0042	<b>7.6</b>	10
difenoconazole	S	<i>Chironomus riparius</i>	0.015	Chronic	0.0042	<b>3.6</b>	10

Carrots, 3 x 125 g as/ha, 14 days interval between treatments.

Test substance	N/S	Organism	Toxicity end point (mg as/L)	Time scale	PEC <sub>i</sub> (mg/L)	TER	Annex VI Trigger <sup>1</sup>
SCORE 250EC	S	Rainbow trout	0.65	Acute	0.0027	241	100
difenoconazole	S	Fathead minnow (ELS)	0.0076	Chronic	0.0027	<b>2.8</b>	10
difenoconazole	S	<i>Mysidopsis bahia</i>	0.15	Acute	0.0027	<b>56</b>	100
difenoconazole	S	<i>Daphnia magna</i>	0.0056	Chronic	0.0027	<b>2.1</b>	10
difenoconazole	S	<i>Scenedesmus subspicatus</i>	0.032	Chronic	0.0027	12	10
difenoconazole	S	<i>Chironomus riparius</i>	0.015	Chronic	0.0027	<b>5.6</b>	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Refined aquatic risk assessment using higher tier FOCUS modelling.

### FOCUS Step 3

Pome fruit Southern EU, 4 x 75 g as/ha, 7 days interval between treatments (covers also pome fruit in Northern EU, 4 x 56.25 g as/ha, 7 days interval between treatments).

Test substance	Scenario <sup>1</sup>	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC <sub>sw</sub> global max. (mg/L)	TER	Annex VI trigger
difenoconazole	D3	ditch	<i>Daphnia magna</i>	chronic	0.0056	0.00179	<b>3.1</b>	10
difenoconazole	D4	pond	<i>Daphnia magna</i>	chronic	0.0056	0.000241	<b>23</b>	10
difenoconazole	D4	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00168	<b>3.3</b>	10
difenoconazole	D5	pond	<i>Daphnia magna</i>	chronic	0.0056	0.000240	<b>23</b>	10
difenoconazole	D5	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00181	<b>3.1</b>	10
difenoconazole	R1	pond	<i>Daphnia magna</i>	chronic	0.0056	0.000227	<b>25</b>	10
difenoconazole	R1	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00137	<b>4.1</b>	10
difenoconazole	R2	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00182	<b>3.1</b>	10
difenoconazole	R3	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00194	<b>2.9</b>	10
difenoconazole	R4	stream	<i>Daphnia magna</i>	chronic	0.0056	0.00138	<b>4.1</b>	10

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

Carrots, 3 x 125 g as/ha, 14 days interval between treatments.

Test substance	Scenario <sup>1</sup>	Water body type	Test organism	Time scale	Toxicity end point (mg as/L)	PEC <sub>sw</sub> global max. (mg/L)	TER	Annex VI trigger
difenoconazole	D3	ditch	<i>Daphnia magna</i>	chronic	0.0056	0.000573	<b>9.8</b>	10
difenoconazole	D6	ditch	<i>Daphnia magna</i>	chronic	0.0056	0.000570	<b>9.8</b>	10
difenoconazole	R1	pond	<i>Daphnia magna</i>	chronic	0.0056	0.000082	<b>68</b>	10
difenoconazole	R1	stream	<i>Daphnia magna</i>	chronic	0.0056	0.000376	<b>15</b>	10
difenoconazole	R2	stream	<i>Daphnia magna</i>	chronic	0.0056	0.000504	<b>11</b>	10
difenoconazole	R3	stream	<i>Daphnia magna</i>	chronic	0.0056	0.000530	<b>11</b>	10
difenoconazole	R4	stream	<i>Daphnia magna</i>	chronic	0.0056	0.000713	<b>7.9</b>	10

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

### FOCUS Step 4

Pome fruit Southern EU, 4 x 75 g as/ha, 7 days interval between treatments (covers also pome fruit in Northern EU, 4 x 56.25 g as/ha, 7 days interval between treatments).

Scenario <sup>1</sup>	Water body type	Test organism	Time scale	Toxicity end point (mg as/L)	Buffer zone distance	PEC <sub>sw</sub> global max (mg/L)	TER	Annex VI trigger
D3	ditch	<i>Daphnia magna</i>	long term	5.6	14	0.326	17	10
D3	ditch	<i>Daphnia magna</i>	long term	5.6	20	0.325	17	10
D4	pond	<i>Daphnia magna</i>	long term	5.6	14	0.101	55	10
D4	pond	<i>Daphnia magna</i>	long term	5.6	20	0.064	88	10
D4	stream	<i>Daphnia magna</i>	long term	5.6	14	0.351	16	10
D4	stream	<i>Daphnia magna</i>	long term	5.6	20	0.183	31	10
D5	pond	<i>Daphnia magna</i>	long term	5.6	14	0.101	55	10
D5	pond	<i>Daphnia magna</i>	long term	5.6	20	0.064	88	10
D5	stream	<i>Daphnia magna</i>	long term	5.6	14	0.378	15	10
D5	stream	<i>Daphnia magna</i>	long term	5.6	20	0.197	28	10
R1	pond	<i>Daphnia magna</i>	long	5.6	14	0.095	59	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Scenario <sup>1</sup>	Water body type	Test organism	Time scale	Toxicity end point (mg as/L)	Buffer zone distance	PEC <sub>sw</sub> global max (mg/L)	TER	Annex VI trigger
			term					
R1	pond	<i>Daphnia magna</i>	long term	5.6	20	0.067	84	10
R1	stream	<i>Daphnia magna</i>	long term	5.6	14	0.287	20	10
R1	stream	<i>Daphnia magna</i>	long term	5.6	20	0.230	24	10
R2	stream	<i>Daphnia magna</i>	long term	5.6	14	0.381	15	10
R2	stream	<i>Daphnia magna</i>	long term	5.6	20	0.198	28	10
R3	stream	<i>Daphnia magna</i>	long term	5.6	14	0.407	14	10
R3	stream	<i>Daphnia magna</i>	long term	5.6	20	0.292	19	10
R4	stream	<i>Daphnia magna</i>	long term	5.6	14	0.444	13	10
R4	stream	<i>Daphnia magna</i>	long term	5.6	20	0.444	13	10

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

## Carrots, 3 x 125 g as/ha, 14 days interval between treatments.

Scenario <sup>1</sup>	Water body type	Test organism	Time scale	Toxicity end point (mg as/L)	Buffer zone distance	PEC global max (mg/L)	TER	Annex VI trigger
D3	ditch	<i>Daphnia magna</i>	long term	5.6	5	0.151	37	10
D6	ditch	<i>Daphnia magna</i>	long term	5.6	5	0.150	37	10
R1	pond	<i>Daphnia magna</i>	long term	5.6	5	0.044	127	10
R1	stream	<i>Daphnia magna</i>	long term	5.6	5	0.162	35	10
R2	stream	<i>Daphnia magna</i>	long term	5.6	5	0.180	31	10
R3	stream	<i>Daphnia magna</i>	long term	5.6	5	0.206	27	10
R4	stream	<i>Daphnia magna</i>	long term	5.6	5	0.392	14	10

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

Bioconcentration			
	Active substance	Metabolite CGA 205375	Metabolite CGA 71019
logP <sub>ow</sub>	4.36	3.8	-1
Bioconcentration factor (BCF) ‡	330*	no data, not needed	-
Annex VI Trigger for the bioconcentration factor			
Clearance time (days) (CT <sub>50</sub> )	1 day	-	-
(CT <sub>90</sub> )	ca 3 days	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	not relevant	-	-

\* based on total <sup>14</sup>C

## Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD <sub>50</sub> µg as/bee)	Acute contact toxicity (LD <sub>50</sub> µg as/bee)
difenoconazole ‡	>177	>100

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

# List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Test substance	Acute oral toxicity (LD <sub>50</sub> µg as/bee)	Acute contact toxicity (LD <sub>50</sub> µg as/bee)
<b>Field or semi-field tests</b>		
No significant effects on bee mortality, foraging behaviour, flight activity or brood health in semi-field study with the formulation SCORE 250EC.		

## Hazard quotients for honey bees (Annex IIIA, point 10.4)

Seed treatment of 60 mg as/kg seed, corresponding to 12.3 g as/ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
difenoconazole	Contact	not relevant	50
difenoconazole	oral	0.069	50
Preparation	Contact	not relevant	50
Preparation	oral	not relevant	50

## Spray application to pome fruit, 75 g as/ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
difenoconazole	Contact	0.75	50
difenoconazole	oral	0.42	50
Preparation	Contact	not relevant	50
Preparation	oral	not relevant	50

## Spray application to carrots, 125 g as/ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
difenoconazole	Contact	1.25	50
difenoconazole	oral	0.71	50
Preparation	Contact	not relevant	50
Preparation	oral	not relevant	50

## Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR <sub>50</sub> g as/ha)
<i>Typhlodromus pyri</i> ‡	difenoconazole	Mortality	178
<i>Aphidius rhopalosiphi</i> ‡	difenoconazole	Mortality	112

## Seed treatment of 60 mg as/kg seed, corresponding to 12.3 g as/ha.

Test substance	Species	Effect (LR <sub>50</sub> g as/ha)	HQ in-field	HQ off-field	Trigger
SCORE 250EC	<i>Typhlodromus pyri</i>	178	0.069	not relevant	2
SCORE 250EC	<i>Aphidius rhopalosiphi</i>	112	0.11	not relevant	2

## Spray application to pome fruit, 4 x 75 g as/ha, 7 days interval.

Test substance	Species	Effect (LR <sub>50</sub> g as/ha)	HQ in-field (foliar/soil)	HQ off-field <sup>1</sup> (foliar)	Trigger
SCORE 250EC	<i>Typhlodromus pyri</i>	178	1.49/0.91	0.15	2
SCORE 250EC	<i>Aphidius rhopalosiphi</i>	112	0.94/0.57	0.094	2

<sup>1</sup> distance assumed to be 3 m in calculation of the drift rate

## Spray application to carrots, 3 x 125 g as/ha, 14 days interval.

Test substance	Species	Effect (LR <sub>50</sub> g as/ha)	HQ in-field (foliar/soil)	HQ off-field <sup>1</sup> (foliar)	Trigger
SCORE 250EC	<i>Typhlodromus pyri</i>	178	1.7/0.64	0.028	2
SCORE 250EC	<i>Aphidius rhopalosiphi</i>	112	1.1/0.40	0.020	2

<sup>1</sup> distance assumed to be 1 m in calculation of the drift rate

## Further laboratory and extended laboratory studies ‡

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) <sup>1,2</sup>	End point	Effect <sup>3</sup>	Trigger value
<i>Aleochara bilineata</i>	adults	DIVIDEND 030FS, treated seeds in moistened sand	23.2 g ai/ha (60 mg as/kg seed and seed density of 379 kg/ha)	LR <sub>50</sub>	>23.2 g as/ha	50% effect
<i>Poecilus cupreus</i>	adults	DIVIDEND 030FS, treated seeds in moistened sand	18.8 g ai/ha (60 mg as/kg seed and seed density of 307 kg/ha)	LR <sub>50</sub>	>18.8 g as/ha	50% effect
<i>Poecilus cupreus</i>	larvae	DIVIDEND 030FS, treated seeds in moistened sand	56.4 g ai/ha (60 mg/kg seed and seed density of 937 kg/ha)	LR <sub>50</sub>	>56.4 g as/ha	50% effect
<i>Aphidius rhopalosiphi</i>	juveniles	SCORE 250EC, fresh residues on glass plates.	5, 127, 253	ER <sub>50</sub>	127 - 253 g as/ha	50% effect
<i>Typhlodromus pyri</i>	proto-nymphs	SCORE 250EC, fresh residues on glass plates.	5, 127, 253	ER <sub>50</sub>	127 - 253 g as/ha	50% effect
<i>Chrysoperla carnea</i>	larvae	SCORE 250EC, fresh residues on glass plates	4, 100, 200	ER <sub>50</sub>	>200 g as/ha	50% effect
<i>Pardosa spp.</i>	adults	SCORE 250EC, direct spray over adults, food and substrate (sand).	4, 100, 200	ER <sub>50</sub>	>200 g as/ha	50% effect
<i>Poecilus cupreus</i>	adults	SCORE 250EC, direct spray over adults, food and substrate (sand).	6, 30, 150, 300	ER <sub>50</sub>	>300 g as/ha	50% effect
<i>Typhlodromus pyri</i>	proto-nymphs	SCORE 250EC, fresh residues on bean leaves	6, 30, 150, 300	ER <sub>50</sub>	152 - 303 g as/ha	50% effect
<i>Chrysoperla carnea</i>	larvae	SCORE 250EC, fresh residues on bean leaves	14, 28, 75, 125, 202, 288	ER <sub>50</sub>	>288 g as/ha	50% effect
<i>Orius laevigatus</i>	nymphs	SCORE 250EC, fresh residues on maize plants	6, 30, 150, 300	ER <sub>50</sub>	>300 g as/ha	50% effect
<i>Aphidius rhopalosiphi</i>	adults	SCORE 250EC, fresh and 14-day old residues on broad beans.	75, 125, 288	ER <sub>50</sub>	>288 g as/ha	50% effect
<i>Trichogramma cacoeciae</i>	adults	SCORE 250EC, fresh and 14-day old residues on broad beans.	15, 75, 125, 288	ER <sub>50</sub>	>288 g as/ha	50% effect
<i>Coccinella septempunctata</i>	larvae	SCORE 250EC, fresh and 14-day aged residues on broad beans.	4 appl. of 125 g ai/ha at 14-day intervals	ER <sub>50</sub>	>4 x 125 g as/ha	50% effect

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) <sup>1,2</sup>	End point	Effect <sup>3</sup>	Trigger value
<i>Episyrphus balteatus</i>	larvae	SCORE 250EC, 14-day aged residues on broad beans.	15, 75, 125, 288	ER <sub>50</sub>	>288 g as/ha for aged residues based on mortality. Results from fresh residues not reliable due to high control mortality.	50% effect
<i>Episyrphus balteatus</i>	larvae	SCORE 250EC, fresh residues on broad beans.	288	Number of viable eggs per female. Aged residues not tested for reproduction. Potential for recovery considered likely.	62% effect when an outlier was excluded.	50% effect

<sup>1</sup> indicate whether initial or aged residues<sup>3</sup> indicate if positive percentages relate to adverse effects or not

## Field or semi-field tests

SCORE 250EC, field study on predatory mites in apple orchards in Italy. 4 applications of 79.5 g as/ha at intervals of 10 or 11 days. No significant effect on population density of predatory mites up to 28 days after the last application, except for an increased population on day 28 after the last application.

SCORE 250EC, field study on predatory mites in apple orchards in Germany. 4 applications of 59.6 g as/ha at intervals of 9 or 12 days. No significant effect on population density of predatory mites up to 28 days after the last application.

## Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point <sup>1</sup>
<b>Earthworms</b>			
<i>Eisenia foetida</i>	difenoconazole ‡	Acute 14 days	LC <sub>50</sub> >610 mg a.s./kg dw soil
<i>Eisenia foetida</i>	difenoconazole ‡	Chronic	no reliable data, assessment based on representative formulation studies
<i>Eisenia foetida</i>	DIVIDEND 030FS	Chronic 56 days, reproduction	NOEC <b>0.2</b> mg a.s./kg dw soil
<i>Eisenia foetida</i>	SCORE 250EC	Acute	LC <sub>50</sub> <b>40</b> (36 – 44) mg a.s./kg dw soil (mg a.s./ha)
<i>Eisenia foetida</i>	SCORE 250EC	Chronic 56 days, reproduction	NOEC 1.7 mg a.s./kg dw soil (<0.17 mg a.s./kg dw soil based on body weight gain, to be discussed).
<i>Eisenia foetida</i>	Metabolite CGA 71019	Acute	LC <sub>50</sub> > <b>1000</b> mg a.s./kg dw soil
<i>Eisenia foetida</i>	Metabolite CGA 71019	Chronic 28 days, reproduction	NOEC <b>0.0708</b> mg a.s./kg dw soil
<i>Eisenia foetida</i>	Metabolite CGA 205375	Acute	LC <sub>50</sub> <b>312</b> (284 – 343) mg a.s./kg dw soil
<b>Other soil macro-organisms</b>			
<b>Collembola</b>			
<i>Folsomia candida</i>	difenoconazole ‡	Chronic 28 days	NOEC <b>500</b> mg a.s./kg dw soil
	Metabolite CGA 71019	Chronic 28 days	NOEC <b>1.8</b> mg a.s./kg dw soil
<b>Soil micro-organisms</b>			
Nitrogen mineralisation	difenoconazole ‡	28 days	<25% effect at day 28 at 1.67 and 16.7 mg a.s./kg dw soil in silty loam, 60% increase in loamy sand
	Metabolite CGA 71019	28 days	<25% effect at day 28 at 0.035 and 0.353 mg a.s./kg dw soil

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

Test organism	Test substance	Time scale	End point <sup>1</sup>
	Metabolite CGA 205375	28 days	<25% effect at day 28 at 0.09 and 0.22 mg a.s./kg dw soil
	SCORE 250EC	28 days	<25% effect at day 28 at 0.33 and 1.67 mg a.s./kg dw soil
Carbon mineralisation	difenoconazole ‡	28 days	<25% effect at day 28 at 1.67 and 16.7 mg a.s./kg dw soil
	Metabolite CGA 71019	28 days	<25% effect at day 28 at 0.035 and 0.353 mg a.s./kg dw soil
	Metabolite CGA 205375	28 days	<25% effect at day 28 at 0.09 and 0.22 mg a.s./kg dw soil
	SCORE 250EC	28 days	<25% effect at day 28 at 0.33 and 1.67 mg a.s./kg dw soil
<b>Single species tests</b>			
<i>Marasmius oraeae</i>	difenoconazole	6 days	NOEC 1.64 mg as/kg
<i>Mucor circinelloides</i>	difenoconazole	3 days	NOEC 4.9 mg as/kg
<i>Paecilomyces marquandii</i>	difenoconazole	17 days	NOEC 16.4 mg as/kg
<i>Phytophthora nicotianae</i>	difenoconazole	17 days	NOEC 16.4 mg as/kg

Field studies<sup>2</sup>

In a litter bag study with SCORE 250EC, a 17% reduction in decomposition rate was observed at direct overspray of 506 g as/ha compared to the control after 168 days. Exposure conditions considered as worst case compared to the representative use of difenoconazole in carrots, pome fruit and as seed treatment.

<sup>1</sup> The values are not corrected due to log Pow >2.0 (e.g. LC<sub>50corr</sub>)

<sup>2</sup> litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

\*not fully reliable

## Toxicity/exposure ratios for soil organisms

Seed treatment of 60 mg as/kg seed, corresponding to 12.3 g as/ha.

Test organism	Test substance	Time scale	Soil PEC (mg as/kg dw, initial)	TER	Trigger
<b>Earthworms</b>					
	difenoconazole ‡	Acute	0.016	>19000	10
	difenoconazole ‡	Chronic	0.016	no data	5
	DIVIDEND 030FS	Chronic	0.016	6.3	5
	Metab. CGA 71019	Acute	0.0006	>770000	10
	Metab. CGA 71019	Chronic	0.0006	54	5
	Metab. CGA 205375	Acute	0.0014	111000	10
	Metab. CGA 205375	Chronic	0.0014	no data	5
<b>Other soil macro-organisms</b>					
<b>Collembola</b>	difenoconazole ‡	Chronic	0.016	31200	5
	CGA 71019	Chronic	0.0006	3000	5
	CGA 205375	Chronic	0.0014	no data	5

Pome fruit Southern EU, 4 x 75 g as/ha, 7 days interval between treatments (covers also pome fruit in Northern EU, 4 x 56.25 g as/ha, 7 days interval between treatments).

Test organism	Test substance	Time scale	Soil PEC (mg as/kg dw, initial)	TER	Trigger
<b>Earthworms</b>					
	difenoconazole ‡	Acute	0.136	147	10
	difenoconazole ‡	Chronic	0.136	no data	5
	SCORE 250EC	Acute	0.136	147	10
	SCORE 250EC	Chronic	0.136	6.3	5
	Metab. CGA 71019	Acute	0.005	190000	10
	Metab. CGA 71019	Chronic	0.005	14	5
	Metab. CGA 205375	Acute	0.012	13000	10
	Metab. CGA 205375	Chronic	0.012	no data	5
<b>Other soil macro-organisms</b>					
<b>Collembola</b>	difenoconazole ‡	Chronic	0.136	3700	5
	CGA 71019	Chronic	0.005	360	5
	CGA 205375	Chronic	0.012	no data	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

## Ecotoxicology

\*lowest NOEC was used in the absence of chronic data on the active ingredient

## Carrots, 3 x 125 g as/ha, 14 days interval between treatments.

Test organism	Test substance	Time scale	Soil PEC (mg as/kg dw, initial)	TER	Trigger
<b>Earthworms</b>					
	difenoconazole ‡	Acute	0.096	208	10
	difenoconazole ‡	Chronic	0.096	1.0	5
	SCORE 250EC	Acute	0.096	208	10
	SCORE 250EC	Chronic	0.096	8.9	5
	Metab. CGA 71019	Acute	0.004	260000	10
	Metab. CGA 71019	Chronic	0.004	18	5
	Metab. CGA 205375	Acute	0.008	19000	10
	Metab. CGA 205375	Chronic	0.008	no data	5
<b>Other soil macro-organisms</b>					
<b>Collembola</b>	difenoconazole ‡	Chronic	0.096	5200	5
	CGA 71019	Chronic	0.004	450	5
	CGA 205375	Chronic	0.012	no data	5

## Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

## Preliminary screening data

Not available.
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## Laboratory dose response tests

Most sensitive species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) emergence	Exposure <sup>1</sup> (g as/ha)	TER	Trigger
<i>Avena sativa</i> , <i>Brassica napus</i> , <i>Glycine maxima</i>	difenoconazole	>10 mg as/kg dw soil (incorporation)	>10 mg as/kg dw soil (incorporation)	not relevant	not relevant	5
<i>Glycine maxima</i>	SCORE 250EC	>100 g as/ha, (spray application)	100 g as/ha, (spray application)	12 (pome fruit) 3.5 (carrots)	8.1 (pome fruit) 28 (carrots)	5

<sup>1</sup> exposure has been estimated for spray applications based on Ganzelmeier drift data at 1 m distance for carrots, 3 m distance for pome fruit. Multiple applications were taken into account. For seed treatment, off-field exposure not relevant.

## Additional studies (e.g. semi-field or field studies)

Not required.
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## Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge, 3 hours exposure	NOEC 32 mg/L, EC <sub>50</sub> >100 mg/L

## Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Parent (difenoconazole), CGA 205375 (pending new studies on soil organisms)
water	Parent (difenoconazole)
sediment	Parent (difenoconazole)
groundwater	None

## Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance

## RMS/peer review proposal

R50/53

DIVIDEND 030FS

## RMS/peer review proposal

R52/53

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

**List of end points**

Rapporteur Member State	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

**Ecotoxicology**

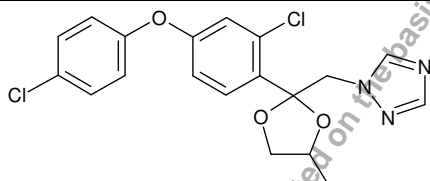
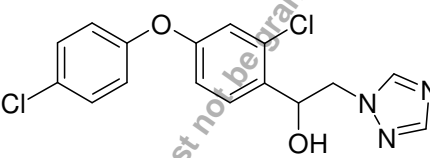
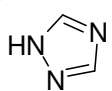
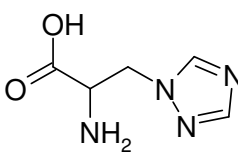
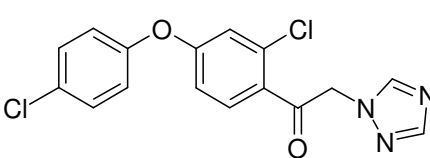
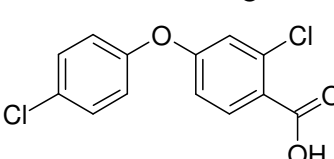
SCORE 250EC

<b>RMS/peer review proposal</b>
R50/53

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of end points	Month and year	Active Substance (Name)
Sweden	May 2006 Updated December 2006	Difenoconazole

# Appendix 1– Used compound code(s) in the list of end points

CODE/TRIVIAL NAME	CHEMICAL NAME	STRUCTURAL FORMULA
DIFENOCONAZOLE	1-[2-[2-CHLORO-4-(4-CHLORO-PHENOXY)-PHENYL]-4-METHYL[1,3]DIOXOLAN-2-YLMETHYL]-1H-[1,2,4] TRIAZOLE	
CGA 205375	1-[2-[2-CHLORO-4-(4-CHLORO-PHENOXY)-PHENYL]-2-1H-[1,2,4]TRIAZOL-YL]-ETHANOL	
CGA 71019	1H-1,2,4-TRIAZOLE	
CGA 131013 TRIAZOLYL ALANINE	2-AMINO-3- [1,2,4] TRIAZOL-1-YL-PROPIONIC ACID	
CGA-205374	1-[2-CHLORO-4-(4-CHLORO-PHENOXY)-PHENYL]-2-[1,2,4]TRIAZOL-1-YL-ETHANONE	
CGA-189138	2-CHLORO-4-(4-CHLORO-PHENOXY)-BENZOIC ACID	
TRIAZOLE LACTIC ACID CGA 205369	[1,2,4]TRIAZOL-1-YL-LACTIC ACID	