CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2

Substance Name: Tebuconazole

EC Number: **403-640-2**

CAS Number: **107534-96-3**

Index Number: **603-197-00-7**

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Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1 Substance identity

Substance name:	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-l-ylmethyl)pentan-3-ol
EC number:	403-640-2
CAS number:	107534-96-3
Annex VI Index number:	603-197-00-7
Degree of purity:	≥ 950 g/kg
Impurities:	No (Eco)toxicological relevant impurities are present.

1.2 Harmonised classification and labelling proposal

Table 2 The current Annex VI entry and the proposed harmonised classification

	CLP Regulation	**Directive 67/548/EEC (DSD)**
Current entry in Annex VI, CLP Regulation	Repr. 2 (H361d***) Acute Tox. 4* (H302) Aquatic Chronic 2 (H411)	Repr. Cat. 3; R63 Xn; R22 N; R51/53
Current proposal for consideration by RAC	Removal of (*) from Acute Tox 4 Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) M-factor: Acute M-factor of 1 Chronic M-factor of 10	 N; R50/53 SCL: $C_n \geq 25\%$: N; R50-53 $2,5\% \leq C_n < 25\%$: N; R51-53 $0,25\% \leq C_n < 2,5\%$: R52-53
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Repr. 2 (H361d***) Acute Tox. 4 (H302) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) M-factor Acute M-factor 1 Chronic M-factor 10	Repr. Cat. 3; R63 Xn; R22 N; R50/53 SCL: $C_n \geq 25\%$: N; R50-53 $2,5\% \leq C_n < 25\%$: N; R51-53

		0,25% ≤ C_n < 2,5%: R52-53

*Minimum classification; Cn = is the concentration of tebuconazole in a mixture.

1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or DSD criteria

A review of the available aquatic toxicity data for tebuconazole has revealed that the classification listed in Annex VI of Regulation EC no.1272/2008 (including the 1st ATP) is not in agreement with the data. This proposal seeks to amend the current aquatic environment classification and labelling of tebuconazole. In addition, we propose an update regarding the acute toxicity classification listed in Annex VI, part 3, Table 3.1, for tebuconazole

Pursuant to Commission Regulation (EC) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, both acute and chronic M-factors are derived.

According to Directive 67/548/EEC and Directive 1999/45/EC as amended by Directive 2006/8 no distinction between acute and chronic SCLs can be made since only acute aquatic toxicity data are allowed for deriving classifications and SCLs. Therefore, only one set of SCL are proposed for tebuconazole according to DSD criteria.

Table 3 Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives				conclusive but not sufficient for classification
2.2.	Flammable gases				conclusive but not sufficient for classification
2.3.	Flammable aerosols				conclusive but not sufficient for classification
2.4.	Oxidising gases				conclusive but not sufficient for classification
2.5.	Gases under pressure				conclusive but not sufficient for classification
2.6.	Flammable liquids				conclusive but not sufficient for classification
2.7.	Flammable solids				conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures				conclusive but not sufficient for classification
2.9.	Pyrophoric liquids				conclusive but not sufficient for classification
2.10.	Pyrophoric solids				conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures				conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases				conclusive but not sufficient for classification
2.13.	Oxidising liquids				conclusive but not sufficient for classification
2.14.	Oxidising solids				conclusive but not sufficient for classification
2.15.	Organic peroxides				conclusive but not sufficient for classification
2.16.	Substance and mixtures corrosive to metals				conclusive but not sufficient for classification
3.1.	Acute toxicity - oral	Acute Tox. 4 (H302)		Acute Tox. 4* (H302)	
	Acute toxicity - dermal				conclusive but not sufficient for

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
					classification
	Acute toxicity - inhalation				conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation				conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation				conclusive but not sufficient for classification
3.4.	Respiratory sensitisation				conclusive but not sufficient for classification
3.4.	Skin sensitisation				conclusive but not sufficient for classification
3.5.	Germ cell mutagenicity				conclusive but not sufficient for classification
3.6.	Carcinogenicity				conclusive but not sufficient for classification
3.7.	Reproductive toxicity	Repr. 2 (H361d)#		Repr. 2 (H361d)#	
3.8.	Specific target organ toxicity –single exposure				conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure				conclusive but not sufficient for classification
3.10.	Aspiration hazard				conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1	Acute M-factor 1 Chronic M-factor 10	Aquatic Chronic 2	
5.1.	Hazardous to the ozone layer				conclusive but not sufficient for classification

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification
This dossier does not propose a change in the classification of this hazard property

Labelling:

Signal word: Warning

Pictograms: GHS07, GHS08, GHS09

Hazard statements: H361d, Suspected of damaging the unborn child

H302, Harmful if swallowed

H410, Very toxic to aquatic life with long lasting effects

Precautionary statements: No precautionary statements are proposed since precautionary statements are not included in Annex VI of Regulation EC no. 1272/2008.

Proposed notes assigned to an entry:

A note is not proposed.

Table 4 Proposed classification according to DSD

Hazardous property	Proposed classification	Proposed SCLs	Current classification [1)]	Reason for no classification [2)]
Explosiveness				conclusive but not sufficient for classification
Oxidising properties				conclusive but not sufficient for classification
Flammability				conclusive but not sufficient for classification
Other physico-chemical properties				conclusive but not sufficient for classification
Thermal stability				conclusive but not sufficient for classification
Acute toxicity	Xn; R22#		Xn; R22#	
Acute toxicity – irreversible damage after single exposure				conclusive but not sufficient for classification
Repeated dose toxicity				conclusive but not sufficient for classification
Irritation / Corrosion				conclusive but not sufficient for classification
Sensitisation				conclusive but not sufficient for classification
Carcinogenicity				conclusive but not sufficient for classification
Mutagenicity – Genetic toxicity				conclusive but not sufficient for classification
Toxicity to reproduction – fertility				conclusive but not sufficient for classification
Toxicity to reproduction – development	Repr. Cat. 3; R63#		Repr. Cat. 3; R63#	
Toxicity to reproduction – breastfed babies. Effects on or via lactation				conclusive but not sufficient for classification
Environment	N; R50/53	$C_n \geq 25$ %: N; R50-53 2,5 % $\leq C_n <$ 25 %: N; R51-53 0,25 % $\leq C_n <$ 2,5 %: R52-53 Where C_n is the concentration of is tebuconazole.	N; R51/53	

[1)] Including SCLs

[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification
This dossier does not propose a change in the classification of this hazard property

Labelling:	Indication of danger:	Xn; N	Harmful; Dangerous for the environment
	R-phrases:	R22	Harmful if swallowed
		R63	Possible risk to the unborn child
		R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
	S-phrases:	S2	Keep out of the reach of children
		S22	Do not breathe dust
		S36/37	Wear suitable protective clothing and suitable gloves
		S60	This material and its container must be disposed of as hazardous waste
		S61	Avoid release to the environment.

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

Tebuconazole has been assessed as an active biocidal and plant protection substance according to the Directives 98/8/EC (concerning the placing of biocidal products on the market) and 91/414/EEC (concerning the placing of plant protection products on the market) respectively, with Denmark as Rapporteur Member State. In 2008, tebuconazole was included in Annex I to Directive 98/8/EC as entry No 6 as well as in Annex I to Directive 91/414/EEC as entry No 274.

Tebuconazole was added to Annex I of Directive 67/548/EEC in the 29th ATP (Commission Directive 2004/73/EC of 29 April 2004) with classification Repr. Cat. 3;R63, Xn;R22, N;R51/53.

Justification for the classification according to Directive 67/548/EEC (29th ATP)

Toxicological effects:

R22, Lowest LD_{50} found in rats was 1700 mg/kg bw.

R63, Embryotoxic and teratogenic effects seen without marked maternal toxicity.

Environmental effects:

R51/53, The acute aquatic toxicity was observed between 1 and 10 mg/L (lowest acute EC_{50}-values: Fish 4.4 mg/L, Daphnia 2.79 mg/L, algae 3.8 mg/L), tebuconazole is not ready degradable and has an octanol/water partition of 3.7[1].

Tebuconazole is currently listed (entry 603-197-00-7) in Annex VI of Regulation EC no. 1272/2008 with the same classification as was listed in the 29th ATP to Directive 67/548/EEC.

2.2 Short summary of the scientific justification for the CLH proposal

An assessment report is available because of the evaluation of tebuconazole as product-type 8 (Wood Preservatives) carried out in the context of Directive 98/8/EC (CAR: Directive 98/8/EC concerning the placing of biocidal products on the market Assessment report, November 2007, RMS Denmark). However, this CLH dossier presents mainly information presented in the assessment of tebuconazole under Directive 91/414/EEC (Draft Assessment Report (DAR) 2007 and subsequent addendum April 2008, RMS Denmark).

The available data on tebuconazole do not support the current harmonised classification with Aquatic Chronic 2 (R51/53). This dossier proposes to change the classification of tebuconazole to Aquatic Acute 1 and Aquatic Chronic 1 (R50/53) and inclusion of SCLs/M-factors as described in Article 10 of CLP.

According to data presented in the DAR, the lowest oral LD_{50} values found were 1700 mg/kg bw and 1615 mg/kg bw in rats and mice, respectively. Tebuconazole is considered not acutely toxic via dermal and inhalation routes. In accordance with the CLP regulation 1272/2008, tebuconazole should be classified as Acute Chronic 4. The reference indicating minimum classification (*) is no longer necessary.

[1] It is assumed that the LogKow is meant and not the Kow.

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

Table 5 Current Annex VI table 3.1 classification and labelling

Classification		Labelling		
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)
Repr. 2 Acute Tox 4* Aquatic Chronic 2	H361d*** H302 H411	GHS08 GHS07 GHS09 Wng	H361d*** H302 H411	

2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

Table 6 Current Annex VI table 3.2 classification and labelling

Classification	Labelling
Repr. Cat. 3; R63 Xn; R22 N; R51-53	Xn; N R: 22-51/53-63 S: (2-)36/37-61

2.4 Current self-classification and labelling

Not applicable

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

Self-classification notifications for tebuconazole by industry are available in the C&L Inventory database[2]. All notifications classify tebuconazole as Acute Tox. 4; Repr. 2; Aquatic Chronic 2.

2.4.2 Current self-classification and labelling based on DSD criteria

Not applicable

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Tebuconazole was included in Annex I to Directive 98/8/EC as entry No 6 as well as in Annex I to Directive 91/414/EEC as entry No 274. In accordance with article 36 (2) of the CLP regulation, tebuconazole is therefore subject to harmonised classification and labelling.

[2] ECHA website: http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

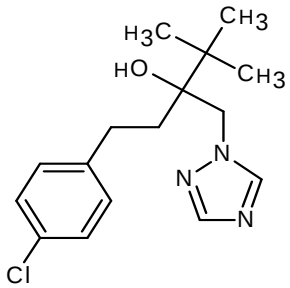
1.1 Name and other identifiers of the substance

Table 7 Substance identity

EC number:	403-640-2
EC name:	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
CAS number (EC inventory):	107534-96-3
CAS number:	107534-96-3
CAS name (CA)*:	1H-1,2,4-Triazole-1-ethanol, α-[2-(4-chlorophenyl)ethyl]- α-(1,1-dimethylethyl)
IUPAC name:	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-l-ylmethyl)pentan-3-ol
CLP Annex VI Index number:	603-197-00-7
Molecular formula:	$C_{16}H_{22}ClN_3O$
Molecular weight range:	3

Tebuconazole as technical grade (material) is in the form of a racemic mixture 1:1.

Structural formula:



1.2 Composition of the substance

Table 8 Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
Tebuconazole	Minimum 950 g/kg	-	-

Current Annex VI entry:

Table 3.1: Repr. 2 (H361d***), Acute Tox 4* (H302), Aquatic Chronic 2 (H411)
Table 3.2: Repr.Cat.3;R63, Xn;R22, N;R51-53

Table 9 Impurities (non-confidential information)

Impurity	Typical concentration	Concentration range	Remarks
			All impurities have been claimed confidential. However, based on the DAR there are no (eco)toxicological relevant impurities present.

Current Annex VI entry:

Table 10 Additives (non-confidential information)

Additive	Function	Typical concentration	Concentration range	Remarks
				Not applicable

Current Annex VI entry:

1.2.1 Composition of test material

1.3 Physico-chemical properties

Table 11 Summary of physico - chemical properties

Property	**Value**	**Comment (e.g. measured or estimated)**	**Reference (Taken from DAR)**
State of the substance at 20°C and 101,3 kPa	Pure: colorless crystalline powder with no characteristic ordour. Purity: 99.5% Technical: white to beige powder with slight characteristic ordour		
Melting/freezing point	105ºC. Purity: 99.9%	measured	Krohn, 1993a
Boiling point	Not measurable, decomposition above 165°C. Purity: 99.5%	measured	Mix and Berg, 1988
Relative density	1.25 g/cm^3 at 26ºC (density). Purity: 99.5%	measured	Weber, 1987
Vapour pressure	1.7 × 10-6 Pa at 20 °C. Purity: 95.6% 1.7 × 10-6 Pa at 20ºC. Purity: 99.1%	measured	Krohn, 1993b Weber, 1988
Surface tension	64.26 mM/m at 20ºC (saturated aq. soln.) and 28.8 mg/L	measured	Imre, 1989
Water solubility	Purity: 99.5% pH 5.3 (buffered): 38 mg/L at 20ºC pH 7.2 (buffered): 36 mg/L at 20ºC pH 9.4 (buffered): 36 mg/L at 20ºC	measured	Krohn, 1995
Partition coefficient n-octanol/water	Purity: 99.1% Log Kow = 3.70 at 20ºC The effect of pH (4 - 9) was not investigated because there is no influence of pH on the water solubility.	measured	Krohn 1984
Flash point	Not applicable	Substance is solid	
Flammability	Purity: 98.1% Not highly flammable	measured	Mueller, 1991
Explosive properties	Purity: 97.6% No explosive properties	measured	Eberz, 1999
Self-ignition temperature	Data not available		
Oxidising properties	Purity: 98.1% No oxidising properties	From structural reasons the test substance has not oxidising properties	Mueller, 1991
Granulometry	Data not available		
Solubility in organic solvents and identity of relevant degradation products	Temperature: 20°C. Purity: 99.5% Hexane 0.08 g/L Polyethylen glycol 46 g/L Toluene 57 g/L Acetonitrile 89 g/L 1-Octanol 96 g/L 2-propanol 99 g/L PEG + ethanol 1:1 140 g/L Acetone > 200 g/L Dichloromethane > 200 g/L Dimethylformamide > 200 g/L Dimethylsulfoxide > 200 g/L	measured The active substance as manufactured didn't include any organic solvent	Krohn 1988c
Dissociation constant	no pKa value in water	Tebuconazole is a very weak base which can only be	Placke, 1987

		completely protonised in non-aqueous systems in the presence of very strong acids. It is not possible to specify a pK value for water	
Viscosity	Data not available		

DAR = Draft Assessment Report

2 MANUFACTURE AND USES

2.1 Manufacture

Not relevant for this dossier

2.2 Identified uses

Tebuconazole is a fungicide for foliar and seed treatment applications on a wide range of different crops.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

No changes in the classification for the physico-chemical endpoints are proposed in this dossier. For this reason, it is considered not warranted to present the data relating to physical hazards in this dossier. However, a summary of relevant physico-chemical properties is shown in table 11 of section 1.3 of this report.

4 HUMAN HEALTH HAZARD ASSESSMENT

The human health hazards of tebuconazole has been assessed as an active biocidal and plant protection product substance to the Directives 98/8/EC and 91/414/EEC, respectively, with Denmark as Rapporteur Member State. The following summaries is derived from the assessment for the review under Directive 91/414/EEC (Draft Assessment Report, July 2006, RMS Denmark).

Based on a review of the available data on acute toxicity, an update in the classification is needed. The summaries included in this proposal are copied from the DAR, its addenda and assessment reports. Details of some of the summaries were not included when not considered important for a decision on the classification and labelling of this substance. References to individual studies are not included. For more details the reader is referred to the DAR and its addenda.

In this proposal we include only information related to the following hazard class, acute toxicity. In addition, to provide an overview of the substance information related to the toxicokinetics of tebuconazole is included.

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

4.1.1 Non-human information

Table 12 Overall summary on absorption, distribution, excretion and metabolism

Type of study	Dose level (mg/kg b.w.)	Animal species, sex; strain	Substance	Findings	References
ADME study -single dose study	2 and 20 mg/kg bw	Rat, Wistar (BOR:WISW), males and females	Tebuconazole (HWG 1608)	Almost complete absorption of tebuconazole after oral administration. A large part of the elimination of tebuconazole was via the bile	Weber, 1987; Chopade, 1992; Weber, 1993
Whole-body autoradiographic distribution	20 mg/kg bw	Rat, Wistar (BOR:WISW), male	Tebuconazole (HWG 1608)	The study showed an even distribution of tebuconazole. 1 hour after administration radioactivity was detectable in all body tissues with the exception of the compact bone substance.	Weber, 1988
Metabolism study	Single dose: 2 or 20 mg/kg bw; in some groups pretreatment with 2 mg/kg of non-radioactive substance	Rat, Wistar (BOR:WISW), male and female	Tebuconazole (HWG 1608)	Tebuconazole was efficiently metabolised as hardly any unchanged parent compound was found in the excreta 72 h after administration	Ecker et al, 1987; Chopade, 1991

4.1.2 Human information

No data available.

4.1.3 Summary and discussion on toxicokinetics

The absorption of tebuconazole from the gastro-intestinal tract of the rat is rapid and complete based on urinary (7.4%) and biliary (90.9%) excretion by the cholecystotomized animals within 48 hours. Peak relative concentration in the blood plasma was found from 20 to 100 minutes after administration.

The distribution in the body was studied in a whole-body autoradiographic study. One hour after administration, radioactivity was detectable in all body tissues with the exception of compact bone substance indicating the substance to be evenly distributed.

The excretion mainly took place via faeces as 65 - 80% of the dose was eliminated by the biliary and faecal route, whereas elimination in urine amounted to about 16-35%. Biliary and faecal elimination was greater in males than in females. The amount excreted was not related to the administered dose. The results indicate that enterohepatic recirculation occurs in intact animals. Less than 1% of the administered dose was recovered in the tissues two to three days after administration, with the liver containing most of the tissue residues. Male animals in all groups had higher residue levels than females. Only a very small amount of radioactivity (0.032%) was detected in the exhaled air within 3 days of oral administration of 20 mg/kg bw.

The metabolism study revealed that tebuconazole is efficiently metabolised as hardly any unchanged parent compound is found in the excreta 72 h after administration. Distinct sex differences were seen in the metabolic pattern of tebuconazole, which mainly involves oxidations as phase 1- reactions, resulting in hydroxy, carboxy, triol and ketoacid metabolites and the phase 2 - conjugates were glucuronides and sulphates. Furthermore the break-down product 1,2,4-triazole amounted to 5% in the urine of the male and 1.5% in that of the female rat.

4.2 Acute toxicity

The results of relevant oral, dermal and inhalation acute toxicity studies are summarized in Table 13.

Table 13 Summary table of relevant acute toxicity studies

Method	Results	Remarks	Reference
Oral Toxicity			
OECD 401	LD_{50} male: 4000 mg/kg bw (3300–5800 mg/kg bw) LD_{50} female: 1700 mg/kg bw (1400-2200 mg/kg bw)	Sprague-Dawley rat (Crj:CD)	Ohta, 1991
OECD 401	LD_{50}: > 5000 mg/kg bw	Wistar rats/Bor:WISW (SPF-Cpb)	Flucke, 1987
Based on relevant OECD/EU guidelines	LD_{50} male: LD_{50} > 5000 mg/kg bw (fasted), LD_{50}: 4264 mg/kg bw (non-fasted) LD_{50} female: LD_{50}: 3933 mg/kg bw (fasted), LD_{50}: 3352 mg/kg bw (non-fasted)	Wistar rats/Bor:WISW (SPF-Cpb)	Heimann and Pauluhn, 1983
OECD 401	LD_{50} male: 2800 mg/kg bw (1200 – 4900 mg/kg bw) LD_{50} female: 5200 mg/kg bw	ICR (Crj:CD-1) mice	
Based on relevant OECD/EU guidelines	LD_{50} male: 1615 mg/kg bw LD_{50} female: 3023 mg/kg bw	NMRI mice	Ohta, 1991
Based on relevant OECD/EU guidelines	LD_{50}: > 1000 mg/kg bw (male and female)	Albino rabbits (HC:NZW)	Heimann and Pauluhn, 1983 Heimann and Pauluhn, 1983
Inhalation Toxicity			
OECD 403	LC_{50} > 371 mg/m^3 (aerosol) and LC_{50} > 5093 mg/m^3 (dust)	Wistar rats/Bor:WISW (SPF-Cpb)	Pauluhn, 1988
OECD 403	LC_{50} > 818 mg/kg bw (1x4 hrs) and > 240 mg/m^3 for 5 times 6 hrs inhalation	Wistar rats/Bor:WISW (SPF-Cpb)	Heimann and Pauluhn, 1983
Dermal Toxicity			
OECD 402	LD_{50} > 2000 mg/kg bw (male and female)	Sprague-Dawley rats (Crj: CD, SPF) Limit test	Heimann and Pauluhn, 1983
OECD 402	LD_{50} > 5000 mg/kg bw (male and female)	Wistar rats/Bor:WISW (SPF-Cpb) Limit test	Sheets, 1988

4.2.1 Non-human information

4.2.1.1 Acute toxicity: oral

Rats

Tebuconazole (purity 98.0%), using polyethylene glycol 400 as vehicle, was administered orally by gavage to groups of 5 male and 5 female rats in a single dose at dose levels 1600, 2300, 3000, 3900 and 5000 mg/kg body weight (males) and 730, 950, 1230, 1600, 2300, 3000, 3900 and 5000 mg/kg body weight (females). A total of 7 males and 22 females died. The observed clinical symptoms were considered to be similar to those of central nervous system depressants such as anaesthetic agents. There was no sex difference in observed symptoms (main symptoms were sedation, abnormal gait, paralytic gait and emaciation), the onset and the disappearance time of the symptoms and time to death, but tebuconazole was more acutely toxic to female rats than male rats. At termination abnormal findings in the liver (yellow-white patchy areas) and the testis (atrophy) for males were observed. Changes in the urinary bladder (reddish content), the adrenals (redness and hypertrophy) and in the trachea (retention of foamy fluid) were observed in animals that died during the observation period. Abnormal findings in the liver were considered to be due to tebuconazole because these were observed dose-dependently. Because the findings in the urinary bladder, the adrenals and the trachea were observed only in a few animals, these were not considered to be due to tebuconazole administration. The following LD_{50} values were established: LD_{50} 4000 mg/kg bw (male) and LD_{50} 1700 mg/kg bw (female).

Tebuconazole (purity 94.7%), using Cremophor EL/demineralized water (2%) as vehicle, was administered orally by gavage to 5 male rats in a single dose at dose 5000 mg/kg body weight. One rat died at day six. There were no treatment related effects on body weight and body weight development at the end of the study. Clinical signs including bristled fur, apathy, reduced motility, spastic gait, staggering, dyspnoea, salivation, diarrhea was observed. At termination abnormal findings in the liver (thin yellowish layer), lungs (patchy, dark spots) and scarlike changes were observed. The following LD_{50} was established: $LD_{50} > 5000$ mg/kg bw (male).

Tebuconazole (purity 97.1%), using Cremophor EL/water as vehicle, was administered orally by gavage to groups of 5 to 10 male and 5 female Wistar rats in a single dose at dose levels 1000, 2500, 4500 and 5000 mg/kg bw (fasted male) or 1000, 2500, 3150, 3550 and 5000 mg/kg bw (fasted female) and 500, 1000, 3550, 3750, 4000, 5000 mg/kg bw (non-fasted males) or 500, 1000, 2500, 3550, 4250, 4500 mg/kg bw (non-fasted female), in a volume level of 10 mL/kg bw. A total of 2 fasted males (5000 mg/kg bw) and 7 fasted females (from 3150-5000 mg/kg bw) and a total of 9 non-fasted males (from 3750-5000 mg/kg bw) and 12 non-fasted females (from 2500-4500 mg/kg bw) died. Weight loss was observed in the first week of the post-treatment observation period but normalized at the end of the period. The main clinical symptoms seen were behavioural disturbances, breathing disturbances, motility disturbances, staggering, spastic gait, sternal, lateral recumbency, loss of hair, cramped posture, increased urine excretion and poor reflexes which were observed in males and females. Animals that died during post-treatment observation period showed: lungs (spotted, distended), liver (patchy, pale, lobulation, enlarged), glandular stomach (reddened). Animals sacrificed at termination: no treatment-related findings. This acute oral toxicity study of tebuconazole was performed in accordance with GLP and OECD/EU guidelines and found acceptable.The following LD_{50} values were established: $LD_{50} > 5000$ mg/kg bw (male fasted): 4264 mg/kg bw (male non-fasted) and LD_{50} 3933 mg/kg bw (female fasted): 3352 mg/kg bw (non-fasted).

Mice
Tebuconazole (purity, 98.0%), using polyethylene glycol 400 as vehicle, was administered orally by gavage to groups of 5 male and 5 female mice in a single dose at dose levels 1600, 2300, 3000, 3900 and 5000 mg/kg body weight (males) and 3000, 3900 and 5000 mg/kg body weight (females). A total of 13 males (from 1600-5000 mg/kg bw) and 4 females (from 3900-5000 mg/kg bw) died. The observed clinical symptoms were considered to be similar to those of central nervous system depressant such as anaesthetic agent. There was no sex difference in observed symptoms (main symptoms were sedation, abnormal gait, paralytic gait and hypnosis), the onset and the disappearance time of the symptoms and time to death, but tebuconazole was more acutely toxic to male mice than female mice. Abnormal findings in the digestive system were considered to be due to tebuconazole. The following LD_{50} values were established: LD_{50} 2800 mg/kg bw (male) and LD_{50} 5200 mg/kg bw (female).

Tebuconazole (purity 97.1%), using Cremophor EL/water as vehicle, was administered orally by gavage to groups of 5 male and 5 female mice in a single dose at dose levels 100, 500, 1000, 1800, 2500, 3150 and 3550 mg/kg bw (male) and 500, 1000, 1800, 2500, 3550 and 5000 mg/kg bw (females) in a volume level of 10 mL/kg bw. A total of 17 fasted males mice (1000-3550 mg/kg bw) and 10 fasted females mice (from 1800-5000 mg/kg bw) died. Weight loss was observed in the first week of the post-treatment observation period (female: 5000 mg/kg bw) but normalized at the end of the period. The main clinical symptoms seen were behavioural disturbances, breathing disturbances, motility disturbances, staggering, spastic gait, sternal, lateral recumbency, and poor reflexes in males and females. Pathology revealed spotted, distended lungs; patchy, pale, lobulation, enlarged liver; patchy spleen; patchy kidney and reddened glandular stomach. This acute oral toxicity study of tebuconazole was performed in accordance with GLP and OECD/EU guidelines and was found acceptable. The following LD_{50} values were established: LD_{50} 1615 mg/kg bw (male) and LD_{50} 3023 mg/kg bw (female).

Rabbit
Tebuconazole (purity 97.1%), using Cremophor EL/water as vehicle, was administered orally by gavage to groups of 3 male and 3 female rabbits in a single dose (0.5 mL/kg bw) at dose levels 500 and 1000 mg/kg bw. No mortality was observed during the study. There were no treatment related effects on body weight. A general loss of appetite was observed. In animals sacrificed at termination the following were observed: lung slightly distended, spotted, kidney slightly patchy. Tebuconazole was slightly toxic to fasted male and female rabbits after acute oral administration. The following LD_{50} values were established: LD_{50} > 1000 mg/kg bw (male and female).

4.2.1.2 Acute toxicity: inhalation

Two acute inhalation studies are available.

The acute inhalation toxicity of tebuconazole (purity 96.2%) was investigated in groups of 5 male and 5 female Wistar rats (in accordance with OECD 403). The study was performed in inhalation chambers under dynamic conditions where rats were nose/head only exposed to the aerosol (371 mg/m^3) and to the dust (5093 mg/m^3). The study was performed at the maximum concentrations, which could be obtained in the experimental design with respect to both aerosol, and dust. A control group was included (conditioned air with similar exposure conditions as were used for the test substance). Animals were exposed for 4 hours and a post-treatment observation period lasted for 14 days. Neither lethality nor clinical effects were observed. There were no indications of specific local lung toxicity or damage of organs at gross pathology. The study shows that tebuconazole has

virtually no acute inhalation toxicity, either as aerosol or as dust at the concentrations tested. An LC_{50} > 371 mg/m^3 (aerosol) and LC_{50} > 5093 mg/m^3 (dust) was established.

In a second study (in accordance with OECD 403) actual concentrations of 16, 49, 387 and 818 mg/m^3 for aerosol exposure of 1x4 hrs; 0, 24, 60 and 240 mg/m^3 for aerosol exposure of 5x6 hrs were applied to rats (nose only). The study was performed in inhalation chambers under dynamic conditions. Animals were exposed for 1x4 hrs (acute inhalation) and 5x6 hrs (range-finding study). A vehicle control group was included in the 1x4 hrs study. The post-treatment observation period lasted for 14 days. In the 1x4 hrs study particle size was approx. 50% ≤ 5 µm (not test-specific data). In the 5x6 study the MMAD of the aerosol particles in the atmosphere ranged from 4.6-7.1 µm at different concentrations (geometric standard deviation ranged from 1.8-2.0 µm. No mortality was observed during the study. There were no treatment related effects on body weight. In the 1x4 study reduced motility (lassitude) was observed in the 250, 2500, 5000 mg/m3 dose groups. In the 5x6 study non-specific disturbed behaviour (lassitude) was observed in all groups. There were no indications of specific local lung toxicity or damage of organs at gross pathology. An LC_{50} > 818 mg/kg bw (1x4) and > 240 mg/m^3 for (5x6) was established.

4.2.1.3 Acute toxicity: dermal

Two studies are available.

In the first study, performed according to OECD 402 limit test, tebuconazole (purity 98%) was administered dermally to rats in a single dose at a level of 2000 mg/kg bw. The test substance was mixed with polyethylene glycol 400 and applied to the skin (semi-occlusive conditions) for 24 hours. The post-treatment observation period lasted 14 days. No effects were observed with respect to mortality, bodyweight, clinical signs, skin irritation or pathological findings in rats dermally treated with tebuconazole in a single dose at a level of 2000 mg/kg bw. The dermal toxicity of tebuconazole is low.

In a second study, performed according to OECD 402 limit test, tebuconazole (purity 97.1%) was administered dermally to rats in a single dose at a level of 5000 mg/kg bw. The test substance was mixed with physiological saline solution and applied to the skin (occlusive dressing method) for 24 hours. The post-treatment observation period lasted 14 days. No effects were observed with respect to mortality, bodyweight, clinical signs, skin irritation or pathological findings in rats dermally treated with tebuconazole in a single dose at a level of 5000 mg/kg bw. The dermal toxicity of tebuconazole is low.

4.2.1.4 Acute toxicity: other routes

No data available.

4.2.2 Human information

No data available.

4.2.3 Summary and discussion of acute toxicity

A number of studies were available for tebuconazole performed in rats, mice and rabbits.

In the oral studies low to moderate oral toxicity in the rodent species rat and mouse were observed. Clear sex differences were observed with females rats being most sensitive, while it was opposite

with mice. Administration of high oral doses to rats induced sedation, spastic gait, abnormal breathing, locomotor in-coordination and emaciation, the symptoms beginning within 5 hours at the dose 950 mg/kg bw for females and within 20 minutes at the dose 1600 mg/kg bw for males. The lowest oral LD_{50} values obtained were 1700 mg/kg bw and 1615 mg/kg bw in rats and mice, respectively. Tebuconazole was of low oral toxicity to fasted male and female rabbits after administration at the dose 1000 mg/kg bw.

In the dermal studies low toxicity was seen in limit tests where doses of 2000 and 5000 mg/kg bw were administered to the rat. No mortality, clinical signs or local effects were seen in either of the two studies.

In the inhalation studies with rats no deaths occurred and LC50 >371 mg/m^3 (aerosol) and >5093 mg/m^3 (dust) was determined by nose/head-only exposure under dynamic conditions. No clinical symptoms were observed at these maximum attainable concentrations.

4.2.4 Comparison with criteria

The lowest LD_{50} values of tebuconazole were 1700 mg/kg bw (female rat) and 1615 mg/kg bw (male mice) via the oral route. Tebuconazole is considered not acutely toxic via dermal and inhalation routes.

CLP

According to the CLP tebuconazole should be classified as Acute Tox Cat 4 because the LD_{50} is within the limits, 300 < ATE ≤ 2000 (oral, mg/kg bw). The minimum classification Acute Tox Cat 4*, is considered no longer necessary.

67/548/EEC

The current classification according to 67/548/EEC remains unchanged. According to 67/548/EEC tebuconazole should be classified as Xn;R22 because the LD_{50} per oral, rats is within the limits, 200 < LD_{50} ≤ 2000 mg/kg.

4.2.5 Conclusions on classification and labelling for acute toxicity

Table 14 Conclusion on classification for acute toxicity

	CLP Regulation	**Directive 67/548/EEC (DSD)**
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Acute Tox. 4 (H302)	Xn: R22

5 ENVIRONMENTAL HAZARD ASSESSMENT

The environmental fate and ecotoxicological properties of tebuconazole were evaluated when tebuconazole was assessed as an active biocidal and plant protection product substance under Directives 98/8/EC and 91/414/EEC, respectively, with Denmark as Rapporteur Member State. The following studies are taken from the assessment for the review under Directive 91/414/EEC (Draft Assessment Report, July 2006, RMS Denmark).

Based on a review of the available data on aquatic toxicity, a change in the environmental classification is needed. The summaries included in this proposal are partly copied from the DAR, its addenda and assessment reports. Details of some of the summaries were not included when not considered important for a decision on the classification and labelling of this substance. References to individual studies are not included. For more details the reader is referred to the DAR and its addenda.

The current classification of Aquatic Chronic 2 (R51) is based on acute aquatic toxicity observed the lowest acute EC50-values: Fish 4.4 mg/L, *Daphnia* 2.79 mg/L, algae 3.8 mg/L (DAR addenda (2008), Annex B4 Proposals for classification and labelling, section B.4.1).

Available information on the aquatic toxicity of tebuconazole supports a classification that is more stringent than the current classification (see sections 5.4.3 and 5.5). The lowest acute aquatic toxicity values for tebuconazole are 0.46 mg/L and 0.237 mg/L for invertebrates and aquatic plants (*Lemna gibba*), respectively. Tebuconazole therefore fulfils the criteria for classification as Aquatic Acute Cat. 1. Furthermore, the lowest NOEC is 0.01 mg/L obtained for *Daphnia* magna which lies in the toxicity range 0,001 < NOEC ≤ 0,01 mg/L. Tebuconazole therefore fulfils criteria for classification as Aquatic Chronic Cat.1

No changes are proposed to the conclusions on degradation and bioaccumulation. However, to provide an overview of the substance, we have also included information on degradation and bioaccumulation.

5.1 Degradation

Table 15: Summary of relevant information on degradation of tebuconazole

Method	Results	Remarks	Reference

Method	Results	Remarks	Reference
EPA §161-1	No hydrolytic degradation after 28 days incubation at pH 5.0, pH 7.0 and pH 9.0 at 25°C.	Hydrolytically stable	Coffman and Sietsema, 1984
EPA §161-2	No photolytic degradation after 30 days incubation at pH 5.0, pH 7.0 and pH 9.0 at 22°C.	Stable to photolysis	Coody, 1987
EPA §162-4 Water/Sediment	Radiolabelled test substance transformed to carbon dioxide was found to be 10 and 20%, respectively in 2 different systems after 52 days. No major metabolites were found in water/sediment systems	Under experimental conditions: indicative of slow degradation No calculation of actual degradations in water	Fritz, 1987b; Fritz 1987c; Fritz 1988b
OECD guidance document 'Freshwater Lentic Field studies (Outdoor microcosms and mesocosms) June 2000 (draft)	Average DT50 for the total (water/sediment) system is 54 days (SFO calculation)	The DAR states that the rapporteur considers the Heimbach study (2003) as the best water/sediment study available.	Heimbach, 2003; Chapple et al., 2003

5.1.1 Stability

Hydrolysis

A hydrolysis study using radio-labelled tebuconazole was run at pH 5, 7 and 9 at 25°C for 28 days (Coffman and Sietsema, 1984). At the end of the study no degradation of tebuconazole was observed. The material balance ranged from 97.3% to 106.9%, which was expected, given the non-volatility of the substance. A separate hydrolysis study was performed with the metabolite 1,2,4-triazole *(M26*). The hydrolysis of radio-labelled *M26* in sterile aqueous solution was run at pH 5, 7 and 9 at 25°C under exclusion of light by Spare (1983). Throughout the study *M26,* accounted for 90 to 98% of the radioactivity indicating that it is stable under test conditions. The half-life in water at pH 5 – 9 is greater than 30 days.

Photolysis in water

Coody (1987) studied the photochemical degradation of tebuconazole in soil and water. Radio-labelled tebuconazole in sterile solution of water at pH 7 was irradiated by natural sunlight for 30 days at 22°C in the presence of a dark control. The recovery rate at all sampling dates (0, 5, 10,18 and 30) ranged from 94% to 100% and was totally assigned to the parent compound. The extrapolated half-life of tebuconazole was 590 days. Degradation in water by direct photo-transformation processes can therefore be excluded.

Tebuconazole does not show an absorbance of UV-light at wavelengths above 290 nm (Hellpointner, 1990). Consequently, no further steps were performed to determine a half-life for photo-degradation and to calculate a quantum yield. Two photochemical degradations studies are available for the metabolite, *M26* in water. In the first study, the molar absorptivity at 295 nm

measured at pH 5, 7, and 9 was found to be < 0.1 L x mol^{-1}x cm^{-1}. Thus, photolytic degradation is not expected. A second study determined no significant degradation of M26 by sunlight in either distilled water or in humic acid solution or distilled water with acetone as a sensitiser.

5.1.2 Biodegradation

5.1.2.1 Biodegradation estimation

No estimation of biodegradation was made in the DAR.

5.1.2.2 Screening tests

There is no ready biodegradation study available for tebuconazole.

5.1.2.3 Simulation tests

The rapporteur states in the DAR, that tebuconazole is persistent and does not mineralise significantly in studies using either the phenyl or the triazole radiolabels and concludes that the substance is not ready biodegradable.

Biodegradation in water/sediment systems

Aerobic water/sediment system

An aerobic water/sediment simulation study using radio-labelled tebuconazole is available (Fritz, 1987b; Fritz 1987c and Fritz 1988b). The study was run for 52 weeks at 22°C (± 2%) using two systems: from the drainage ditch of a fruit orchard (IJsendoorn, The Netherlands) and from a re-cultivated gravel pit of agriculturally used areas at Lienden (The Netherlands).The dissipation of tebuconazole from the aqueous phase by degradation and adsorption to the sediment occurs slowly in the case of the system Lienden and relatively rapid in case of IJzenboorn due to its higher content of organic material. Approximately 34% of the applied radioactivity was absorbed to the sediment of the system Lienden and 61% to that of the system IJzendoorn. The percentage of the applied radioactivity that is transformed into carbon dioxide after 52 weeks of incubation was 10.0% and 20.9%, respectively. None of the unidentified metabolites detected reached concentrations above 3%.

The amount of unchanged parent compound in the surface water phase decreased with ongoing time and reached after 52 weeks about 23% and 8% in the water from Leinden and IJzendoorn system, respectively. The dissipation of tebuconazole in both water-sediment systems is a slowly ongoing process. After one year 56% (Leinden system) or 67% (IJzendoorn system), of the applied radioactivity was attributed to ebuconazole. There was no calculation of actual degradations rates in water, the results of the water/sediment study were interpreted as indicating a relatively slow ongoing degradation process for tebuconazole.

Heimbach (2003) conducted an outdoor microcosm to study of the dissipation of tebuconazole in outdoor stagnant water bodies. Three interconnected test microcosms located at Monheim am Rhein, Germany, were chosen and filled with natural ground water and sediment half a year before the application of the test substance. The pH of the water was around 8.0, oxygen concentrations varied between 10 and 12 mg/L and water temperature fluctuated around 17°C (increased to 25°C in August) and decreased towards the end of the study to 11°C. Two treatment levels with a nominal concentration of 3.2µg/L and 32µg/L were tested. One of the three microcosms served as a

control. Results showed consistent dissipation behaviour of tebuconazole in both treatments. The average half-life for disappearance from the water body was calculated to be 30.9 days and for the disappearance from the total system 38.7 days.

Using the TOXWA model, the DT50 for the whole-sediment system from the Heimbach study was refitted using the measured output form the microcosm study (Chapple et al. 2003). The calculated average dissipation DT50 for the total water/sediment study is 54 days. The dissipation DT50 for the water phase is 42 days and one year (default) for the sediment.

Biodegradation in soil

Aerobic degradation
Lee and Hann-Bey (1987) tested the aerobic biodegradation of 14C-tebuconazole. The metabolism of tebuconazole was studied in a laboratory system at an application rate of 10 mg/kg soil, corresponding to 13 kg/ha. The data suggest a slow degradation in soil with a DT50(lab) longer than 1year with 67.4% remaining after 1 year.

Field studies
In a total of 24 field dissipation trials (18 conducted in Northern Europe between 1987 and 1993, four more conducted in Northern Europe between 2000 and 2001 and two conducted in Southern Europe between 1995 and 1996) tebuconazole was tested at application rates ranging between 250 and 500 g per hectare. The newer studies were performed because it became more and more evident that the studies performed before 1993 suffered from shortcomings caused by a variety of factors, such as application into the standing crop and a sampling technique far from optimum. The 18 trials of the older studies resulted in a geometric mean of the DT50-values of 94 days. The corresponding mean values for the trials conducted in Northern Europe between 2000 and 2001 and in Southern Europe between 1995 and 1996 were 57 (36 to 77 days, n=4) and 26 days (20 to 34 days n=2), respectively.

The DT50field-values were transformed to standard conditions for comparison to each other and with laboratory data (Schad T, 2001 and 2002). As a result the geometric mean of the DT50-values referenced to 20°C was calculated to be 29.4 days. The value corresponds to a DT50-value of approximately two months under field conditions in northern Europe with an annual mean of the soil temperature of 10°C, which is in line with the experimental DT50-values measured in field dissipation trials in northern Europe. Tebuconazole appeared to be persistent in soil studies under laboratory conditions, in contrast to the situation in the field where shows to be moderately degradable.

5.1.2 Summary and discussion of degradation

Tebuconazole was found to be stable to hydrolysis in environmental conditions. Direct photodegradation of tebuconazole in water is low. No data on ready biodegradation are available but based on the available degradation data in water / sediment systems and soil, tebuconazole is considered to be not rapidly degradable

5.2 Environmental distribution

The adsorption/desorption behaviour of tebuconazole in six different soils of low organic content was investigated by Fritz according to EPA-Guideline § 163-1 (Fritz, 1988 and 1993). The

adsorption constants Kd calculated from the adsorption range from 7.67 to 19.39 mL/g. These values normalised to the content of organic carbon correspond to Koc-values between 803 and 1249 mL/g, with an arithmetic mean of 992. Due to the results tebuconazole is considered as a substance with a low mobility potential in soil.

5.3 Aquatic Bioaccumulation

Table 16. Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
EPA-Guideline 165-4 GLP: yes Exposure period: 28 days	BCF = 78		Surprenant , 1988c
OECD TG 305E GLP: yes Exposure period: 3 days	BCF = 35 – 59* BCF = 55 - 93**	*Based on specific compound **Based on total ^{14}C	Grau et al, 1988

5.3.1 Aquatic bioaccumulation

5.3.1.1 Bioaccumulation estimation

Based on experimentally data tebuconazole has a logKow value of 3.70 at 20°C.

5.3.1.2 Measured bioaccumulation data

Two bioaccumulation studies in fish are available.

In the first study, performed according to EPA Guideline No. 165-4, bluegill sunfish (*Lepomis macrochirus)* were exposed to radio-labelled tebuconazole (96.28% purity) over a 28-day exposure period (Surprenant, 1988c). A test concentration of 60 µg/L was used. Tebuconazole is bioaccumulated and excreted rapidly by bluefish sunfish, yielding a mean BCF of 78 for the whole fish. It was observed that steady state was reached after 10 days. The BCF may be overestimated as it is based on radioactivity and not analysed for active substance.

In the second study, bluegill sunfish (*Lepomis macrochirus)* was evaluated over a 3-day exposure period according to the OECD-305E guideline (Grau et al, 1988). The study was run with radio-labelled tebuconazole (radio purity > 99% and chemical purity 99.5%). Mean water concentrations of approximately 0.211 mg/L or 0.018 mg/L were used. A bioconcentration factor in the range 55 – 93 was obtained for the whole fish based on the total radioactivity. However, basing the result on tebuconazole a BCF in the range of 35 – 59 was obtained. It was reported, that steady state was achieved at least in the higher of the two concentrations used during the exposure period of 3 days. The BCF based on radioactivity may be overestimated.

5.3.2 Summary and discussion of aquatic bioaccumulation

Tebuconazole has logK_{ow} of 3.70. Measured bioaccumulation data showed that the bioaccumulation potential of tebuconazole is low, BCF factors ranged from 55 to 93.. These BCF values do not fulfil the criteria for bioaccumulating potential conform Directive 67/548/EEC, since it does note exceed the value of 100 nor conform Regulation EC 1272/2008, since it does not exceed the value of 500.

5.4 Aquatic toxicity

Only reliable and acceptable ecotoxicity tests from the Draft Assessment Report were used.

Table 17. Summary of relevant information on aquatic toxicity

Method	Results	Remarks	Reference
Fish Short-term Toxicity			
DIN 38412 GLP: No, GLP not compulsory at the time of study Purity: 97.1% Species: *Leuciscus idus melanotus* Exposure: Acute 96 h, static	LC50 = 8.7 mg/L	Nominal concentration	Grau, 1983 (amended,: 1987)
EPA Guideline 72-1 GLP: yes Deviations: minor, two test substances used with different purity; feeding during 48 hr before the test, slight water hardness. Purity: 94.7 – 96.28% Species: *Salmo gairdneri* Exposure: Acute 96 h, flow-through	LC50 = 4.4 mg/L 95% CI = 3.8 – 5.2	Mean measured concentration	Surprenant, 1987
EPA: FIFRA Guideline 72-1 GLP: yes Purity: 96.28% Species: *Lepomis macrochirus* Exposure: Acute 96 h, flow-through	LC50 = 5.7 mg/L	Mean measured concentration	Surprenant, 1987b
EPA: FIFRA 72-1 GLP: yes Purity: 96.28% Species: *Cyprinodon variegatus* Exposure: Acute 96 , flow-through	LC50 = 5.9 mg/L	Mean measured concentration	Surprenant, 1988a
Fish Long-term Toxicity			
EPA Guideline 72-4 GLP: yes Purity: 96.3% Species: *Salmo gairdneri* Exposure: 83 d, flow-through	NOEC = 0.012 mg/L	Mean measured concentration	Surprenant, 1988b
EPA Guideline 72-4 GLP: yes Purity: 96.4% Species: *Cyprinodon variegatus* Exposure: 36 d, flow-through	NOEC = 0.0219 mg/L	Mean measured concentration	Ward, 1991
EPA Guideline 72-5 GLP: yes Purity: 96.4% Species: *Cyprinodon variegatus* Exposure: 203 d, flow-through	NOEC = 0.0436 mg/L	Mean measured concentration	Wheat, 1993

Method	Results	Remarks	Reference
Aquatic invertebrates Short-term Toxicity			
EPA Guideline 72-2 GLP: Yes Purity: 96.3% Species: *Daphnia magna* Exposure: 48 h, flow through	EC50 = 2.79 mg/L	Mean measured concentration	Dorgerloh, 1998
EPA Guideline 72-3 GLP: Yes Purity: 96.3% Species: *Crassostrea virginica* Exposure: 96 h, seawater flow through	EC50 = 3.0 mg/L	Mean measured concentration	Surprenant, 1988d
EPA Guideline 72-2 GLP: Yes Purity: 96.3% Species: *Mysidopsis bahia* Exposure: 96 h, seawater flow through	LC50 = 0.46 mg/L 95% CI = 0.29 – 0.61	Mean measured concentration	Surprenant, 1988e
Aquatic invertebrates Long-term Toxicity			
EPA Guideline 72-4 GLP: Yes Purity: 96.28% Species: *Daphnia magna* Exposure: 21 d, flow through	NOEC = 0.12 mg/L	Based on survival and young/adult reproduction Mean measured concentration	Burgess, 1988
OECD TG 211 GLP: Yes Purity: 99.6% Species: *Daphnia magna* Exposure: 21 d, static renewal	NOEC = 0.01 mg/L	Based on survival and young/adult reproduction Nominal concentration	Noack, 1999
EPA Guideline 72-4 GLP: Yes Purity: 97.5% Species: *Mysidopsis bahia* Exposure: 28 d, seawater flow through	NOEC = 0.035 mg/L	Mean measured concentration	Sousa, 1991

Method	Results	Remarks	Reference
Algae and Aquatic Plants Toxicity			
ECD TG 201 GLP: Yes Purity: 97.5%, tebuconazole Species: Scenedesmus subspicatus Exposure: 72 h, static	ErC50 = 5.30 mg/L NOEC = 0.10 mg/L	Nominal concentration	Heimbach, 1987a
OECD TG 201 GLP: Yes Purity: 96.7%, tebuconazole Species: Selenastrum Capricornutum Exposure: 72 h, static	ErC50 = 3.80 mg/L NOEC = 1.19 mg/L	The initial test duration was 96 hours. The raw data have been recalculated by the applicant to comply with OECD TG 201 referring to 72 hours. ** Pseudokirchneriella subcapitata newer name for Selenastrum capricornutum	Bowers, 1996
EPA Guideline 123-2 GLP: Yes Purity: 96.7%, tebuconazole Species: Lemna gibba Exposure: 14 d, static renewal	ECr50 (7d) = 0.237 mg/L ECr10 (7d) = 0.036 mg/L	Calculated growth rate based on reported frond counts after 7 days Mean measured concentration	Bowers, 1997

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

The acute toxicity of tebuconazole to *Leuciscus idus melanotus* was tested at five concentrations (3.5-18 mg/L) for 96-h under static test conditions following German guideline DIN 38412. After 2, 48 and 96 hours 105%, 105.4% and 103.2% of the nominal concentration was detected. Based on nominal concentrations, as measured values were within the acceptable range, a LC_{50}-value of 8.7 mg/L was determined for tebuconazole (Grau, 1983).

A study was performed on *Salmo gairdneri* following EPA guideline 72-1. Fish were exposed to tebuconazole at five nominal concentrations (1.3-7.5 mg/L) for 96-h under flow-through conditions. Mean measured concentrations were 1.1, 1.5, 2.5, 3.9 or 6.1 mg/L tebuconazole At 6.1mg/L and 3.9 mg/L the surviving fishes show loss of equilibrium and extended (sometimes abrupted) abdomen . At 2.5 mg/L only after 96-h exposure one fish exhibited a partial loss of equilibrium and one exhibited darkened pigmentation. The measured concentrations show no relevant deviations during the exposure time. No mortalities were found in the controls. Based on mean concentrations the LC_{50} (96 h) of 4.4 mg/L was determined observed with *Salmo gairdneri* (Surprenant, 1987).

The acute effect of tebuconazole to *Lepomis macrochirus* was assessed according to EPA 72-1 guidelines (Surprenant, 1987b). *Lepomis macrochirus* were exposed at five nominal concentrations (1.3-7.5 mg/L) for 96-h under flow-through conditions. Mean measured concentrations were 1.4, 1.9, 2.9, 4.2, or 6.4 mg/L. An LC_{50} of 5.7 was obtained.

The acute aquatic toxicity of tebuconazole was tested at five nominal concentrations (1.3-7.5 mg/L) in *Cyprinodon variegates* in a 96-h flow-through study following EPA guidelines with analytical

monitoring of the test concentrations. Twenty organisms were exposed in duplicate test chambers for 96 h under flow-through conditions to a control, a solvent control at mean measured concentrations of 1.2, 1.9, 2.8, 4.3, or 6.8 mg/L. Based on mean measured concentrations an LC_{50} of 5.9 mg/L was determined in this study (Surprenant, 1988a).

Aquatic toxicity studies of metabolites of tebuconazole
No metabolites were found in the water of the water/sediment metabolism study. HWG-1608-pentanoic acid *(M-25*), HWG-1608-lactone (*M17*) and 1,2,4-triazole *(M-26)* are the only major metabolites to tebuconazole which could be detected in supplementary degradation studies in water. Studies have been conducted with these metabolites to evaluate their effects on fish (see Annex I, Table I-a). Acute toxicity studies show that the toxicity of metabolites (LC50-values ≥ 10 mg/L) in fish is lower than the parent compound.

Conclusion: Acute toxicity values of tebuconazole to fish are between 1 and 10 mg/L. The lowest LC_{50} of 4.4 mg/L was obtained with *Salmo gairdneri.*

5.4.1.2 Long-term toxicity to fish

In the first study *Salmo gairdneri* was exposed to tebuconazole according to EPA 72-4 guideline at five nominal concentrations ranging from 0.012 to 0.23 mg/L for 83 days under flow-through conditions (Surprenant, 1988b). The mean measured concentrations of tebuconazole ranged from 5.04 to 99.3 µg/L. Observations were made on embryo viability, organism survival at hatch and larval survival and growth after 60 d post-hatch. Exposure to all concentrations tested did not adversely affect embryo viability. Similarly, survival of organisms at the complete of the hatching period was comparable to the control. The larval survival was significantly reduced at the four highest concentrations. Throughout the post-hatch exposure period larval exhibited abnormal appearance and behaviour at concentrations ≥ 0.025 mg/L. Based on mean measured concentrations the 83-d NOEC was determined as 0.012 mg/L.

In a second study, the chronic toxicity of tebuconazole to *Cyprinodon variegates* was tested according to EPA 72-4 guideline at five nominal concentrations (6.25 – 100 µg as/L) for 36 days under flow-through conditions (Ward, 1991). The mean measured concentrations of tebuconazole were 5.04, 9.2, 21.9, 47.5 or 99.3 µg as/L. Based on hatching success, fry survival, and fry growth a 36-d NOEC for tebuconazole was determined as 0.0219 mg as/L.

In a third study, *Cyprinodon variegates* was exposed to tebuconazole in a flow-through full life cycle test design during 203 days at five nominal concentrations (12.5–200 µg/L) for a complete life-cycle (Wheat, 1993). This study was performed following EPA 72.5 guideline. 13 biological endpoints were statistically evaluated during this study. Abnormalities in the F_0 were observed in all treatments including controls at a low incidence (n ≤ 3) and were not dose-related. Abnormalities in F_1 were not observed. Based upon growth (length at day 33) the NOEC for the most sensitive biological endpoint for tebuconazole was determined as 0.0436 mg/L

C*hronic toxicity studies of metabolites of tebuconazole*
Available chronic study in fish shows that the toxicity of the metabolite *M26* (28-d NOEC (sublethal) = 3.2 mg/L) is lower than that of the parent compound (see Annex I, Table I-b).

Conclusion: The chronic toxicity of tebuconazole to fish is high, the NOEC values were observed to be lower than 1 mg/L. The lowest NOEC value of 0.012 mg/L was obtained with *Onchorhynchus mykiss.*

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

The acute toxicity of tebuconazole to *Daphnia magna* was tested according to EPA 72-2 guideline at five mean measured concentrations (0.46, 0.74, 1.6, 2.6 or 6.2 mg/L). *Daphnia* were exposed under flow-through test conditions for 48 hours. A 48-h EC_{50} of 2.79 was obtained in this study (Dorgerloh, 1998).

Crassostrea virginica were exposed in a flow-through test system for 96-h to a control, solvent control (acetone) and mean measured concentrations ranging from 1.7 to 9.3 mg/L. The shell deposition was measured and the concentration determined which caused 50% reduction of the shell deposition. 78% mortality was observed in the mean measured concentration of 9.3 mg as/L. The 96-h EC_{50} for the influence of tebuconazole on the shell deposition of Eastern oysters in this study was determined as 3.0 mg/L (Surprenant, 1988d).

Mysid shrimp (Mysidopsis bahia; ≤ 24 h old, 20 per concentration*)* were exposed in a seawater flow-through system for 96 h to a control, solvent control (acetone) and five mean measured concentrations of 0.30, 0.45, 0.79, 1.6 and 3.4 mg/L. Behavioral effects were observed at all higher concentrations higher than 0.30 mg as/L. The 96-h LC_{50} for tebuconazole has been determined as 0.46 mg /L (Surprenant, 1988e).

Acute toxicity studies of metabolites of tebuconazole
Acute toxicity studies to *Daphnia magna* show that the toxicity of metabolites (EC50-values > 100 mg/L) is lower than that of the parent compound (see Annex II, Table IIa)

Conclusion: The lowest acute toxicity of tebuconazole to aquatic invertebrates was obtained with *Mysidopsis bahia*, LC_{50} of 0.46 mg/L.

5.4.2.2 Long-term toxicity to aquatic invertebrates

In the first study, *Daphnia magna* were exposed at five concentrations (0.042–0.51 mg/L, mean measured) according to EPA guideline 72-4 using a flow-through test design (Burgess, 1988). After a 21-d exposure to tebuconazole, daphnid survival was significantly different ($P < 0.05$) from the controls at the highest concentration tested (0.51 mg as/L). The 21-d NOEC for *Daphnia magna* exposed to tebuconazole was 0.12 mg/L based on survival and young/adult reproduction at the end of the study. All young produced at all levels during the study appeared normal.

In a second study, *Daphnia magna* were exposed at five concentrations (0.01- 0.9 mg as/L) following a standard test using a static-renewal test design for 21-d (Noack, 1999). Mean values of recovery rate including new and old media were in the range of 87 – 136%. Significant numbers of stillborn were observed in the highest test concentration of 0.9 mg /L. The number of living juveniles per parent was statistically reduced at all concentrations higher than 0.01 mg /L. Body weight and body length were not affected at all test concentrations. The NOEC (21-d) for the reproduction was determined to be 0.01 mg/L.

The chronic toxicity to *Mysidopsis bahia* was tested in a flow-through test design for 28 days, in accordance to EPA guideline 72-4. *Mysidopsis* were exposed at five concentrations (8.7–150 µg/L, mean measured) (Sousa, 1991). Endpoints recorded were mortality, reproduction

(offspring/female/reproductive day) and growth (total dry body weight) of parent animals at the end of the test. The NOEC (28-d) for mysid shrimp in this study was determined to be 0.035 mg/L.

Conclusion: In chronic toxicity studies for aquatic invertebrates NOEC values below 1 mg/L were obtained. The lowest NOEC value observed was 0.01mg/L (nominal) for *Daphnia Magna.*

5.4.3 Algae and aquatic plants

Aquatic algae

A study was performed on *Scenedesmus subspicatus*, following OECD test guideline 201 (Heimbach, 1987a). Strain 86/81 SAG was exposed under static conditions for 72 hours at five nominal concentrations (0.32-10 mg/L). At the time the study was performed, analytical verification of test concentrations was not required. Thus, no analysis was performed. An inhibition of cell proliferation was seen at concentrations above 0.1 mg/L and a complete inhibition was found at 10 mg/L. The EC_{50} of growth rate after 72 hours was 5.3 mg/L and the NOEC was 0.10 mg/L.

A study was performed on *Selenastrum Capricornutum* following OECD test guideline 201 (Bowers, 1996). Strain 136 was exposed under static conditions for 72 hours at five concentrations (0.68-10.9 mg/L, mean measured). The EC_{50} of growth rate after 72 hours was 3.80 mg/L and the NOEC was 1.19 mg/L.

Aquatic plant

The toxicity of tebuconazole to duckweed (*Lemna gibba*) was tested according to EPA-FIRFA guideline 123-2 (Bowers, 1997). Over a 14-day period *Lemna gibba* was exposed under static-renewal test conditions at five nominal concentrations 0.0313, 0.0625, 0.125, 0.250 and 0.500 mg/L (in addition to control and solvent control). Three replicate vessels were prepared for each concentration. The frond count in each vessel was determined on Day 0, 2, 5, 7, 9, 12 and 14. The pH and conductivity were measured in the control, solvent control, low, middle, and high test solutions on Day 0, 7 and 14. Samples of tebuconazole test solutions, including controls were taken on day- 0, 7 (new solution) and 14 (old solution to measure actual exposure concentration).

The mean initial measured concentration of the substance was 0.0307, 0.0623, 0.1279, 0.2086 and 0.488. mg/L, which represents 76 to 110% of the nominal concentration. The *Lemna* fronds were described as smaller than controls in the 0.128, 0.209, and 0.489 mg/L test vessels. The authors of the study calculated a 14-day NOEC and E_rC_{50} based on frond counts, resulting in a value of 0.0623 mg/L and 0.144 mg/L. To be more in line with the OECD guideline 221 (*Lemna* sp. Growth Inhibition Test) in which a 7-day exposure is recommended, a 7-day NOEC, EC_{10} and EC_{50} values were derived. Based on the frond numbers reported the NOEC and EC10 of the growth rate between day 0 and 7 was calculated, resulting in a value of 0.0307mg/L and 0.0360 mg/L**.** The E_rC_{50} (7-d) was determined to be 0.237 mg/L.

Studies of toxicity of metabolites to algae

Studies show that toxicity of metabolites is lower than that of the parent compound (see Annex III, Table III-a).

Conclusion: The lowest E_rC_{50} and E_rC_{10} for growth to aquatic algae/plant for tebuconazole was 0.237 mg/L and 0.036 mg/L, respectively.

5.4.4 Other aquatic organisms (including sediment)

Whole-sediment studies with benthic organisms are not standard tests for classification and labelling as there are no criteria available, and the data can be used only as additional information. Two studies are available and are mentioned only for informational purposes (See Annex IV).

The effects of tebuconazole on sediment-dwelling organisms using test species, *Chironomus riparius,* have been studied. The first study is a limit test with one concentration (Heimbach, 1996). In this study no effects could be detected in the highest test concentration, 0.1 mg/L. A later study showed an EC 15 of 2.51 mg/L (Dorgerloh, 2003).

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

Summary of the lowest $L(E)C_{50}$ and NOEC values obtained in aquatic toxicity studies:

Acute toxicity

Fish	*Salmo gairdneri*	96 h LC50 = 4.4 mg/L
Invertebrates	*Mysidopisis bahia*	96 h LC50 = 0.46 mg/L
Algae/aquatic plant	*Lemna gibba*	7 d EC50 = 0.237 mg/L

Chronic toxicity

Fish	*Salmo gairdneri*	NOEC = 0.012 mg/L
Invertebrates	*Daphnia magna*	NOEC = 0.01 mg/L
Algae/aquatic plant	*Lemna gibba*	EC_{10} = 0.036 mg/L

Degradation

Tebuconazole is considered to be not rapidly degradable (see section 5.1.1).

Bioaccumulation

Tebuconazole does not fulfil the criteria for bioaccumulating potential conform Directive 67/548/EEC, since the BCF values ranging between 55 - 93 does not exceed the value of 100 nor for Regulation EC 1272/2008, since it does not exceed the value of 500 (see section 5.3.2).

CLP Acute aquatic hazard

$L(E)C_{50}$ values are available for all three trophic levels. The lowest acute aquatic toxicity values for tebuconazole are 0.46 mg/L and 0.237 mg/L in invertebrates and aquatic plants, respectively. Tebuconazole therefore fulfils the criteria for classification as Aquatic Acute Cat. 1. The $L(E)C_{50}$ values obtained in invertebrates and aquatic algae both fall within the $0.1 < L(E)C_{50} \leq 1$ mg/L band. An M-factor of 1 for acute toxicity is assigned.

CLP Chronic aquatic hazard

Tebuconazole is considered not rapidly degradable.

Chronic aquatic toxicity values for tebuconazole are available for all trophic levels. The lowest NOEC is 0.01 mg/L obtained for *Daphnia* magna which lies in the toxicity range $0{,}001 < NOEC \leq 0{,}01$ mg/L. Tebuconazole therefore fulfils criteria for classification as Aquatic Chronic Cat.1 with a M-factor of 10.

Directive 67/548/EEC

The lowest acute aquatic toxicity values for tebuconazole are 0.46 mg/L and 0.237 mg/L in invertebrates and aquatic plants, respectively. Tebuconazole is not readily degradable. However, it does not fulfil the criteria for bioaccumulation. Tebuconazole, therefore fulfils the criteria for classification with N;R50/53. The specific concentration limits (SCL) of $C_n \geq 25\%$ N; R50-53, $2,5\% \leq C_n < 25\%$ N; R51-53 and $0,25\% \leq C_n < 2,5\%$; R52-53 where C_n is the concentration of tebuconazole in a mixture are proposed.

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

Table 18 Conclusion on environmental classification

	CLP Regulation	**Directive 67/548/EEC (DSD)**
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) M-factor Acute M-factor 1 Chronic M-factor 10	N; R50-53 SCL: $C_n \geq 25\%$: N; R50-53 $2{,}5\% \leq C_n < 25\%$: N; R51-53 $0{,}25\% \leq C_n < 2{,}5\%$: R52-53

6 OTHER INFORMATION

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8 ANNEXES

Annex I. Summary of the aquatic toxicity of metabolites to fish

Table I-a Summary of the short-term toxicity of metabolites to fish

Method	Results	Remarks	Reference
EPA-FIFRA § 72-1 GLP: yes Deviation: yes Metabolite: HWG-1608-pentanoic acid *(M-25*) Purity: 94.1% Species: *Oncorhynchus mykiss* Exposure: Acute 96 h, static	LC50 = ≥ 10 mg/L*	Nominal concentration of the pure metabolite Deviation: A limit test was performed at 10 mg/L (instead of typically used 100 mg/L, because the low availability of test item) in order to demonstrate thte the LC50 is greater than this concentration. The DAR states that the rapporteur found the reduction of the exposure from 100 mg/L to 10 mg/L acceptable.	Dorgerloh, 2003a
EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 GLP: yes Metabolite: HWG-1608-lactone *(M-17*) Purity: 99.2% Species: *Oncorhynchus mykiss* Exposure: Acute 96 h, static	LC50 = ≥ 10 mg/L*	Nominal concentration of the pure metabolite Deviation: same remark as for M-25 (see above)	Dorgerloh, 2003b
OECD TG 203 GLP: yes Metabolite: 1,2,4- triazole (M 26) Purity: 91.9% Species: *Oncorhynchus mykiss* Exposure: Acute 96 h, static	LC50 = 498 mg/L*	Mean measured concentration of the pure metabolite	Rufli, 1983

* = pure metabolite

Table I-b. Summary of the long-term toxicity of metabolites to fish

Method	Results	Remarks	Reference
OECD TG 215 GLP: yes Metabolite: 1,2,4- triazole (*M 26*) Purity: 99.9% Species: *Oncorhynchus mykiss* Exposure: 28 d , static-renewal system	NOEC (sublethal)= 3.2 mg/L based on behaviour NOEC (mortality) = ≥ 100 mg/L, the highest concentration tested	Based on nominal concentration of the pure metabolite and growth rate calculations	Dorgerloh and Sommer, 2002

Annex II. Summary of the aquatic toxicity of metabolites to aquatic invertebrates

Table II-a. Summary of the short-term toxicity of metabolites to aquatic invertebrates

Method	Results	Remarks	Reference
OECD TG 202 GLP: yes Metabolite: HWG-1608-pentanoic acid *(M-25*) Purity: 94.1% Species: *Daphnia magna* Exposure: 48 h, static	EC50 = > 100 mg/L	Nominal concentration of the pure metabolite	Dorgerloh, 2003c
OECD TG 202 GLP: yes Metabolite: HWG-1608-lactone *(M-17*) Purity: 99.2% Species: *Daphnia magna* Exposure: 48 h, static	EC50 = > 100 mg/L	Nominal concentration of the pure metabolite	Dorgerloh, 2003d
OECD TG 202 GLP: yes Metabolite: 1,2,4-triazole *(M-26*) Purity: 100.8% Species: *Daphnia magna* Exposure: 48 h, static	EC50 = > 100 mg/L	Nominal concentration of the pure metabolite	Bell, 1995

Annex III. Summary of the aquatic toxicity of metabolites to aquatic invertebrates

Table III-a. Summary of studies of toxicity of metabolites to algae

Aquatic toxicity of metabolites to aquatic algae			
Method	**Results**	**Remarks**	**Reference**
OECD TG 201 GLP: yes Metabolite: HWG-1608-pentanoic acid *(M-25*) Purity: 94.1% Species: *Pseudokirchneriella subcapitata* Exposure: 72 h, static	E_rC50 = > 100 mg/L NOEC = > 100 mg/L	Nominal concentration of the pure metabolite	Dorgerloh, 2003e
OECD TG 201 GLP: yes Metabolite: HWG-1608-lactone *(M-17*) Purity: 99.2% Species: *Pseudokirchneriella subcapitata* Exposure: 72 h, static	E_rC50 = > 100 mg/L NOEC = > 100 mg/L	Nominal concentration of the pure metabolite	Dorgerloh, 2003f
OECD TG 201 GLP: yes Metabolite: 1,2,4-triazole *(M-26*) Purity: 99% Species: *Pseudokirchneriella subcapitata* Exposure: 72 h, static	EC50 = > 31 mg/L NOEC = 6.8 mg/L	Mean measured concentration of the pure metabolite	Palmer et al, 2001

Annex IV. Effect on sediment dwelling organisms

Method	Results	Remarks	Reference
None Study was done according to a Proposal for a BBA-Guideline: "Effects of plant protection products on development of sediment dwelling larvae of *Chironomus riparius* in water-sediment system. GLP: Yes Purity: 96.9% Species: *Chironomus riparius* Exposure: water/sediment 28 d, static	EC50 = > 0.1 mg/L EC15 = > 0.1 mg/L NOEC = ≥ 0.1 mg/L	Based on emergence Study was conducted as limit test with only one test concentration, 0.1 mg/L	Heimbach, 1996a
None Study was done according to a Proposal for a BBA-Guideline: "Effects of plant protection products on development of sediment dwelling larvae of *Chironomus riparius* in water-sediment system. GLP: Yes Purity: 97.0% Species: *Chironomus riparius* Exposure: water/sediment 28 d, static	EC50 = 2.78 mg/L EC15 = 2.51 mg/L NOEC = 1.33 mg/L	Based on emergence Initial measured concentrations were: 0, 0.729, 1.33, 2.33, 4.08 and 7.29 mg/L The start of emergence was not delayed at any test concentration where emergence occurred. However, no emergence at all was observed at test conctrations of 4.08 and 7.29 mg/L.	Dorgerloh, 2003g