CLH report

Proposal for Harmonised Classification and Labelling

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

Substance Name: Fipronil

EC Number: **424-610-5**

CAS Number: **120068-37-3**

Index Number: **608-055-00-8**

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Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	Fipronil (ISO)
EC number:	424-610-5
CAS number:	120068-37-3
Annex VI Index number:	608-055-00-8
Degree of purity:	95%
Impurities:	See the confidential annex (separate document)

1.2 Harmonised classification and labelling proposal

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

	CLP Regulation
Current entry in Annex VI, CLP Regulation	Acute Tox 3* - H301 Acute Tox 3* - H311 Acute Tox 3* - H331 STOT RE 1 – H372** Aquatic acute 1 - H400 Aquatic chronic 1 - H410 M-factor acute : 10
Current proposal for consideration by RAC	Aquatic acute 1 - H400 Aquatic chronic 1- H410 M-factor acute : 10000

	M-factor chronic : 10000
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Acute Tox 3* - H301 Acute Tox 3* - H311 Acute Tox 3* - H331 STOT RE 1 – H372** Aquatic acute 1 - H400 Aquatic chronic 1- H410 M-factor acute : 10000 M-factor chronic : 10000

*minimal classification obtained from conversion of DSD classification
**route of exposure not specified as the necessary information is not available (conversion of DSD classification)

1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or 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			-	
2.2.	Flammable gases			-	
2.3.	Flammable aerosols			-	
2.4.	Oxidising gases			-	
2.5.	Gases under pressure			-	
2.6.	Flammable liquids			-	
2.7.	Flammable solids			-	
2.8.	Self-reactive substances and mixtures			-	
2.9.	Pyrophoric liquids			-	
2.10.	Pyrophoric solids			-	
2.11.	Self-heating substances and mixtures			-	
2.12.	Substances and mixtures which in contact with water emit flammable gases			-	
2.13.	Oxidising liquids			-	
2.14.	Oxidising solids			-	
2.15.	Organic peroxides			-	
2.16.	Substance and mixtures corrosive to metals			-	
3.1.	Acute toxicity - oral			Acute Tox 3*	
	Acute toxicity - dermal			Acute Tox 3*	
	Acute toxicity - inhalation			Acute Tox 3*	
3.2.	Skin corrosion / irritation			-	
3.3.	Serious eye damage / eye irritation			-	
3.4.	Respiratory sensitisation			-	
3.4.	Skin sensitisation			-	
3.5.	Germ cell mutagenicity			-	
3.6.	Carcinogenicity			-	
3.7.	Reproductive toxicity			-	
3.8.	Specific target organ toxicity –single exposure			-	
3.9.	Specific target organ toxicity – repeated exposure			STOT RE 1	
3.10.	Aspiration hazard			-	

4.1.	Hazardous to the aquatic environment	Aquatic acute 1 Aquatic chronic 1	M (acute) = 10 000 M (chronic) = 10 000	Aquatic acute 1 Aquatic chronic 1 M=10	
5.1.	Hazardous to the ozone layer			-	

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Pictograms: GHS06, GHS09, GHS08

Signal word: Dgr
Hazard statements: H301, H311, H331, H372, H410
Precautionary statements: not harmonised

Proposed notes assigned to an entry: none

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

Fipronil is an active Biocide substance in the meaning of Regulation EC 528/2012 and an active Plant Protection Product in the meaning of Regulation EC 1107/2009.

The harmonised classification of fipronil was first introduced in the 30^{th} ATP (Directive 2008/58/EC) of DSD based on the assessment of fipronil under PPP regulation. It has not been modified since then. Summary records of the discussions leading to the environmental classification of fipronil at the time of the 30^{th} ATP are not available.

New data available from the Biocide risk assessment and from literature now demonstrate the need to revise M-factors for environmental classification. The CAR (Doc IIIA 1 and Doc IIIA 7.1) is publicly available on ECHA website (http://dissemination.echa.europa.eu/Biocides/factsheet?id=0033-18). All other available data (DAR) has been considered while drafting this proposal.

It is recognised that the current Annex VI entry for fipronil includes acute toxicity, oral, dermal and inhalation, and STOT RE 1 as a minimum classification as indicated by the reference * in the column "Classification" in Table 3.1. However, it was recognised it was worth modifying the M-factors in order to impact the C&L of the biocidal product but that toxicological resources would not be allocated for digging into the acute data. Therefore, this proposal considers specifically environmental end points.

2.2 Short summary of the scientific justification for the CLH proposal

Available toxicity data show that invertebrates are the most sensitive species for acute and chronic effects of fipronil.

Considering that the 96h-EC_{50} = 0.0325 µg/L value was obtained for *Chironumus dilutus* is lower than 1 mg/L, fipronil meets the criteria for classification as **Aquatic Acute 1** for environmental hazard according to CLP criteria. This value is extracted from a recent publication dated on 2014, for which FR-MSCA considers sufficient information available to be considered. As this value is within the range of 0.00001-0.0001 mg/L, an **M-factor of 10000** is allocated.
It is necessary to point out that according to CLP regulation, acute toxicity is usually determined using a CL_{50} 96h for fish, a CE_{50} 48h for crustacean or a CE_{50} 72/96h for algae and other aquatic plant. The regulation also explicates that other species data can be considered if test method is approved. FR-MSCA considers the study with *Chironomus dilutus* reliable and given that this species has a much longer life-cycle than *Daphnia magna*, FR-MSCA considers that this 96h test can be considered as an acute toxicity test. Therefore FR-MSCA accepts this study for classification.

Considering that fipronil is not readily biodegradable and that the 28d-NOEC = 0.0077 µg/L value obtained for *Mysidopsis bahia* is lower than 0.1 mg/L, fipronil meets the criteria for classification as **Aquatic Chronic 1** for environmental hazard according to CLP criteria. As the value is within the range of 0.000001-0.00001 mg/L, an **M-factor of 10000** is allocated.

2.3 Current harmonised classification and labelling

The classification of fipronil is harmonised in Annex VI of CLP under the index number 608-055-00-8 as follows:

Table 3.1 (CLP)
Acute Tox 3* - H301 Acute Tox 3* - H311 Acute Tox 3* - H331 STOT RE 1 – H372** Aquatic acute 1 - H400 Aquatic chronic 1 - H410 M-factor = 10

*minimal classification obtained from conversion of DSD classification
**route of exposure not specified as the necessary information is not available (conversion of DSD classification)

2.4 Current self-classification and labelling

It is noted that some notifications in the C&L inventory includes a classification Acute Tox 2 – H330 in application of the harmonized minimal classification Acute Tox 3*.

No other additional or diverging classifications are observed.

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Harmonised classification and labelling for CMR and respiratory sensitisation is a Community-wide action under Article 115. Proposals for harmonised classification for other endpoints should include here the reasons why there is a need for action at the Community level.

Fipronil is an active Biocide substance in the meaning of Regulation EC 528/2012 and an active Plant Protection Product in the meaning of Regulation EC 1107/2009. In accordance with Article 36(2) of the CLP Regulation, fipronil shall be subjected to harmonised classification and labeling for all endpoints. Fipronil already has a harmonized classification but available data demonstrate the need to revise M-factors for environmental classification. Therefore, this proposal considers specifically environmental endpoints.

Part B.

SCIENTIFIC EVALUATION OF THE DATA

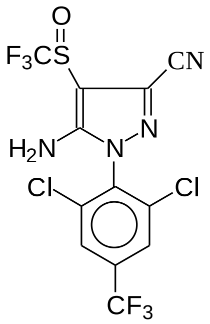
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 4: Substance identity

EC number:	424-610-5
EC name:	-
CAS number (EC inventory):	-
CAS number:	120068-37-3
CAS name:	1H-Pyrazole-3-carbonitrile, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-
IUPAC name:	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile (Isomeric ratio 1:1)
CLP Annex VI Index number:	608-055-00-8
Molecular formula:	$C_{12}H_4Cl_2F_6N_4OS$
Molecular weight:	437.15 g/mol

Structural formula:



1.2 Composition of the substance

Table 5: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
1H-Pyrazole-3-carbonitrile, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]- CAS 120068-37-3		Min 95%	

See the confidential annex for impurities (separate document)

1.3 Physico-chemical properties

Table 6: Summary of physico - chemical properties

Property	**Value**	**Reference**	**Comment (e.g. measured or estimated)**
State of the substance at 20°C and 101,3 kPa	White powder	Chabassol, Y. ; Hunt, G.M. 1991x	Purity: 96.8-99.3%
Melting/freezing point	204.1 – 204.5°C	Daum, A. 2004	Purity: 99.7% Measured, capillary method in metal block and DSC
Boiling point	At ca. 220°C decomposition started indicated by an exothermic effect and gas evolution at 238°C. No boiling point was observed.	Daum, A. 2004	Purity: 99.7% Measured, capillary method in metal block and DSC
Relative density	D^{20}_{4} = 1.705	Nobuhiro, K. 2001x	Purity: 99.8% Measured, specific gravity bottle method
Vapour pressure	< 2.0 x 10^{-6} Pa	Nobuhiro, K. 2001x	Purity: 99.4% Temperature: 25°C Measured, gas flow method
Henry's law constant	< 2.31 x 10^{-4} $Pa.m^{3}.mol^{-1}$	Bascou, J.P. 2002x	At 25°C Calculated
Surface tension	72.5 mN/m at a concentration of about 2 mg/l	Cousin, J. 1996x	Purity: 96.2% Temperature: 20 °C Measured, ring tensiometer method
Water solubility	5.84 mg/l in deionised water (pH 5.7) 5.29 mg/l at pH 4 3.35 mg/l at pH 7 3.97 mg/l at pH 9	Daum, A. 2005	Purity: 98.9% at 20 °C Measured, column elution method
	3.78 mg/l in deionised water at pH 6.58	Nobuhiro, K. 2001b	Purity: 99.3% at 20 °C Measured, column elution method
	pH 5: 2.4 mg/l, 20°C pH 7: 1.9 mg/l, 20°C pH 9: 2.2 mg/l, 20°C	Chabassol, Y. Reynaud R. 1991c	Purity: technical, 954 g/kg Column elution method
Partition coefficient n-octanol/water	logKow= 4.0	Chabassol, Y. ; Reynaud, R. 1991x	shake flask method, at 99.3% and 20°C, pH not recorded
	log Kow= 3.5	Cousin, J. ; 1997x	HPLC method, at 99.9% and 20°C, pH not recorded
Flash point	Not required as melting point is >40 °C	-	-
Flammability	Not highly flammable up to 200°C (sample	Cousin, J. ; Fillion, J. 1996x	Purity: 96.2%

	melted)		Measured
Explosive properties	Not explosive	Tran Thanh Phong, J. 1999a	Purity: 96.2% Measured
Self-ignition temperature	Not auto-flammable up to 200°C (sample melted)	Cousin, J. ; Fillion, J. 1996x	Purity: 96.2% Measured
Oxidising properties	No oxidizing properties	Tran Thanh Phong, J. 1999a	Purity: 96.1% - 95.7% Measured
Granulometry	Not provided	-	-
Stability in organic solvents and identity of relevant degradation products	Not known	-	-
Dissociation constant	No dissociation is expected in the pH range (4-9) based on structural considerations and lack of pH dependence of water solubility	Cichy, M. 2001x	-
Viscosity	Not required as material is not liquid	-	-
Reactivity towards container material	During manufacturing handling or storage, corrosiveness of fipronil on packaging material, containers or apparatus was never observed. Storage stability data on wet fipronil indicated no reactivity towards container material (polyethylene).	Cousin, J. 1997	Purity: 95.2 %

2 MANUFACTURE AND USES

2.1 Manufacture

The process for the synthesis of fipronil is confidential.

2.2 Identified uses

Fipronil was included in the Annex I of the Biocide Directive 98/8/EC as an insecticide (PT 18) and is restricted under PPP regulation to the treatment of seeds intended to be sown in greenhouses and of seeds of leek, onions, shallots, and of the group of Brassica vegetables intended to be sown in fields and harvested before flowering (Reg. 781/2013).

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Not relevant for this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for this dossier.

5 ENVIRONMENTAL HAZARD ASSESSMENT

5.1 Degradation

Table 7: Summary of relevant information on degradation

Method	**Results**	**Remarks**	**Referenc e**

BIOTIC DEGRADATION			
Ready biodegradation OECD 301-B (CO2 Evolution Test) EC method C.4-C	Day 28 - 47%	Inoculum is a mixed population of activated sewage sludge microorganisms. Not readily biodegradable	Mead, C (1997)
Simulation test : Degradation in Two Water/Sediment Systems SETAC Guidelines	**DT50 (days)** **1 Sand** Water 32.8 (20°C) 62.2 (12°C)* Total system 76.0 (20°C) 144.1 (12°C)* **2 Clay loam** Water 22.7 (20°C) 43.0 (12°C)* Total system 39.1 (20°C) 74.1 (12°C)* **DT90 (days)** **1 Sand** Water 319.3 Total system 347.3 **2 Clay loam** Water 99.4 Total system 169.1	Initial TS concentration : 60 µg fipronil per replicat vessel Total recovery of TS : 93.33% of applied a.s. (overall mean)	Roohi, A; Buntain I (2002)
Simulation test : Aerobic aquatic metabolism EPA 162-4	Mixture of a fresh sandy loam sediment and pond water **DT50 (days)** Total system 14.5 (25°C) 41.2 (12°C)*	Initial TS concentration : 0.05 ppm fipronil per replicat vessel Total recovery of TS : 95.7-106.4% of applied a.s.	Feung C.S., Yenne S.P. (1997)
Simulation test : Degradation and retention in two water/sediment systems	**DT50 (days)** **1 Sandy clay loam** Water 13.41 (9°C) 10.55 (12°C)* Sediment 47.54 (9°C) 37.40 (12°C)* Total system 21.20 (9°C) 16.68 (12°C)* **2 Sandy loam** Water 5.85 (8°C) 4.25 (12°C)* Sediment 74.80 (8°C) 54.32 (12°C)* Total system 31.68 (8°C) 23.00 (12°C)* **DT90 (days)** **1 Sandy clay loam** Water 46.83 (9°C) 34.01 (12°C)* Sediment 97.63 (9°C) 70.89 (12°C)* Total system 64.76 (9°C) 47.03 (12°C)* **2 Sandy loam** Water 34.69 (8°C)	Initial TS concentration : 91.85 µg fipronil in 130 µL of acetonitrile to water phase of each vessel Total recovery of TS : - 94.4 % of applied a.s. for sandy clay loam - 96.1% of applied a.s. for sandy loam	Ayliffe J.M. (1998)

	25.19 (12°C)* Sediment 161.63 (8°C) 88.32 (8°C)* Total system 117.37 (9°C) 88.29 (12°C)*		
Aerobic degradation in soil USEPA and BBA Aerobic Soil Metabolism	**DT50 (days)** **1 Sandy loam** 128 (362 at 12°C*) **2 Sand** 308 (871 at 12°C*)	Initial TS concentration : 0.2 mg/kg fipronil Total recovery of TS : 93.7-103% of applied a.s. Hydrolysis to RPA 200766 and oxidation to MB 46136	Waring, A. R (1993)
Aerobic degradation in soil No guideline Aerobic Soil Metabolism	**DT50 (days)** **1 Clay loam** 20°C 304 (576.5 at 12°C*) 10°C 686 (584 at 12°C*) **2 Clay loam** 20°C 102 (193.4 at 12°C*) 10°C 358 (305.1 at 12°C*) **3 Clay loam** 20°C 31 (58.8 at 12°C*) **4 Sandy loam** 20°C 221(419.1 at 12°C*)	Initial TS concentration : 0.02 mg/kg fipronil Total recovery of TS : 100.9% of applied a.s.(overall mean) Hydrolysis to RPA 200766 and by oxidation to MB 46136 and reduction to MB 45950	Fitzmaurice, MJ. Mackenzie, E (2002)
ABIOTIC DEGRADATION			
Hydrolysis USEPA N, 161-1	DT50 à 25°C pH 5 and 7 : not applicable pH 9 : DT_{50}= 28 days DT50 à 12°C pH 5 and 7 : not applicable pH 9 : DT_{50}= 76.2 days	pH 5: Stable pH 7 : nearly stable (2% loss in 30 days) pH 9 : k = 0.0243 day^{-1} pH 5: Stable pH 7 : nearly stable (2% loss in 30 days) pH 9 : k = 0.0243 day^{-1}	Corgier, M.C; Plewa, A.P (1992)
Photolysis in water US EPA 161-2	T1/2 : 0.33 days	k = 0.0176 days	Corgier MMC; Plewa, A.P (1992)

* recalculated value to reflect an average EU outdoor temperature

5.1.1. Stability

The hydrolytic stability of [^{14}C]-Fipronil, was studied in the dark, under sterile conditions, at pHs 5, 7 and 9. Hydrolyse of Fipronil is pH-dependant: Fipronil has been shown to be hydrolytically stable at pH 5 and 7. At pH 9, Fipronil is unstable with only RPA 200766 as breakdown product. At this pH, the rate of conversion is best modelled by pseudo-first order kinetics with a half life of 28 days and a rate constant k = 0.0243 day^{-1}(Corgier, M.C; Plewa, A.P, 1992).

The photolysis in water of [^{14}C]-Fipronil, was studied at pH 5 at 25 ± 1°C, under sterile conditions. Two major degradation products were formed under condition of test. The major organic extract photo-product was MB 46513 (43.4 % of the applied radioactivity) and a minor component (HPLC RT = 2 min) accounting for 4.0% of applied radioactivity. The aqueous extract photo-products RPA 104615 and a minor component (HPLC RT = 3.3 min) accounted for 8.2 and 5.6% of applied radioactivity, respectively. The kinetics of photolytic degradation were first order with a half-life of 3.63 hours under the xenon lamp corresponding to 0.33 days of summer sunlight in Florida and a rate constant k = 0.0176 $days^{-1}$. Photolysis can be considered as a major route of fipronil degradation when it reaches the aqueous environment (Corgier MMC; Plewa, A.P, 1992).

5.1.1 Biodegradation

5.1.1.1 Biodegradation estimation

5.1.1.2 Screening tests

A ready biodegradation test has been performed where fipronil attained 47% degradation after 28 days in OECD 301B (CO_2 evolution test). According to OECD criteria a test material may be considered to be readily degradable if > 60% degradation is attained after 28 days. Therefore, since there was only 47% degradation, fipronil cannot be considered readily degradable under the strict terms and conditions of the OECD guidelines (Mead, C., 1997).

5.1.1.3 Simulation tests

Biodegradation in water/sediment systems

A [14C]-Fipronil degradation in two water/sediment systems showed that in an aerobic aquatic environment, fipronil (the position of 14C- in radiolabelled compound is uniformly incorporated in the phenyl ring) partitions steadily into the underlying sediment where it degrades partly by reduction to MB 45950. MB 45950 is further degraded by hydrolysis to MB 46126. Fipronil is also hydrolysed to RPA 200766 and, to a much lesser extent oxidised to MB 46136. There is evidence than RPA 200766 and MB 46136 are further transformed to RPA 105320 via oxidation or hydrolysis respectively. MB 46126 reaches a max. 6.33% in water and max. 6.48% in sediment. Amongst all those metabolites identified, RPA 200766 is a major metabolite in water (max. 20%) and MB 45950 is a major metabolite in sediment (max. 54.69% at 163 days) (Roohi, A; Buntain I, 2002).

Two other water/sediment degradation studies were provided from the PPP dossier.

The results of the first one (Feung C.S., Yenne S.P., 1997) showed that the majority of the test substance, [14C]-fipronil, was rapidly transferred/adsorbed to the sediment within 7 days of incubation with less than 4% in the water phase after 7 days. The half-life of [14C]-fipronil under aerobic aquatic conditions was 14.5 days. MB 45950 was found as the major metabolite in the sediment and accounted for <1% in the water phase.
The results of the second one (Ayliffe J.M., 1998) showed that fipronil was readily degraded in aerobic water with anaerobic sediment systems with DT50 values in the water of less than 14 days and in the total system less than 35 days. Fipronil was the only major component found in the water. It rapidly transferred to the sediment (up to 20 to 40% of applied) and was reduced to MB 45950 which was the major metabolite in the sediment, which undergoes further degradation.

The geometric mean degradation half-lives were calculated based on these values for water and total system compartments as follows:
DT50 water = 18.61 days at 12°C (9.81 days at 20°C); DT50 total system = 44.17 days at12°C (34.19 days at 20°C).

Aerobic degradation in soil

In the study A7.2.1/01, the degradation of [^{14}C]-Fipronil was investigated in two soils. The half life of [^{14}C]-Fipronil determined by HPLC in a UK sandy loam soil and a German sandy soil under aerobic conditions were 128 and 308 days respectively, in the standard test conditions. The recalculation to reflect an average EU outdoor temperature (12°C according to the TGD) gives half lives of 362 and 871 days respectively.
Degradation proceeded mainly via hydrolysis to RPA 200766 (35.7% at day 336) and oxidation to MB 46136 (22.43% at day 336). Small quantities of MB45950 (<5%) formed by reduction and MB46513 (1%) formed by photolysis were also detected in soil. The un-extractable soil residues remained low reaching a maximum of ca 15%.

In the study A7.2.2.1/01 of [^{14}C]-Fipronil degradation in four soils at 20°C and two soils at 10°C, Fipronil was steadily degraded under aerobic conditions by hydrolysis to RPA 200766 (38.44% at day 219) and by oxidation to MB 46136 (34.34% at day 182). The rate of degradation was temperature dependent with more rapid degradation at 20°C than 10°C. The rate of degradation was also related to the soil microbial biomass activity.
The reduced metabolite MB 45950 was found in minor quantities (<10%), except in one soil (16.99% at day 91) where there was reduced oxygen status under these laboratory conditions. Several other minor metabolites were also observed, the hydrolysis products RP 200761 and RPA 105320 in the high pH and high biomass soil. The DT_{50} of Fipronil ranged from 31 to 304 days at 20°C and the DT_{90} from 102 to 1010 days. At 10°C, the DT_{50} of Fipronil ranged from 358 to 686 days, and the DT_{90} from 1189 to 2279 days. It was not possible to derive the DT_{50} values for the metabolites. The level of un-extractable soil bound residues was low (max. 10%). No volatile products were detected.

The geometric mean value (DT_{50}) of 334 days from all the submitted studies (with converted half-lives at 12°C) was calculated.

From laboratory studies, the two major metabolites of Fipronil identified in soil are RPA 200766 and MB46136.

5.1.2 Summary and discussion of degradation

According to the results presented above, Fipronil is not readily biodegradable.

Two metabolites are considered as relevant in soil : RPA 200766 and MB 46136.

5.2 Environmental distribution

Method	Results					Remarks
Adsorption/ desorption test USEPA 163-1 Soil 1 : Speyer 2.2 Loamy sand, Soil 2 : Sandy loam Soil 3 : Loam Soil 4 : Sandy-clay-loam-1 Soil 5 : Sandy-clay-loam-2	Absorbed a.s. [%] Not given	K_a 1 14.32 4.19 20.69 9.32 10.73	K_{aOC} 2 427 1248 486 800 673 Mean value: 727	K_d 3 13.35 7.25 21.51 10.14 12.88 Mean value: 13.03	K_{dOC} 4 398 2162 506 870 808 Mean value: 949	1 K_a = Adsorption coefficient 2 K_{aOC} = Adsorption coefficient based on organic carbon content. 3 K_d = Desorption coefficient). 4 K_{dOC} = Desorption coefficient based on organic carbon content

5.2.1 Adsorption/Desorption

The soil adsorption/desorption properties of [^{14}C]-Fipronil were investigated using five European soil types using the slurry technique. The adsorption constants (K) obtained ranged from 4.19 in a UK sandy loam to 20.69 in a UK loam. The value of K increased with increasing organic carbon content of the soil suggesting that more fipronil was adsorbed. The K_{OC} values obtained ranged from 427 to 1248 with a mean of 727. The Freundlich desorption constants increased with the increasing desorption cycles, the results suggest that the adsorption was reversible with similar processes involved in the desorption as the adsorption. The results indicated that fipronil is unlikely to demonstrate significant mobility in soil due to its relatively high sorption to soil. According to McCall's designation, fipronil would be expected to show medium to low mobility (Godward, PJ; Quarmby, DL; Austin, D. J, 1993).

5.2.2 Volatilisation

Due to its low vapour pressure of 2 x 10^{-6} Pa and due to its intended uses, fipronil is very unlikely to be present in air.

Moreover, the study Van der Gaauw, A (2001) in which the degradation of the molecule by photo-oxidation in air was estimated using the Atkinson method presents a DT_{50} of 0.167 day (24h photoperiod). Reactions of Fipronil with OH-radicals or with ozone are supposed to be improbable.

5.2.3 Distribution modelling

Not performed.

5.3 Aquatic Bioaccumulation

Table 8: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
USEPA - N, 165-4 Flow through	BCF = 321 L/kg (whole fish)	Log K_{ow} = 3.5-4.0 Metabolites : MB045950, MB046136: rapidly eliminated Initial concentration of a.s.: 0.85 µg/L Depuration time >99% eliminated from whole fish within 14 days.	Chapleo, S. Hall, B. E. (1992)
TGD for Risk assessment part 2 section 3.8.3.2	BCF=501	Calculated value from log Kow=4	Chabassol Y Reynaud R (1991)

5.3.1 Aquatic bioaccumulation

5.3.1.1 Bioaccumulation estimation

Prediction of the BCF for fish according to the "TGD for Risk Assessment" Part II Section 3.8.3.2 (2003) gives a calculated value of 501 based on the log K_{ow} of 4.

5.3.1.2 Measured bioaccumulation data

Since fipronil has a log K_{ow} greater than 3 the potential for bioaccumulation should be considered. This has been addressed in a bioconcentration study with fish (Chapleo, S. Hall, B. E., 1992) in which the bioconcentration factor and bioaccumulation potential of [^{14}C]-labelled fipronil were measured in bluegill (*Lepomis macrochirus*). The test comprised an uptake phase (continuous flow-through over 35 days) and a depuration stage (14 days continuous flow-through in untreated medium). The uptake kinetics were considered to approach a simple 2-compartment model with measured BCF at steady state close to theoretical values predicted based on the log K_{ow} (501 assuming a log K_{ow} of 4 according to TGD). The steady-state bioconcentration factor (BCF) estimated in whole fish was 321 (see table 22). Uptake residues were rapidly and nearly completely (>99%) eliminated from whole fish within the 14-day depuration phase. The results of this study indicate low concern on the bioaccumulation of fipronil in aquatic animals.

5.3.2 Summary and discussion of aquatic bioaccumulation

The rapid depuration found in the study indicates low potential for steady bioaccumulation of fipronil in fish.

5.4 Aquatic toxicity

Table 9: Summary of relevant information on aquatic toxicity

Method			**Results (µg a.s./L)**	**Remarks**	**Reference**
Secondary consumers	Acute toxicity to **fish**	(*Lepomis macrochirus*- 96h LC50) US EPA FIFRA 72-1	LC_{50} = 85.2 (mmc)	F	Scott-Ward, G (1990) R1
		(*Oncorhynchus mykiss* - 96h LC50) US EPA FIFRA 72-1	LC_{50} = 248 (mmc)	F	Ward G.S.(1991)*
		(*Cyprinus carpio* - 96h LC50) OECD 203	LC_{50} = 430 (mmc)	F	Handley J.W., Sewell I.G., Bartlett A.J.(1991)*
		(*Ictalurus punctatus*- 96h LC50) US EPA FIFRA 72-1	LC_{50} = 560 (mmc)	F	Dionne E. (1997)*
	Chronic toxicity to **fish**	(*Oncorhynchus mykis*- 90d NOEC) US EPA FIFRA 72-4	NOEC = 15 [a] (mmc)	ELS/F Fipronil (96,7%)	Machado, M W (1992) / R1
	Acute toxicity to **saltwater fish**	(*Cyprinodon variegatus* – 96h LC50) USEPA FIFRA 72-3	LC_{50} = 130 (mmc)	F	Machado, M W (1993)*
	Chronic toxicity to **saltwater fish**	(*Cyprinodon variegatus* – 35d NOEC) USEPA FIFRA 72-4	NOEC = 2.9 [b] (mmc)	ELS/F	Sousa J.V. (1998)*
		(*Cyprinodon variegatus* – NOEC) USEPA FIFRA 72-5	NOEC = 6 (mmc)	LC/F	Dionne E. (2000)*
Primary consumers	Acute toxicity to **freshwater invertebrates**	***(Chironomus dilutus – 96h EC50) Recent study from American Chemical Agency***	**EC50= 0.0325 (imc)**	**S**	**Weston, D.P., 2014** [c]
		(Fallceon quilleri **– 48h EC50) Recent study from American Chemical Agency**	**EC50= 0.077 (imc)**	**S**	**Weston, D.P., 2014** [d]
		(*Daphnia magna* – 48h EC50) USEPA FIFRA Guideline 72-2	EC_{50} = 190 (mmc)	F	McNamara P.C (1990) / R2[e]
		(*Hexagenia sp.* – 96h LC50) ASTM Guideline E-729	LC_{50} = 0.44 (mmc)	SS Fipronil (99.7%)	Putt, A.E., 2003 / R1
		(*Daphnia magna* – 48/96h EC50) USEPA FIFRA 72-2	EC_{50} = 12.9 (mmc)	F	Ward G.S., Rabe B.A. (1989)*
	Chronic toxicity to **freshwater invertebrates**	(*Daphnia magna* – 21d NOEC) OECD Guideline 202 Part II, *Daphnia* sp. Reproduction Test (adopted April 1984).	NOEC= 9.8 [d] (mmc)	F	Machado, M W (1992) McNamara P.C. (1990) / R2[f]

		(Chironomus riparius- 28d NOEC) OECD Draft guideline 219 "Sediment-Water Chironomid Toxicity Test Using Spiked Water"	NOEC = 0.12 [e]	S Fipronil (99,14%)	Funk, M (2004) /R2[g]
	Acute toxicity to **saltwater invertebrates**	*(Crassostrea virginica* – 96h EC50) USEPA FIFRA 72-3	EC_{50} = 770 (mmc)	F	Dionne E. (1993)*
		(Mysidopsis bahia – 96h LC50) USEPA FIFRA 72-3	LC_{50} = 0.14 (mmc)	S	Machado M.W. (1994)*
	Chronic toxicity to **saltwater invertebrates**	***(Mysidopsis bahia* – 28d NOEC)** **USEPA FIFRA 72-4**	**NOEC = 0.0077 (mmc)**	**F**	**Machado M.W. (1995) / R1**
		(Mysidopsis bahia – 28d NOEC) OPPTS Draft Guideline 850.1350	NOEC = 0.06 (imc)	S	Cafarella, M.A.(2005) / R1
Primary producers	Toxicity to **freshwater algae and aquatic plants**	*(Scenedesmus subspicatus* – 96h) OECD Guideline No. 201 and EEC Commission Directive 87/302	E_bC_{50} = 68 [f] (nc+) NOE_rC = 40(nc+)	S	Handley, J. W.; Mead, C.; Bartlett, A. J (1991) / R2[h]
		(Selenastrum capricornutum – 120h) USEPA FIFRA Guidelines 122-2 and 123-2	EC_{50} > 140 (mmc)	S	Hoberg J.R. (1993)*
		(Anabaena flos-aquae - 120h) USEPA FIFRA Guidelines 122-2 and 123-2	EC_{50} > 170 (mmc)	S	Hoberg J.R. (1993)*
		(Navicula pelliculosa - 120h) USEPA FIFRA Guidelines 122-2 and 123-2	EC_{50} > 120 (mmc)	S	Hoberg J.R. (1993)*
		(Lemna gibba – 14d) USEPA FIFRA Guidelines 122-2 and 123-2 (1982)	NOEC > 81[g] (mmc)	S	Hoberg, J.R. (1991) / R2[i]
	Toxicity to **saltwater algae**	*(Skeletonema costatum*- 120h) USEPA FIFRA 122-2 and 123-2	EC_{50} > 140 (mmc)	S	Hoberg J.R. (1993)*

ELS: early life-stage; LC: full life -cycle;
S: Static; SS: Semi-static; F: Flow-through;
R1/R2 : reliability of the study
mmc: mean measured concentration; nc+ = nominal concentrations with analytical verification, imc = initial measured concentration
[a] NOEC calculated from larval survival (refer to Machado, M W (1992) for full details).
[b] NOEC corresponds to the highest concentration tested. Data are from the pesticide risk assessment document of fipronil.
[c] EC50 calculated from inability to thrash when gently prodded
[d] EC50 calculated from inability to swim[e] The results show an unclear concentration-effect relationship: at test termination, 85, 35, 0, 10 and 5 % of the daphnids were immobilised in the treatment levels of 280, 160, 110, 52 and 34 µg/L respectively.
[f] NOEC calculated from mean body length. During the final six days of the study, survival of the dilution water control daphnids unexpectedly decreased (50%), thus all the statistical comparisons to determine treatment level effects have been performed using the solvent control data.
[g] The NOEC in this study (spiked water, 28-d) based on initial measured water concentrations is 0.120 µg/L. Considering a degradation half-life in water/sediment of 32.53 days at 20°C, the NOEC value became 0.091 µg/L..Nevertheless as it was stated at the biocide technical meeting IV-09, since the initial measured concentrations were in the same range that the TWA concentration, the initial measured concentrations (0.12µg/L) were used to the risk assessment.

Concentrations in water of fipronil in the spiked-water toxicity test on sediment-dwelling organisms.

Nominal Water Concentrations ng/l	Initial Water Concentrations (measured) ng/l	Initial measured corrected for radiochem purity ng/L	TWA Water concentrations (estimated) ng/l

7.3	9.8	7.2	5.42
14.6	20.2	14.7	11.07
29.2	40.9	29.9	22.52
58.4	80.5	58.8	44.28
116.8	**165.1**	**120.5**	**90.75**
233.6	332.8	242.9	182.93

[h] According to OECD Guideline 201, the test endpoint is inhibition of growth (ErC50) expressed as average growth rate over the test duration (normally days 0-3). As the ErC50 has been calculated from the average daily growth 24 – 48 hours (days 1-2), the obtained value (ErC50 = 74 µg a.s./L) is not considered reliable. The additional endpoint EbC50 is calculated from the area under the growth curve.
[i] NOEC based on frond number and corresponds to a significant effect of 7.7 %. Only one concentration was tested (Han Hoberg, J. R.(1991) for full details).
*Studies not submitted for biocide risk assessment but submitted in the pesticide risk assessment document of fipronil.

Based on aquatic toxicity testing, the most sentitive trophic level for fipronil is invertebrates. Therefore, the details of the two key studies used for deriving acute and chronic M-factors are presented in section 5.4.2 below.

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

Four acute studies for freshwater fish species are listed for fipronil with a lowest LC_{50} of 85.2 µg/L (based on mean measured concentrations). One acute toxicity test for saltwater fish is also listed with a LC_{50} of 130 µg/L (based on mean measured concentrations)

5.4.1.2 Long-term toxicity to fish

One long-term study for freshwater fish species is listed for fipronil with a NOEC value of 15 µg/L (based on mean measured concentrations). Two chronic toxicity studies for saltwater fish are also listed with a lowest NOEC of 2.9 µg/L (based on mean measured concentrations)

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

Freshwater invertebrate species
For the short term toxicity of fipronil to aquatic invertebrates (Chironomidae, Culicidae and Decapoda) non GLP (Good Laboratory Practice) studies may provide valuable additional information. The whole set of data from GLP studies along with the information from the scientific literature (see table 23 above) clearly shows that insects are undoubtly the most sensitive taxonomic group to short-term exposure and that Chironomidae is the most sensitive species studied.

A recent publication (D.P.Weston and M.J.Lydy, 2014) assesses the toxicity of Fipronil on 14 benthic macroinvertebrates species. In this study, several invertebrates are tested. *Hyalella azteca* and *Chironomus dilutus* were obtained from cultures maintained at the University of California Berkeley. *Hexagenia sp*. (25−30 mm long) was field-collected from the Great Lakes region, and provided by a commercial supplier (Aquatic Research Organisms, Hampton, NH). All other species (*Baetis tricaudatus, Diphetor hageni, Fallceon quilleri, Serratella micheneri, Ephemeralla excrucians, Taenionema sp., Isoperla quinquepunctata, Tricorythodes sp., Hydropsyche sp., Nectopsyche sp., Helicopsyche sp*.) were obtained between February 2012 and April 2013 from northern California waterbodies in areas with minimal development. Leaf litter bags were placed in creeks for approximately two weeks, after which animals were sorted from the litter, and acclimated to laboratory water for 24 h. Although the tests were generally conducted 96-h tests, preliminary tests with some species produced unacceptable mortality, so tests for those species were limited to 48 h.
Tests were done using Milli-Q purified, deionized water made moderately hard by addition of salts. Waters were spiked with fipronil (ChemService, West Chester, PA) dissolved in acetone. Acetone concentrations were <36 µL/L, and

solvent controls never showed any toxicity. Test waters were distributed to three replicate vessels per concentration, with a control and 4−7 concentration steps separated by a factor of 2 (e.g., 2, 4, 8, 16, and 32 ng/L). Glass exposure vessels ranged from 100 mL (*H. azteca*) to 2000 mL (*Hexagenia sp*.), depending on the species. Ten individuals per beaker were used for cultured species; 4−6 individuals per beaker were used for field-collected species for which availability was limited. Tests were done under fluorescent lights with a 16-h light:8-h dark photoperiod. All test vessels contained a 25-cm^2 nylon screen to which the animals could cling, except the *H. azteca* screen which was 1 cm^2. *C. dilutus* received a thin layer of quartz sand for tube building, and *Hexagenia sp*. received glass tubes to mimic their burrows. *H. azteca* and *C. dilutus* were fed 1 mL of yeast/cerophyll/trout food or 0.5 mL of Tetrafin fish food slurry, respectively, on the second day. After 4−6 h to allow for feeding, 80% of the water was replaced with freshly prepared pesticide-spiked solutions. Water change procedures were identical for field-collected species, but they were not fed during tests since appropriate diets have not been established for these nontraditional test species. Water from a concentration step near the expected EC50 based on preliminary tests was analyzed by methods described below for verification of initial Fipronil concentration, with compositing solutions prepared on days 0 and 2. Actual concentrations were near nominal (median 95% of nominal; range 66−131%), but all data were adjusted to reflect actual initial concentrations.

At test completion the number of survivors was recorded and many animals were alive but unable to move normally. A sublethal end point was also reported, which varied depending on the species' normal behavior. That endpoint was inability to swim for *Ephemeroptera* (that normally readily do so), or inability to cling to the nylon screen for *Plecoptera* (that typically do so tenaciously). The sublethal end point for Trichoptera was inability to thrash when gently prodded (*Hydropsyche sp*.), inability to cling to the screen (*Helicopsyche sp*.), or inability to crawl (*Nectopsyche sp*.). To minimize stress on field-collected animals, tests were conducted at in situ temperatures of each species' collection site, ranging from 8 to 23 °C. The effect of temperature on fipronil toxicity was shown to be slight at best, and negligible in comparison to the interspecific EC50 differences, based on preliminary fipronil toxicity assessment to laboratory-cultured *C. dilutus* at 13, 18, and 23 °C.

Probit analysis and CETIS software (Tidepool Scientific Software, McKinleyville, CA) were used to derive EC50 and LC50 values. Two independent tests were done with cultured species, but field-collected species were in sufficient numbers for only one test. Control survival is reported for all tests. The lowest survival was 69% (*Taenionema sp.* tested with fipronil), although in two-thirds of the tests survival was 90% or greater. While 90% is often used as a threshold for acceptability when testing with standard species, as these tests are performed with nonstandard species for which optimal testing conditions have not been established, the author believes some latitude is appropriate. Water quality parameters monitored included temperature, dissolved oxygen, conductivity, pH, alkalinity, hardness, and ammonia.

Among the 14 species tested, four species were more sensitive than any previously studied, indicating that fipronil's acute toxicity to aquatic life could be underestimated.The most sensitive specie to fipronil was *C. dilutus* with a 96-h EC50 of 30−35 ng/L based on the sublethal endpoint ability to thrash when prodded. The thrashing endpoint was assessed using visual analyse described in Pape-Lindstrom and Lydy (1997). The animal, when it thrashes, creates an S shape in one direction, then a backward S in the other direction, which when they do it fast gives the impression of a figure 8. The ones affected by fipronil don't thrash with the same intensity (at most they might make a very sluggish S shape), giving an EC50 = 32,5 ng/L (based on initial measured concentrations).The next-most sensitive species was *Fallceon quilleri* with a 48-h EC50 of 70.7 ng/L ((based on initial measured concentrations), approximately 2- to 3-fold higher, based on the sublethal endpoint inability to swim .

Species	**Control survival (%)**	**EC50 (ng/L)**	**LC50 (ng/L)**
C. dilutus (test 1) – 96h	83	35.0 (21.1-41.5)	>81.5
C. dilutus (test 2) – 96h	87	30.0 (23.3-36.0)	>81.5
Fallceon quilleri – 48h	77	70.7 (36.5-93.5)	>187

For those two species, the control showed respectively a survival of 85% and 77%. Those values are slightly under the 90% threshold of acceptability usually used when testing with standard species. However, as stated by the author, these studies use non-standard species for which optimal testing conditions have not been established and FR MCSA believes that these values are acceptable.

Even if those tests follow a non-normalised protocol (no short-term protocol does exist), it follows EPA guideline for water composition (Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms – EPA) and the OECD guidelines proposal for the test conditions (OECD GUIDELINES FOR THE TESTING OF CHEMICALS – Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment). Therefore, even if those two guidelines refer to long-term exposure with other endpoints, the test conditions used seem to be relevant for the test performed. Furthermore, the test duration matchs with the EPA manual recommendations for acute testing for several invertebrate species (2002) which allows 24, 48 or 96h exposures. Therefore, FR-MSCA proposes to consider these studies in the assessment of classification for fipronil.

Saltwater invertebrate species
The literature database provides two studies, which are not GLP, on the short-term toxicity of fipronil to the crustacean *Mysidopsis bahia*. Results of this 96-hr fipronil toxicity test showed a lowest LC_{50} of 0.14 µg/L.

5.4.2.2 Long-term toxicity to aquatic invertebrates

Freshwater invertebrate species
The database of regulatory laboratory studies on the toxicity of fipronil to aquatic invertebrates, which is summarized above, shows that insects are generally the most sensitive group of freshwater organisms as could be expected for an insecticide. The lowest chronic NOEC value was found at 0.12 µg/L from a spiked-water test with *Chironomus riparus*.

Saltwater invertebrate species
The literature database provides two studies on the long-term toxicity of fipronil. The lowest NOEC value was found at 0.0077 µg/L, from a 28-days test on *Mysidopsis bahia* (mysids). in a study carried out by Machado M.W. 1995). In this study, fipronil was tested in a 28-day life-cycle toxicity test with mysids (≤ 24 hours old) under flow-through conditions according to the requirements of FIFRA Guideline 72-4. In the study, the nominal concentrations 4.4, 8.8, 18, 35 and 70 ng a.s./L (mean measured concentrations 5.0, 7.7, 15, 28 and 57 ng/L) were tested and compared to a solvent and dilution water control. Tested endpoints were survival, behaviour, reproduction success and growth (total body length and dry weight) of the mysids. Test groups consisted of two replicate aquaria with 30 mysids each (in two retention chambers with 15 mysids each) per concentration. At maturity of the mysids (day 15 of exposure), 10 pairs were transferred into pairing chambers. The remaining mysids were maintained until the end of the chronic test and served to replace any dead males in the pairing chambers, if necessary. Dead females were not replaced. After males and females had been paired, the number of dead males and females, the number of offspring produced by each individual female, and any abnormal appearance or behaviour was recorded daily. Dead parental mysids and offspring were recorded, removed, and discarded when observed during the test. The statistical method to be used to evaluate the results was the Williams' Test, coupled with Bartlett's test for determination of homogeneity of variances.Survival of both males and females, length and dry weight of females and reproductive success were statistically comparable to the pooled control up to and including 28 ng a.s./L. Male length was significantly different at and above 15 ng a.s./L, and male dry weight was significantly different at and above 5.0 ng a.s./L. Based on these comparisons, male dry weight was identified as the statistically most sensitive parameter. However, the difference in the male body-weight was 10-16% compared to pooled control, without dose-response throughout a concentration range spanning a factor of 10X. For this reason, the difference in the male body weight was not considered as indicator of toxicity of Fipronil to mysid shrimps. The LOEC for Fipronil and mysid shrimp was based on effects on male length and determined at 15 ng a.s./L and above, since there was a clear and consistent dose-response observed in this parameter. Consequently, the overall NOEC was determined at 7.7 ng a.s./L (based on mean measured concentrations).

5.4.3 Algae and aquatic plants

Two studies are listed for freshwater algae and aquatic plants. The most sensitive test is a 96 hours exposure of *Scenedesmus subspicatus* in static conditions, which shows a EbC50 = 68 µg/L and a NOErC = 40 µg/L (nominal concentration with analytical verification).

5.4.4 Other aquatic organisms (including sediment)

Three toxicity tests on sediment dwelling organisms (*Chironomus sp.*) are available. In one long-term study the test substance was applied to the overlying water in the test vessels (Funk, M, 2004) while in the other study the test substance was applied into sediment (Putt A.E., 2003).
A last chronic toxicity test on *Chironomus riparius* with spiked sediment system complete the available data on sediment compartment.

Table 24 : Toxicity of fipronil to freshwater sediment-dwelling invertebrates

Method		**Results (µg a.s./kg dry sediment)**	**Remarks**	**Reference**
Toxicity to sediment dwelling organisms	(Chironomus riparius - 28d) OECD Draft guideline 219 "Sediment-Water Chironomid Toxicity Test Using Spiked Water"	NOEC = 0.143	S, Fipronil (99.14%)	Funk, M (2004) / R2
	(Chironomus tentans - 10d) EPA OPPTS 850.1735 "Whole Sediment Acute Toxicity Invertebrates, Freshwater"	LC50 = 30 (mmc) NOEC = 16 (mmc)	SS, Fipronil (98.3%)	Putt A.E.(2003) / R2
	(Chironomus riparius - 28d) OECD Guideline 218 "Sediment-Water Chironomid Toxicity test Using Spiked Sediment"	NOEC = 1.39 (mmc)	S, Fipronil (95.4%)	Backfisch, K. and Weltje, L.(2009) R1

S: Static; SS: Semi-static; F: Flow-through;
mmc: mean measured concentration;
R1/R2 : reliability of the study

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

Regarding all available toxicity data, invertebrates are the most sensitive species for acute and chronic effects. These results are used to classify the active substance fipronil.

Considering that the 96h-EC_{50} = 0.0325 µg/L value was obtained for *Chironumus dilutus* is lower than 1 mg/L, fipronil meets the criteria for classification as **Aquatic Acute 1** for environmental hazard according to CLP criteria. This value is extracted from a recent publication dated on 2014, for which FR-MSCA considers sufficient information available to be considered. As this value is within the range of 0.00001-0.0001 mg/L, an **M-factor of 10000** is allocated.
It is necessary to point out that according to CLP regulation, acute toxicity is usually determined using a CL_{50} 96h for fish, a CE_{50} 48h for crustacean or a CE_{50} 72/96h for algae and other aquatic plant. The regulation also explicates that other species data can be considered if test method is approved.
FR-MSCA considers the study with *Chironomus dilutus* reliable and given that this species has a much longer life-cycle than *Daphnia magna*, FR-MSCA considers that this 96h test can be considered as an acute toxicity test. Therefore FR-MSCA accepts this study for classification.

Considering that fipronil is not readily biodegradable and that the 28d-NOEC = 0.0077 µg/L value obtained for *Mysidopsis bahia* is lower than 0.1 mg/L, fipronil meets the criteria for classification as **Aquatic Chronic 1** for environmental hazard according to CLP criteria. As the value is within the range of 0.000001-0.00001 mg/L, an **M-factor of 10000** is allocated.

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

According to CLP Regulation criteria:

Classification:
Aquatic Acute 1; H400
Aquatic Chronic 1; H410

Acute M-factor: 10000
Chronic M-factor: 10000

Labelling:

Pictogram: 
Signal word: Warning
Hazard statements: H410: Very toxic to aquatic life with long lasting effects

6 REFERENCES

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