CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification:

Pendimethalin (ISO)

N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine

EC Number: 254-938-2

CAS Number: 40487-42-1

Index Number: 609-042-00-X

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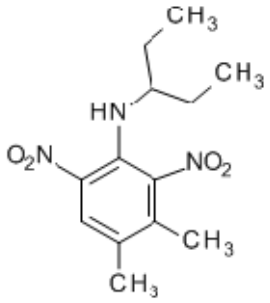
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine
Other names (usual name, trade name, abbreviation)	-
ISO common name (if available and appropriate)	Pendimethalin
EC number (if available and appropriate)	254-938-2
EC name (if available and appropriate)	Pendimethalin
CAS number (if available)	40487-42-1
Other identity code (if available)	CIPAC No. 357
Molecular formula	$C_{13}H_{19}N_3O_4$
Structural formula	
SMILES notation (if available)	CCC(CC)Nc1c(cc(C)c(C)c1N(=O)(=O))N(=O)(=O)
Molecular weight or molecular weight range	281.3 g/mol
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Not relevant
Description of the manufacturing process and identity of the source (for UVCB substances only)	Not relevant.
Degree of purity (%) (if relevant for the entry in Annex VI)	≥ 90%

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	**Concentration range (% w/w minimum and maximum in multi-constituent substances)**	**Current CLH in Annex VI Table 3.1 (CLP)**	**Current self-classification and labelling (CLP)**
Pendimethalin	≥ 90%	Skin Sens. 1 (H317)	Acute Tox. 4 (oral)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
CAS 40487-42-1		Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling
1,2-dichloroethane CAS 107-06-2	≤ 1 g/kg	Flam. Liq 2 (H225) Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOS SE 3 (H335) Carc. 1B (H350)	-	No
Nitroso-pendimethalin	≤ 45 mg/kg	None	-	No

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
None					

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 5: Existing and proposed harmonised classification and labelling according to the CLP criteria for pendimethalin

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	609-042-00-X	pendimethalin (ISO); N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine	254-938-2	40487-42-1	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09	H317 H410	-	-	-
Dossier submitters proposal	609-042-00-X	pendimethalin (ISO); N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine	254-938-2	40487-42-1	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 **Modify** Skin sens. 1B	**Retain** H317 H400 H410 **Add** H361d	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H317 H410 **Add** H361d	-	M = 100 M = 10	-
Resulting Annex VI entry if agreed by RAC and COM	609-042-00-X	pendimethalin (ISO); N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine	254-938-2	40487-42-1	Skin Sens. 1B Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	H317 H361d H400 H410	GHS07 GHS08 GHS09 Wng	H317 H361d H410		M = 100 M = 10	

Table 6: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	Hazard class not assessed in this dossier	No
Flammable gases (including chemically unstable gases)	Hazard class not assessed in this dossier	No
Oxidising gases	Hazard class not assessed in this dossier	No
Gases under pressure	Hazard class not assessed in this dossier	No
Flammable liquids	Hazard class not assessed in this dossier	No
Flammable solids	Hazard class not assessed in this dossier	No
Self-reactive substances	Hazard class not assessed in this dossier	No
Pyrophoric liquids	Hazard class not assessed in this dossier	No
Pyrophoric solids	Hazard class not assessed in this dossier	No
Self-heating substances	Hazard class not assessed in this dossier	No
Substances which in contact with water emit flammable gases	Hazard class not assessed in this dossier	No
Oxidising liquids	Hazard class not assessed in this dossier	No
Oxidising solids	Hazard class not assessed in this dossier	No
Organic peroxides	Hazard class not assessed in this dossier	No
Corrosive to metals	Hazard class not assessed in this dossier	No
Acute toxicity via oral route	Hazard class not assessed in this dossier	No
Acute toxicity via dermal route	Hazard class not assessed in this dossier	No
Acute toxicity via inhalation route	Hazard class not assessed in this dossier	No
Skin corrosion/irritation	Hazard class not assessed in this dossier	No
Serious eye damage/eye irritation	Hazard class not assessed in this dossier	No
Respiratory sensitisation	Hazard class not assessed in this dossier	No
Skin sensitisation	Hazard class assessed in this dossier, Subcategory (1B) added to the current classification.	**Yes**
Germ cell mutagenicity	Hazard class not assessed in this dossier	No
Carcinogenicity	Hazard class not assessed in this dossier	No
Reproductive toxicity	Harmonised classification proposed (Cat. 2)	**Yes**
Specific target organ toxicity-single exposure	Hazard class not assessed in this dossier	No
Specific target organ toxicity-repeated exposure	Hazard class not assessed in this dossier	No
Aspiration hazard	Hazard class not assessed in this dossier	No
Hazardous to the aquatic environment	Hazard class assessed in this dossier, No change to existing entry: Aquatic Acute 1 and Aquatic Chronic 1. Proposal for M-factors added.	**Yes**
Hazardous to the ozone layer	Hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Pendimethalin has previously been assessed for harmonised classification by TC C&L. Pendimethalin has a Annex VI entry as Skin Sens 1 (H317), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Pendimethalin was previously approved as a plant protection product active substance in 2003. Pendimethalin has recently been re-evaluated and renewed under Regulation (EC) 1107/2009 as of the 1st of September 2017.

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

[B] Justification that action is needed at Community level is required.

Reason for a need for action at Community level:

Change in existing entry due to changes in the criteria/new interpretation of existing data

Further detail on need of action at Community level

After evaluation of the available data in the context of the renewal of pendimethalin a change in the current harmonized classification is proposed. The proposed changes consist of addition of the subcategory 1B to the current classification as skin sensitizer and addition of M-factors to the current classification for aquatic toxicity. In addition, during Pesticide Peer Review Meeting (TC 119) it was concluded that pendimethalin should be classified as Repr. Cat. 2 (H361d) on the basis of a re-evaluation of the existing developmental toxicity studies. Indeed, in the developmental toxicity study in rabbits, increased incidence of less than twelve pairs of ribs and missing/incomplete vertebrae were observed in the absence of maternal toxicity.

5 IDENTIFIED USES

Pendimethalin is used as an herbicide.

6 DATA SOURCES

This CLH report was prepared based on the dossier submitted and the renewal assessment report (RAR) prepared in the context of the renewal evaluation of pendimethalin.

7 PHYSICOCHEMICAL PROPERTIES

The information in Table 8 was derived from the renewal assessment report (RAR) of pendimethalin and the EFSA conclusion. A reference list has been included in Annex I.

Table 7: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	orange-yellow solid	Kroehl T., 2011	Measured.
Melting/freezing point	56°C	Kroehl T., 2011	Measured.
Boiling point	246-251°C (overlapped by beginning decomposition in this	Walter D., 2002	Measured.

Property	Value	Reference	Comment (e.g. measured or estimated)
	temperature range)		
Relative density	-		
Vapour pressure	1.39 x 10^{-3} Pa at 20°C 3.34 x 10^{-3} Pa at 25°C	Schneider V., 2001	Measured.
Surface tension	Not required.		
Water solubility	pH 4: 0.260 mg/L at 20°C pH 6: 0.309 mg / l at 20°C pH 9: 0.265 mg / l at 20°C	Walter D., 2000	Measured.
Partition coefficient n-octanol/water	log Pow = 5.4, at 20°C pH 6.5	Walter D., 2001	Measured.
Flash point	175.5°C	Loehr S., 2011	Measured.
Flammability	Non-flammable	Loehr S., 2011	Measured.
Explosive properties	Not explosive	Loehr S., 2011	Measured.
Self-ignition temperature	321°C	Loehr S., 2011	Measured.
Oxidising properties	Not oxidising	Loehr S., 2011	Measured.
Granulometry	No data.		
Stability in organic solvents and identity of relevant degradation products	No data.		
Dissociation constant	pKa = 2.8	American Cyanamid, 1992	Measured.
Viscosity	No data.		

8 EVALUATION OF PHYSICAL HAZARDS

Not addressed in this dossier.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

The mammalian toxicity studies of pendimethalin were assessed in the Renewal Assessment Report (February 2012) in the context of the renewal of the approval (Reg. (EU) No. 2017/1114), under Reg. (EC) 1107/2009. All studies were carried out under GLP unless indicated otherwise. The non-GLP studies were conducted prior to GLP. Generally studies were conducted in accordance with OECD test guideline except for the studies for which no OECD Guideline were available at the time of conduct of the study. All studies were considered acceptable (Klimisch Score 1 or 2) unless indicated otherwise in the remarks.

Table 8: Summary table of toxicokinetic studies

Method	Results	Remarks	Reference
ADME study in rats	70% excreted via feces, 20%	Study not	Study 1, IIA

Method	Results	Remarks	Reference
Non-guideline (not available at time of study), Single dose oral (7.3 and 37 mg/kg bw) Royal Hart Wistar rats, 1 or 2 males per group	via urine 24 hours post-treatment	acceptable. Number of animals too low Metabolite distribution reported in study 2 (Doc ID PM 10-757)	5.1.1/01 DocID PD-M-9-94
ADME study in rats Non-guideline (not available at time of study) Single dose, oral (7.3 and 37 mg/kg bw) Royal Hart Wistar rats, 1 or 2 males per group	Identified metabolites in muscle and blood CL202,347, CL99,900, CL113,072 Identified metabolties in fat CL202,347, CL113,066 and CL99,900	See remarks study 1 (PD-M-9-94)	Study 2, IIA 5.1.1/02 DocID PD-M 10-757
ADME study in rat Non-guideline, Single dose, 37 mg/kg bw. Sprague-Dawley rats, 4/rats per group	Absorption 57% (bile + urine) Predominatly glucuronide conjugates as metabolites.	-	Study 3, UUA 5.1.1/04 = Doc ID MET 00-004
ADME study in rats OECD 417 Single dose, 35 mg/kg bw Wistar rats 10 males, 10 females/dose	>58% excreted via faeces, <31% via urine. Main metabolites M455H015, M455H026/M455H027, M455H047 / M455H048 and M455H050.	-	Study 4, KCA 5.1.1/1 DocID 2011/1070049
ADME study in rats OECD 417 7.3 and 37 mg/kg bw (oral); 7.3 mg/kg bw (intravenous) Wistar rats, 4 females per dose group	Rapid metabolism (parent not detected at 1hr after administration). Tmax metabolites: 8 hours, T1/2 metabolites: ~3 hours	-	Study 5, KCA 5.1.1/3 DocID 2009/1102210

9.1 Short summary and overall relevance of the provided toxicokinetic information on the proposed classification(s)

Two new ADME studies were performed for the purpose of the renewal. Different nomenclature was used in the new studies to identify the metabolites compared to the old studies. The following table matches the old nomenclature to the new one.

Old studies	New studies		Common Term
CL code	BASF metabolite	Reg No.	
CL 92,553	BAS 455 H/M455H000	900072	Pendimethalin
CL 99,900	M455H001	4108474	Acid metabolite
CL 113,066	-	4108469	
CL 113,071	M455H048	4108076	
CL 113,072	M455H050	4108077	
CL 202,078	-	4110478	

CL 202,345	M455H047	4110479	
CL 202,347	M455H025	4110480	Alcohol metabolite
-	M455H029	4982164	Goat metabolite 6
CL 94,756	M455H033	4295966	Metabolite 7
CL 113,070	M455H046	4108075	
CL 206,925	M455H049	4110490	
CL 202,078	M455H065	4110478	
CL 113,066	M455H066	4108469	
CL 206,923	M455H067	4110489	
CL 113,529	M455H068	4108078	
CL 113,530	M455H069	4108079	

Absorption

Results from the biliary excretion study showed that a minimum of 57% of the total dose was absorbed by rats 48 hours after a single oral dose of 35 mg/kg of [^{14}C] CL 92553. The absorption was estimated by pooling the percent total administered doses in bile, urine and cage wash. Approximately 7% of the total dose was excreted in urine (including cage wash) and 50% of the total dose was excreted in the bile.

Distribution

After oral administration, maximum residual radioactivity levels in the soft tissues were found in liver and kidney, while other tissue values of radioactivity were low. After 96 hours, the residual radioactivity in tissues was almost inexistent. Comparison of the 24-hours levels of residual radioactivity for the tissues showed that the levels were reasonably proportional to the administered dose.

A study on plasmakinetics in rat showed that a liver first pass effect with a very high level of biotransformation during resorption and liver passage can be assumed.

Metabolism

The near-quantitative recovery of the administered radioactivity in the excreta indicated that conversion to respiratory $^{14}CO_2$ could not be a significant factor in pendimethalin metabolism. The metabolites identified in the metabolism of pendimethalin in rats indicate an oxidative pathway of degradation. The 4-methyl group on the benzene ring and the N-alkyl side chain of the dinitro-substituted aniline appeared as the predominant sites for oxidation

The pathways for metabolism of pendimethalin in the rat are a) oxidation of the alkyl side chains (methyl and/or 1-ethylpropyl group), that results in hydroxyl and/or carboxyl groups, b) reduction of one or two nitro groups to amine groups and c) cyclisation to a benzimidazole heterocycle. Alongside these transformation steps, some phase I metabolites are conjugated with glucuronic acid, glucose and sulphate. Frequently, cyclisation also occurs upon insertion of units with more than one carbon atom (e.g. insertion of C2/acetate and C18/stearic acid). The proposed metabolic pathway is included in figures 1 and 2 below.

Excretion

In the radiobalance study of pendimethalin, rats received 37 mg/kg of the radiotracer, 95.6 % of the radioactivity was found in excreta within 96 hours after treatment. About 75 % of the dose had been excreted in faeces and 20 % in urine. Pendimethalin was the major compound in the extract of faeces. Not withstanding, a structure for a minor metabolite isolated from faeces, accounting for 4 % of the radioactivity, was proposed to be N-(1-ethyl-2-propenyl)-2,6-dinitro-3,4-xylidine, on the basis of chemical ionization mass spectral data. The metabolites isolated and identified in urine are CL 99,900, CL 113,066, CL 113,072, CL 202,078, CL 202,345 and CL202,347, but existing at least 23 metabolites in urine. Most of the radioactivity in the urine was contributed by 8 metabolites. Metabolite-4 was the principal in urine, while metabolites 5-, 6-, 8-, 9-, 10- and 12 were considered as major metabolites. At least 16 metabolites were detected in the 6-hour urine, 23 metabolites in the 12-hour urine and 21 in 24-hour urine.

The new study submitted for the renewal confirm the results of the older study with the majority of radioacitivity excreted via faeces (>58%) and urine (<31%). In urine, the presence of M455H050 (CL 113,072) and M455H047/M455H048 (CL 202,345/CL 113,071) confirm the results of the previous studies. New metabolites in faeces M455H015, M455H026, M455H027 and M455H031 were also identified. The metabolite patterns in faeces extract were comparable for both sexes. In urine the metabolite pattern were different for female and male rats to some extent. Both share the presence of metabolites M455H050, M455H047 and M455H048, but metabolites M455H001, M455H017 (iso) and M455H019 were only identified in females whereas M455H056 was only found in urine of males.

Figure 1: Proposed Metabolic Pathway (Part 1) Based on Intact Aniline Structure

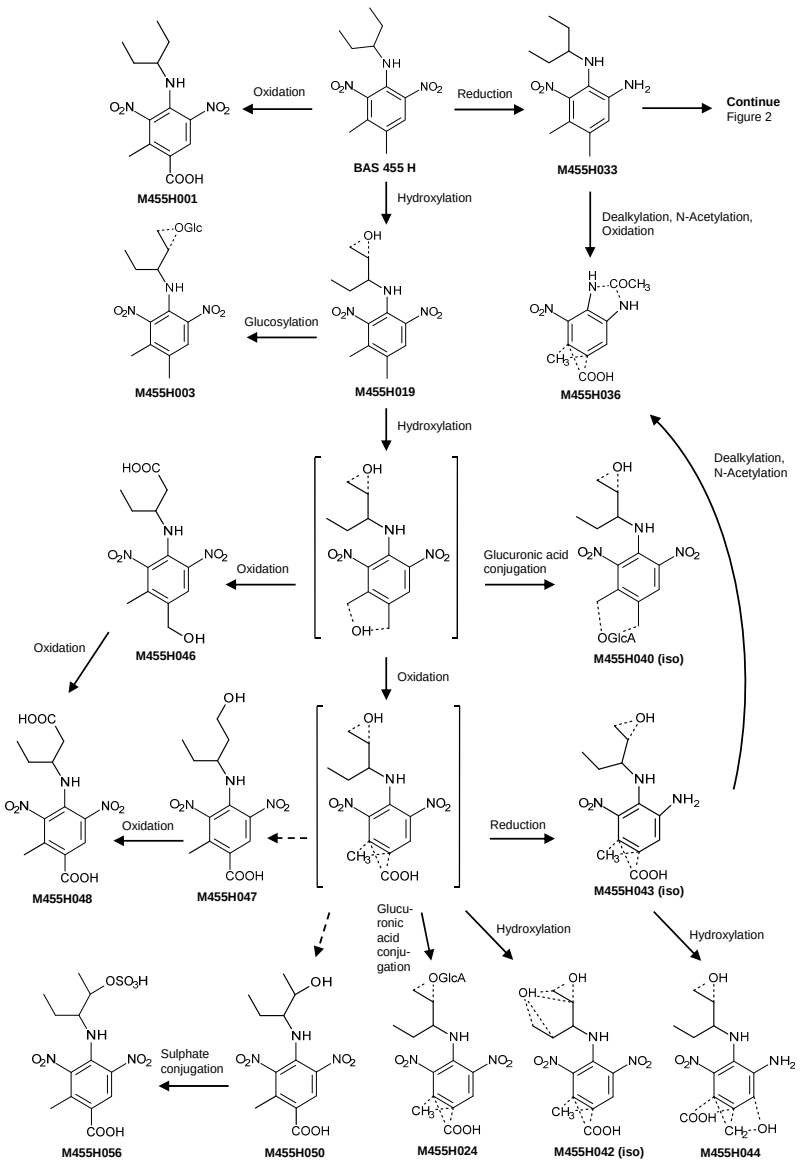
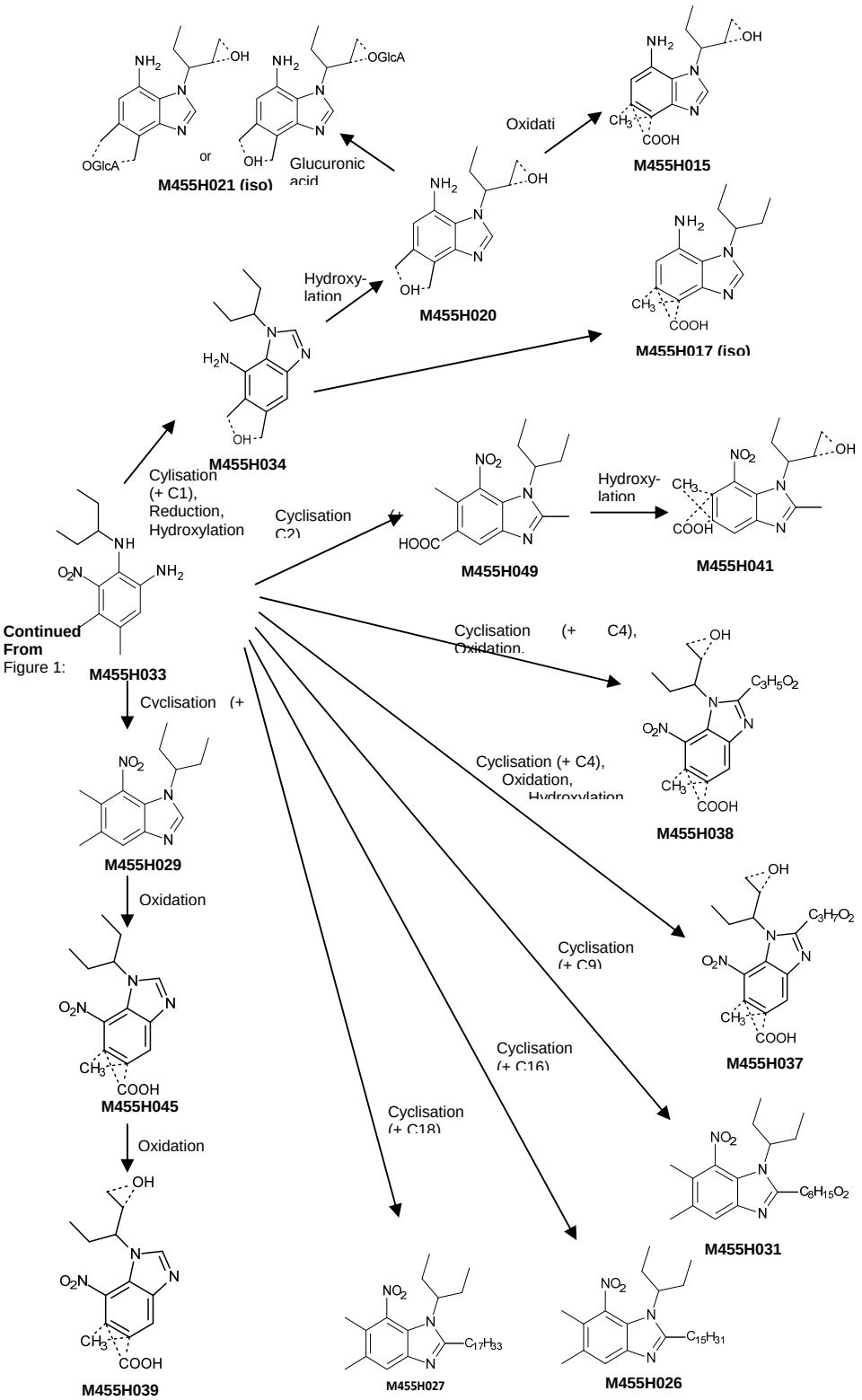

Oxidation
Reduction
Continue
Figure 2
BAS 455 H
M455H001
M455H033
Hydroxylation
Dealkylation, N-Acetylation, Oxidation
Glucosylation
M455H003
M455H019
M455H036
Hydroxylation
Dealkylation, N-Acetylation
Glucuronic acid conjugation
Oxidation
M455H046
M455H040 (iso)
Oxidation
Oxidation
Reduction
M455H048
M455H047
M455H043 (iso)
Glucu-ronic acid conju-gation
Hydroxylation
Hydroxylation
Sulphate conjugation
M455H056
M455H050
M455H024
M455H042 (iso)
M455H044

Figure 2: Proposed Metabolic Pathway (Part 2) Based on a Benzimidazole heterocycle



10 EVALUATION OF HEALTH HAZARDS

10.1 Acute toxicity - oral route

This hazard class has not been evaluated.

10.2 Acute toxicity - dermal route

This hazard class has not been evaluated.

10.3 Acute toxicity - inhalation route

This hazard class has not been evaluated.

10.4 Skin corrosion/irritation

This hazard class has not been evaluated.

10.5 Serious eye damage/eye irritation

This hazard class has not been evaluated.

10.6 Respiratory sensitisation

This hazard class has not been evaluated.

10.7 Skin sensitisation

Table 9: Summary table of animal studies on skin sensitisation

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Results	Reference
EPA 81-6 (Buehler) Deviations: 12 animals were included in the test group instead of 20.	Guinea pigs (Hartley), males, 12/group	Pendimethalin, batch AC 3528-129-1, purity 92.2%	100%, 4x6 cm area, Induction: 3x times per week for 3 weeks (total of 9 treatments), 6 hour exposure Challenge: 6-hr exposure	Negative	Study 1, IIA 5.2.6/01 Doc ID 84-4639A
OECD 406 (Maximisation) Deviations: None	Dunkin Hartey albino Guinea pigs, males, 15/group	Pendimethalin, batch MN/05 (purity not reported)	5% (w/v) Intradermal induction followed by epidermal	Negative	Study 2, IIA 5.2.6/01 Doc ID 8230

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Results	Reference
			booster and challenge.		
EPA 81-6 (Maximisation) Deviations: None	Dunkin Hartley Guinea pigs, 20/test group, 10 control	Pendimethalin, batch AO 86/87, purity not reported.	Intradermal induction : 10% Topical indication: 75% Topical challenge: 25% and 10%.	10% challenge: positive 2/20 animals (24 hours) and 0/20 (48 hours). 25% challenge: positive 11/20 animals (24 hours) and 1/20 animals (48 hours).	Study 3, IIA 5.2.6/01 Doc ID PRO 705

10.7.1 Short summary and overall relevance of the provided information on skin sensitisation

In a Buehler study groups of 12 male albino Guinea pigs (Hartley) were topically administered the test substance: pendimethalin AC 92,553, Batch No. AC 3528-129-1, purity 92.2% (Doc ID 84-4639A). The test substance was applied undiluted. The positive control was 1-chloro-2,4-dinitrobenzene (0.1% w/v). Animals treated with AC 92,553 were observed to have yellow stained hair around test side. There were no other effects and pendimethalin was conluded not to be a skin sensitiser.

In a Guinea pig Maximisation test groups of 15 males were treated with pendimethalin (batch MN/05, purity not reported) (Doc ID 8230). All animals were observed for clinical signs daily during the entire study period. No toxic symptoms were evident in the guinea pigs of either the control or test group. No death occurred. No animals showed positives reactions at the challenge (5% w/v).

In a second Guinea pig Maximisation test groups of 20 (test) or 10 (control) were treated with pendimethaling (batch AO-86/87) (Doc ID PRO 705). Three intradermal injections using: (a) Freund´s complete adjuvant plus distilled water 1:1; (b) A 10% w/v dilution of the test material (Pendimethalin Technical, lot nº AO-86/87, purity not reported) in arachis oil B.P.; c) A 10% w/v dilution of the test material in a 1:1 preparation of Freund´s complete adjuvant plus distilled water. One week later a 75% topical induction was applied and on day 21 topical challenge at 10% and 25%. For 25% challenge positive sensitization reactions (grade 1 erythema) were noted at the challenge sites of eleven animals (55%) 24 hours after removal of dressing, and persisting in one animal 48 hours after removal of dressing. For the 10% challenge dose positive sensitization reactions (grade 1 erythema) were noted in 2 animals 24 hours after removal of patch. No skin reactions were noted in any of the animals for all the test.

10.7.2 Comparison with the CLP criteria

Pendimethalin was negative in a Buehler assay, but was found to be positive in one of the Guinea pig Maximisation test at a 10% intradermal induction dose in 55% of the animals. In addition, another maximisation test, using a lower induction dose of 5% was negative.

According to Regulation EC No 1272/2008 (CLP) Table 3.4.2.2.3.2 substance should be classified for skin sensitisation (Guinea pig maximisation test) when:

Category 1A:

≥ 30 % responding at ≤ 0,1 % intradermal induction dose or

≥ 60 % responding at > 0,1 % to ≤ 1 % intradermal induction dose

Categroy 1B:

≥ 30 % to < 60 % responding at > 0,1 % to ≤ 1 % intradermal induction dose or

≥ 30 % responding at > 1 % intradermal induction dose

Based on the response of 55% at 10% intradermal induction pendimethalin should be classified as a skin sensitiser sub-category 1B. The negative results in the other maximisation study at a lower induction dose exclude sub-category 1A.

10.7.3 Conclusion on classification and labelling for skin sensitisation

Based on the results of the studies pendimethalin should be classified as skin sensitiser, cat. 1B (hazard statement H317 - May cause an allergic skin reaction).

10.8 Germ cell mutagenicity

This hazard class has not been evaluated.

10.9 Carcinogenicity

This hazard class has not been evaluated.

10.10 Reproductive toxicity

10.10.1 Adverse effects on sexual function and fertility

Table 10: Summary table of animal studies on adverse effects on sexual function and fertility

Method, guideline, deviations if any, species, strain, sex, no/group	Test substance, dose levels duration of exposure	Results	Reference
Two generation reproduction study OECD 416 Deviations from current guideline: – No assessment of sperm parameters – No clinical chemistry and hematology – Estrous cyclicity only during mating (daily vaginal smear) – No organ weights of P1 and F1 – Histologic evaluation was performed on F0 and F1 animals:	Pendimethalin (purity 92.6%) 0, 500, 2500 and 5000 ppm (30, 150, 296 mg/kg bw/day for males and 39, 195 and 388 mg/kg bw/day for females) Start exposure 60 days pre-mating till LD 21	<u>NOAEL:</u> Parental: 30 mg/kg bw/day Reproductive: 150 mg/kg bw/day Offspring: 30 mg/kg bw/day <u>Critical effects:</u> <u>Parental:</u> Reduced body weight gain and food consumption at 2500 ppm and 5000 ppm. <u>Reproductive:</u> No effect on vaginal smear	IIA 5.6.1/01 Doc ID CBG/2/90

Method, guideline, deviations if any, species, strain, sex, no/group	Test substance, dose levels duration of exposure	Results	Reference
• Males: testis, epididymides, seminal vesicles prostate, pituitary • Females: uterus (both horns entire structure), ovaries, vagina, pituitary – No sexual maturation parameters were investigated but evaluation of developmental hallmarks as eye opening, tooth eruption etc. in single animal data) Sprague Dawley rats, 25/ sex/dose		pattern, mating performance, fecundity and fertility. <u>Fetal:</u> Reduced pup weight from day 7 at 2500 ppm and 5000 ppm.	

10.10.2 Short summary and overall relevance of the provided information on adverse effects on sexual function and fertility

One hundred Sprague-Dawley rats of each sex were computer randomized into groups of 25 males and 25 females. The study was conducted in accordance with the OECD Guideline 416 (data 1981) which was valid at the time of the study. For two generations the animals were fed AC 92,553 (92.6 % content) in the diet at concentrations 0, 500, 2500, and 5000 ppm, which correspond to 30, 150, 296 mg/kg bw/day for males (M) and 39, 195, 388 mg/kg bw/day for females (F). Following 60 days of treatment, males and females of P1 generation were paired for mating (within dose groups) to produce F1a generation. After 10 days of rest, mating was repeated again to produce F1b generation. At one-hundred days of age males and females of F1 generation were paired to produce F2a generation, and week later were paired again to produce F2b generation. Pairings were always within dose level groups and the females of generation were allowed to litter and rear the next generation to weaning.

There were no significant mortalities either in the P1 and F1 generation related to treatment. Discoloured yellow urine was observed in all treated animals at all dose levels. Yellow fur staining was also observed, mainly in the F1 generation animals in the 296(M)-388(F) mg/kg bw/day dose level (fed 5000 ppm), and to a lesser degree in those of the 150(M)-195(F) mg/kg bw/day dose level (fed 2500 ppm). There were no other treatment-related changes in clinical condition. Lower body weight gain was statistically significant in the animals fed 5000 ppm [296(M)-388(F) mg/kg bw/day] (max-20%), and to a lesser degree in those of 2500 ppm group [150(M)-195(F) mg/kg bw/day] (max -12%). Body weight was significantly reduced at 2500 ppm (max -9%) and 5000 ppm (max -15%).Reduction in food consumption was also related to dose level, being more remarkable in the 5000 ppm group (max -17%) than in the 2500 ppm dose level (max -12%).

There were no significant adverse effect at any dose level on vaginal smear pattern, time-course of mating, performance of mating (males and females), fecundity and fertility in either generation, neither on gestation duration, or outcome of pregnancy.

10.10.3 Comparison with the CLP criteria

According to Regulation EC No 1272/2008 (CLP), Table 3.7.2.2, classification for effects on fertility is based on:

Category 1A:
Known human reproductive toxicant
Category 1B:
Presumed human reproductive toxicant largely based on data from animal studies
— clear evidence of an adverse effect on sexual function and fertility in the absence of other toxic effects, or
— the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects
Category 2:
Suspected human reproductive toxicant
— some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility and
— where the evidence is not sufficiently convincing to place the substance in Category 1 (deficiencies in the study).
— the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects.

No effects on vaginal smear pattern, time-course of mating, performance of mating (males and females), fecundity and fertility was observed and therefore no classification is needed.

10.10.4 Adverse effects on development

Table 11: Summary table of animal studies on adverse effects on development

Method, guideline, deviations if any, species, strain, sex, no/group	**Test substance, dose levels duration of exposure**	**Results**	**Reference**
Two generation reproduction study OECD 416 Deviations from current guideline: – No assessment of sperm parameters – No clinical chemistry and hematology – Estrous cyclicity only during mating (daily vaginal smear) – No organ weights of P1 and F1 – Histologic evaluation was performed on F0 and F1 animals:	Pendimethalin (purity 92.6%) 0, 500, 2500 and 5000 ppm (30, 150, 296 mg/kg bw/day for males and 39, 195 and 388 mg/kg bw/day for females) Start exposure 60 days pre-mating till LD 21	<u>NOAEL:</u> Parental: 30 mg/kg bw/day Reproductive: 150 mg/kg bw/day Offspring: 30 mg/kg bw/day <u>Critical effects:</u> <u>Parental:</u> Reduced body weight gain and food consumption at 2500 ppm and 5000 ppm. <u>Fetal:</u> Reduced pup weight from	IIA 5.6.1/01 Doc ID CBG/2/90

Method, guideline, deviations if any, species, strain, sex, no/group	Test substance, dose levels duration of exposure	Results	Reference
• Males: testis, epididymides, seminal vesicles prostate, pituitary • Females: uterus (both horns entire structure), ovaries, vagina, pituitary – No sexual maturation parameters were investigated but evaluation of developmental hallmarks as eye opening, tooth eruption etc. in single animal data) Sprague Dawly rats, 25/ sex/dose		day 7 at 2500 ppm and 5000 ppm. Slight non-statistical decrease in the number of pups (F1 and F2) at 5000 ppm.	
Developmental toxicity study No guideline reported (generally in line with OECD 414) Deviations from the current OECD guideline were: - Treatment during day 6-15 of gestation - Uterus weight not reported - Foetal sex not determined - 1/3 visceral, 2/3 skeletal - No special skull investigations - Individual pup necropsy data incomplete - No litter incidence reported in study report, but was included in an addendum (Doc ID PN-902-007 (1996)). Sprague-Dawley female rats	Pendimethalin (batch 1984-79-3, purity 94.2%) 0, 125, 250 and 500 mg/kg bw/day GD6-15	NOAEL: Maternal toxicity: 500 mg/kg bw/day Developmental toxicity: 500 mg/kg bw Critical effects: Maternal: No adverse effects up to 500 mg/kg bw/day. Developmental: No adverse effects up to 500 mg/kg bw/day. Slight non-statistical increase in delayed ossification was not considered treatment related.	IIA 5.6.2/01 Doc ID 362-115

Method, guideline, deviations if any, species, strain, sex, no/group	Test substance, dose levels duration of exposure	Results	Reference
25 pregnant females/group			
Developmental toxicity study No guideline reported (generally in line with OECD 414) Deviations from current guideline: - Treatment during GD6-18 - Age of animals missing - Food consumption not reported (only mention of maternal adipsia and anorexia) - 1/3 visceral, 2/3 skeletal evaluation - lack of individual/litter data New Zealand White rabbits 20/group	Pendimethalin (92.3%) 0, 15, 30 and 60 mg/kg bw/day. GD6-18	NOAEL: Maternal: 60 mg/kg bw/day Developmental: 30 mg/kg bw/day Critical effects: Maternal: No adverse findings up to 60 mg/kg bw/day Developmental: Increased incidence of less than twelve pairs of ribs and missing/incomplete vertebrae at 60 mg/kg bw/day.	IIA 5.6.2/02 Doc ID 362-164

10.10.5 Short summary and overall relevance of the provided information on adverse effects on development

In the two-generation study one hundred Sprague-Dawley rats of each sex were computer randomized into groups of 25 males and 25 females (Doc ID CBG/2/90. The study was conducted in accordance with the OECD Guideline 416 (data 1981) which was valid at the time of the study. For two generations the animals were fed AC 92,553 (92.6 % content) in the diet at concentrations 0, 500, 2500, and 5000 ppm, which correspond to 30, 150, 296 mg/kg bw/day for males (M) and 39, 195, 388 mg/kg bw/day for females (F). Following 60 days of treatment, males and females of P1 generation were paired for mating (within dose groups) to produce F1a generation. After 10 days of rest, mating was repeated again to produce F1b generation. At one-hundred days of age males and females of F1 generation were paired to produce F2a generation, and week later were paired again to produce F2b generation. Pairings were always within dose level groups and the females of generation were allowed to litter and rear the next generation to weaning.

There were no significant mortalities either in the P1 and F1 generation related to treatment. Discoloured yellow urine was observed in all treated animals at all dose levels. Yellow fur staining was also observed, mainly in the F1 generation animals in the 296(M)-388(F) mg/kg bw/day dose level (fed 5000 ppm), and to a lesser degree in those of the 150(M)-195(F)

mg/kg bw/day dose level (fed 2500 ppm). There were no other treatment-related changes in clinical condition. Lower body weight gain was statistically significant in the animals fed 5000 ppm [296(M)-388(F) mg/kg bw/day] (max-20%), and to a lesser degree in those of 2500 ppm group [150(M)-195(F) mg/kg bw/day] (max -12%). Body weight was significantly reduced at 2500 ppm (max -9%) and 5000 ppm (max -15%). Reduction in food consumption was also related to dose level, being more remarkable in the 5000 ppm group (max -17%) than in the 2500 ppm dose level (max -12%).

There was a slight non-statistical decrease of the number of pups in the group administered 5000 ppm in both litters of both generations, as compared to the control [Table 10.10.5-1]. This effect only occurred in the presence of maternal toxicity.

Pup weight was significantly decreased at 2500 ppm (max -14.26%) and at 5000 ppm (max -21.3%) from day 7 in the F1a generation and from day 4 in the F1b generation. In the F2a and F2b generation a decrease in body weight was also observed at 2500 ppm and at 5000 ppm, but only at 5000 ppm did the reduction exceed 10%.

Table 10.10.5-1: Number of pups

Generation	0	500	2500	5000
P1 (F1a litter)	15.6	16.1	15.7	14.5
P1 (F1b litter)	15.9	15.1	15.0	14.6
F1 (F2a litter)	14.9	14.5	13.9	11.8
F1 (F2b litter)	15.0	14.2	13.3	12.7

In a rat developmental toxicity study four group of 33 Sprague-Dawley female rats were mated with males (Doc ID 362-115). The test product (94.2 % purity, lot nº 1984-79-3) was orally administered by intubation, using corn oil as a vehicle for the suspension, at dosage levels of 0 (controls, pure corn oil only), 125, 250 and 500 mg/kg bw/day, respectively, from day 6 through day 15 of gestation. The study was carried prio to an OECD guideline. The main deviations from the current OECD Guideline were: treatment during GD6-15, uterus weight was not reported, foetal sex was not determined, 1/3 of the pups were used for visceral examination and 2/3 for skeletal examination and no special skull invesigations were conducted.

There were no significant differences when maternal body weight. There was a significantly higher maternal food consumption on day 20. Increased incidences of urine staining were observed during the treatment (GD6-15, 12.5% at 250 mg/kg bw/day and 39.4% at 500 mg/kg bw/day) and post-treatment (GD16-20, 15.6% at 250 mg/kg bw/day and 54.6% at 500 mg/kg bw/day). Increased incidence of yellow body fat was observed at all dose levels. These effects can be attributed to the physical properties of the test material.

There was no significant difference in pregnancy rate, mean number of implantations, implantation efficiency, incidence of resorption, mean number of live and dead foetuses, incidence of foetal death, foetal viability, and the mean foetal length and weight of the treated groups were compared to controls. A higher number of corpora lutea was observed when the high dose group (500 mg/kg bw/day) was compared to the control group (15.3 vs 13.76).

No external malformations were observed in the control or treated groups. Visceral examination revealed hydronephrosis in one mid-dose fetus which was within historical control range and the effect did not occur in the high dose group. Historicol control data from the testing facility indicate that the fetal incidence of hydronephrosis (renal pelvic cavitation) in control litters ranges from 0.0% to 1.8% (mean 0.76%) and the litter incidence ranges from 0.0% to 8.0%

(mean 4.08%). The historical control data was obtained from 5 studies with Sprague-Dawley rats carried out between 1981-1983 in the same laboratory.

Slight dilated kidney was increased at 125 mg/kg bw/day but did not occur in the mid and high dose group and thereofore was not considered treatment related. An increase in delayed ossification of the extremities was observed in mid and high dose group compared to controls (Table 12). Statistical comparison of the fetal and litter incidences indicate however that the differences from control were not statistically significant. Moreover, no statistically significant linear trend was observed when the data were analyzed by the Cochran-Armitage test, indicating the lack of a dose-response. In addition, there was no treatment-related decrease in group mean ossification of the forelimbs or hindlimbs in any dose group as compared to controls. The mean numbers of ossifications centers in the forelimb were 11.2, 11.4, 11.1 and 11.2 centers at 0, 125, 250 and 500 mg/kg bw/day, respectively. Similarly, the mean ossification sites in the hindlimb were 9.0, 9.0, 8.9 and 9.1 centers, respectively. The historical control data indicate a number of ossification centers in the forelimb in the range of 5.67 to 11.9 (mean 7.86) and in the hindlimb of 5.62-10.67 (mean 7.67). The number of ossification centers in controls was obtained from a total of 3978 Sprague-Dawley foetuses from 479 litters. The dates of these historical control studies was not reported. No historical control data is available for the lagging ossicifcation in extremities.

Overall, it was concluded that the slight increase in the incidence of delayed ossification were not treatment-related.

Table 12:**:** Incidence of delayed ossification in extremities

Concentration (mg/kg bw/day)	**0**	**125**	**250**	**500**
Number of Live foetuses examined	234	242	232	254
Number of litters examined	29	29	28	30
Delayed ossification in extremities				
Fetal incidence	6 (2.6%)	3 (1.2%)	13 (5.6%)	13 (5.1%)
Litter incidence	3 (10.3%)	3 (10.3%)	7 (25%)	7 (23.3%)

In a developmental toxicity study in New Zealand White rabbits groups of 20 females were exposed to 0, 15, 30 and 60 mg/kg bw/day (Doc ID 362-164). The test product was administered daily by gavage, at the aforementioned dose levels, as a suspension in corn oil from day 6 through 18 of the gestation. The dose levels were based on a pilot study using dose levels of 31.25, 62.5, 125, 250 and 500 mg/kg bw/day.

The only maternal finding that was observed in the study was an increased incidence of anorexia at 60 mg/kg bw/day (Table 13). However, the incidence was still below the control incidence of the pilot study (3/5, 60%). In addition, there was no significant effect on mean maternal body weight. It was therefore concluded that there was no sign of maternal toxicity in the study.

Table 13: Summary of maternal findings

Dose (mg/kg bw/day)	**0**	**15**	**30**	**60**
Anorexia	4/20	4/20	6/20	8/20

Pregnancy rate, corpora lutea, implantations as well as foetal weights, lengths and size were similar in the control and treated groups. An increase in the mean incidence of skeletal anomalies unique to foetuses in the mid- and high- dose groups, consisting of less than twelve pairs of ribs and or missing/incomplete vertebral column, was observed [Table 14]. The observed increase in missing/incomplete vertebrae at 60 mg/kg bw/day all occurred in one litter group. The observed increase of less than twelve pairs of ribs occurred in 2 litters at the high dose, which included the litter with missing/incomplete vertebrae.

The terminology used in the study report and the available historical control data differ. There appears to be no historical control data available for missing/incomplete nor missing/incomplete vertebrae. The term less than twelve ribs is not used in the historical control data base, but it does report and incidence of rib agenesis in 1 foetus in four out of eight studies, indicating that the incidence is outside of the historical control range. The historical control data came from 8 studies with New-Zealand White rabbits carried out in the same lab between 1982-1985. Additional historical control data was provided from literature on the fetal incidence of missing ribs which is shown in Table 15. These historical control data are from 1994 to 2010 and are therefore much more recent than when the study was carried out in 1981. No information is available in the public literature data on litter incidence. In the pendimethalin study the fetal incidence of 4 out of 107 examined (3.7%), which is above the HCD.

Three of the foetuses with less than twelve pairs of ribs were observed in one litter (litter 27928). The 2 foetuses with missing/incomplete vertebrae also occurred in this litter. It was argued by the applicant that if this litter would be excluded that the remaining incidence of less than twelve pairs of ribs would be within historical control data and that the effect was therefore not treatment related. However, during the pesticide peer review meeting if was considered that if the effect was incidential due to a genetic aetiology than it is expected that this would have been reflected in the historical control data as well. Furthermore, it was noted that the effect was also observed in another litter in the mid-dose as well as in the top-dose. Therefore it was concluded that there was not sufficient evidence to exclude the finding and that it should be considered as treatment related.

The study was conducted prior to an OECD guideline, but was mainly in accordance with OECD 414. The main deviations were the exposure duration (GD6-18), the age of animals was missing and food consumption was not reported. In addition, there was a lack of individual/litter data in the study report although the litter incidences have been provided seperataly (doc. no. PN-902-007). One other limitation of the study was that only Alizarin Red staining was performed (which only stains the ossified parts of the bones) and no staining for cartilage was included. Therefore, it is difficult to conclude if the less than twelve pairs of ribs trully reflect rib agenesis as was reported in the HCD or may reflect a lack of ossification. However, there were no other indications of a treatment related effect on foetal skeletal ossification in the study.

The foetuses with less than four ribs also had fused/forked ribs and malaligned thoracic vertebral arches and contra. It was argued that the apparent reduction in the number of ribs was due to fused ribs being counted as one entity rather than two (see Annex 1). However, it is noted that fused/forked ribs was also observed in the control albeit at a lower incidence.

Table 14: Developmental skeletal anomalies in rabbits

Dose (mg/kg bw/day)	**0**	**15**	**30**	**60**
Number of foetuses examined	111	106	118	107
Number of litters examined	17	17	17	17
Number of foetuses with skeletal anomalies	0	0	2	5
Foetuses with less than twelve pairs of ribs				
- fetal incidence	0	0	1	4[1]
- litter incidence	0	0	1	2[1]

Foetuses missing/incomplete vertebrae				
- fetal incidence				
- lumbar	0	0	1	2[1]
- sacral (incomplete)	0	0	0	2[1]
- caudal	0	0	0	3[1]
- litter incidence				
- lumbar	0	0	1	1[1]
- sacral (incomplete)	0	0	0	1[1]
- caudal	0	0	0	1[1]

[1] Three out of four foetuses came from one litter (#27928). The observed foetuses with missing/incomplete vertebrae also come from this litter.

Table 15: Historical control information from literature for absent ribs (Ema et al. 2012)

Laboratory	**03**	**14**	**02**	**13**	**12**	**18**	**19**	**09**		
1994-2000	0.12 (0-1.39)					0.15 (0-0.8)		0.09 (0-0.65)		
Laboratory	**16**	**03**	**11**	**07**	**14**	**10**	**04**	**06**	**12**	**02**	**18**
2001-2010	0.09 (0-0.90)		0.22 (0-1.64)	0.12 (0-1.30)	0.10 (0-1.05)	0.06 (0-1.2)	0.04 (0-0.50)		0.22 (0-0.62)		0.23 (0-0.7)

10.10.6 Comparison with the CLP criteria

According to Regulation EC No 1272/2008 (CLP), Table 3.7.2.2, classification for effects on development is based on:

Category 1A:

Known human reproductive toxicant

Category 1B:

Presumed human reproductive toxicant largely based on data from animal studies

— clear evidence of an adverse effect on development in the absence of other toxic effects, or

— the adverse effect on development is considered not to be a secondary non-specific consequence of other toxic effects

Category 2:

Suspected human reproductive toxicant

— some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on development and

— the evidence is not sufficiently convincing to place the substance in Category 1 (deficiencies in the study).

— the adverse effect on development is considered not to be a secondary non-specific consequence of the other toxic effects

According to the CLP criteria classification as Repr. 1A is based on human data. No human data is available for pendimethalin and therefore, classification as Repr 1A is not justified.

In the 2-generation study reduced pup weight was observed from day 7, which only occurred at concentrations also inducing maternal toxicity. In the rat developmental toxicity study no effects occurred which would warrant classification for development.

In the rabbit developmental toxicity study an increase in the incidence of less than twelve pairs of ribs and an increase in the incidence of missing/incomplete vertebrae was observed. Although the skeletal finding in the top dose mainly occured in one litter, it was also observed in the mid-dose as well as in another litter in the top-dose. It was considered that since the effects was observed in multiple litters and considering the low reported historical control incidence that the finding should be considered as treatment related. The effects occurred in the absence of maternal toxicity.
There were some limitations to the study as it was not conducted fully in accordance with OECD guidelines. One of the limitations was that only Alizarin Red staining was performed and no staining for cartilage was included. It is therefore difficult to conclude if the less than twelve pairs of ribs trully reflect fully missing ribs as was reported in the study report. However, there were no other indications of foetal skeletal ossification being affected.

Based on the observed developmental effects in the absence of clear maternal toxicity and taking into consideration the limitation of the developmental rabbit study it is proposed to classify pendimethalin with Category 2.

10.10.7 Adverse effects on or via lactation

No additional study carried out.

10.10.8 Short summary and overall relevance of the provided information on effects on or via lactation

No additional study carried out.

10.10.9 Comparison with the CLP criteria

According to Regulation EC No 1272/2008 (CLP), Table 3.7.2.2.2, classification for lactation effects is based on:

(a) human evidence indicating a hazard to babies during the lactation period; and/or

(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or

(c) absorption, metabolism, distribution and excretion studies that indicate the likelihood that the substance is present in potentially toxic levels in breast milk.

In the 2-generation study in rats an effect on pup body weigth occurred during the lactation period starting from day 7. However, the effect only occurred in the presence of maternal toxicity in the form of reduced body weight (-9% mid-dose, -15% high dose) reduced body weight gain (-12% mid-dose, -20% high dose) and reduced food consumption (-12% mid-dose, -17% high-dose). Therefore, this effect on pup weight is not considered to be sufficient for classification and labelling.

10.10.10 Conclusion on classification and labelling for reproductive toxicity

Classification as reproductive toxicity category 2 is proposed for pendimethalin; H361d (Suspected of damaging the unborn child).

10.11 Specific target organ toxicity-single exposure

This hazard class has not been evaluated.

10.12 Specific target organ toxicity-repeated exposure

This hazard class has not been evaluated.

10.13 Aspiration hazard

This hazard class has not been evaluated.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

The environmental studies of pendimethalin were assessed in the Renewal Assessment Report (February 2012) in the context of the renewal of the approval (Reg. (EU) No. 2017/1114), under Reg. (EC) 1107/2009. All studies were carried out under GLP unless indicated underwise. Generally studies were conducted in accordance with OECD test guideline. All studies were considered acceptable (Klimisch Score 1 or 2) unless indicated otherwise in the remarks.

11.1 Rapid degradability of organic substances

Table 16: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
Ready biodegradability OECD 301 B, EPA 835.3110, (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to (EC) No 1907/2006 of European Parliament and of Council on the REACH - Part C.4, ISO 9439	Pendimethalin was not readily biodegradable Theoretical carbon dioxide ($ThCO_2$) values of <10 % $CO_2/ThCO_2$ at the end of the exposure	RI = 1	CA 7.2.2.1/1 Doc ID 2013/1125987
Hydrolysis	Hydrolytically stable at pH 5, 7 and 9 at room temperature	non-GLP RI = 2	IIA 2.9.1/01, Doc ID PD-M 11-73
Hydrolysis	Hydrolytically stable at pH 5, 7 and 9 at 37°C and 50°C	non-GLP RI = 2	IIA 2.9.1/02, Doc ID 1578
Hydrolysis	Hydrolytically stable at pH 4, 7 and 9 at 50°C	RI = 2	IIA 2.9.1/03 Doc ID CYA-004/7/20
Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test OECD 309 (April 2004)	DT50 193 days	Study not suited to investigate biodegradation. Too much uncertainty in degradation half-life. Endpoint not accepted.	CA 7.2.2.2./1 Doc ID 2013/1125943
Water sediment study Richtlinien fur die	Water: DT50 1.0-1.6 days.	RI = 2	CA 7.2.2.3/1 Doc ID 2002/1026399 CA 7.2.2.3/5 Doc ID

Method	Results	Remarks	Reference
Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren, Part IV, 5-1, BBA, Germany	Whole system DT50 4.5-5.0 days		2013/1132577
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems BBA IV 5-1, EPA 162-4, SETAC, OECD 308	Whole system DT50 26.4 days	RI = 2	CA 7.2.2.3/2 Doc ID 2004/1022517 CA 7.2.2.3/6 Doc ID 2007/1042029
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems OECD 308, EPA 835.430w	Water DT 50: 0.41-0.42 days Whole system DT50 101-103 days	RI = 1	CA 7.2.2.3/3 Doc ID 2012/1187651
Aerobic and Anaerobic Transformation in Soil SETAC Part 1 section 1.1	Soil DegT50: 146 days	RI = 2	CA 7.1.1.1/1 Doc ID PN-620-072 (study); CA 7.1.2.1.1/6 DocID 2013/1110109 (kinetic evaluation)
Aerobic and Anaerobic Transformation in Soil OECD 307	Soil DegT50: 53.6-57.8 days	RI = 2	CA 7.1.2.1.1/5 Doc ID 2011/1257593 (study); CA 7.1.2.1.1/9 Doc ID 2013/1110110 (kinetic evaluation)
Aerobic and Anaerobic Transformation in Soil OECD 307	Soil DegT50: 97.0 days	RI = 1	CA 7.1.1.1/4 Doc ID 2012/1051587
Aerobic and Anaerobic Transformation in Soil OECD 307	Soil DegT50: 177.7 days (DFOP-slow fase)	RI = 1	CA 7.1.1.1/3 Doc ID 2001/1031363 (study); CA 7.1.2.1.1/7 Doc ID 2013/1110111 (kinetic evaluation)
Direct photochemical degradation EEC 94/37 2.9.2, EEC 94/37 2.9.3, SETAC Procedures for assessing the environmental fate and ecotoxicity of pesticides - Part 1 Fate and behaviour in the environment - 10 - Aqueous photolysis, Draft OECD Test Guideline: Phototransformation of Chemicals in Water - Direct and Indirect Photolysis (OECD Aug. 2000), Phototransformation of chemicals in water. Part A Direct phototransformation. Umweltbundesamt Berlin FRG (Sep. 1990)	DT50 35 hours	RI = 2	CA 7.2.1.2/2 Doc ID 2002/1026397
Direct photochemical	DT50 5 days	RI = 1	CA 7.2.1.2/3 Doc ID

Method	Results	Remarks	Reference
degradation EEC 94/37 2.9.2, EEC 94/37 2.9.3, JMAF Guideline (No. 12-Nouan-8147, 2000)	DT90 16.7 days		2005/1026762
Direct photochemical degradation FAO Revised Guidelines, Rev. #, JMAF Guideline (No. 12-Nouan-8147, 2000), OECD Guideline Proposal, December 2007	DT50 4.1 days	non-GLP RI = 2	CA 7.2.1.2/4 Doc ID 2012/1282999
Indirect photochemical degradation FAO Revised Guidelines on Environmental Criteria for the Registration of Pesticides Revision 3 (28 August 1993), EEC 94/37, EEC 91/414, JMAFF No 12 Nosan No 8147	DT50 3.4 days	RI = 1	CA 7.2.1.3/1 Doc ID 2005/1026763

11.1.1 Ready biodegradability

The ready aerobic biodegradability of BAS 455 H - pendimethalin was investigated in water containing mineral salts and a microbial inoculum (activated sludge from a municipal sewage plant) in accordance with OECD 301 (CA 7.2.2.1/1). Pendimethalin was added to the test medium and the inoculum to achieve a concentration of 20 mg TOC/L corresponding to approximately 36 mg pendimethalin /L. Duplicate control systems containing the microbial inoculum without test or reference substance were used to determine the endogenous microbial CO2 evolution. Duplicate test systems dosed with the test substance at a nominal concentration of 20 mg TOC/L were used to monitor biodegradation of the test substance. A reference substance system containing readily biodegradable aniline at a nominal concentration of 20 mg TOC/L was also tested to verify the viability of the microbial inoculum. All systems were sampled on days 0, 1, 4, 7, 11, 14, 18, 22, 25, 27, 28 and 29. The average CO2 evolved from the control systems was subtracted from the CO2 evolved in the test and reference substance systems. The test substance systems yielded mean theoretical carbon dioxide (ThCO2) values of <10 % CO2/ThCO2 at the end of exposure. Therefore, pendimethalin was not biodegradable under the conditions of the test. Biodegradation in the reference substance system reached 85 % CO2/ThCO2 at the end of the study, verifying that the microbial inoculum was viable and active. From the results obtained, it was concluded that pendimethalin is classified as not readily biodegradable.

This study is conducted according to the Guidelines and no limitations are reported. Therefore, the study is considered reliable (Ri = 1). Endpoints can be used for classification purposes.

11.1.2 BOD_5/COD

No data.

11.1.3 Hydrolysis

The hydrolys of pendimethalin was evaluated in three studies (CA 2.9.1/01; CA 2.9.1/02; CA 2.9.1/03) of which two were carried out with the formulations PROWL and STOMP. Two of the three studies were not carried out under GLP and no guideline is mentioned in any of the studies. However, all studies showed that pendimethalin was stable to hydrolytic conditions at pH levels of 4, 5, 7 and 9 and temperatures of 20, 22, 37 and 50°C.

These studies are conducted according to the Guidelines, but two out of three studies are before the GLP framework was established. No limitations are reported, however the evaluation was very concises. Therefore, the overall conclusion based on three studies is considered reliable but with Ri = 2. Endpoints can be used for classification purposes.

11.1.4 Other convincing scientific evidence

11.1.4.1 Field investigations and monitoring data (if relevant for C&L)

No data.

11.1.4.2 Inherent and enhanced ready biodegradability tests

No data.

11.1.4.3 Water, water-sediment and soil degradation data (including simulation studies)

The rate of biodegradation of pendimethalin was investigated in natural river surface water under aerobic conditions in accordance with OECD 309 (CA 7.2.2.2/1). The test systems were incubated in the dark for a period of 63 days at 20.7 + 0.2°C. Microbial activity of the test system was proven by the degradation of [^{14}C(U)]benzoic acid. Samples were taken for work-up after 0, 1, 3, 8, 14, 28 and 63 days of incubation. Despite the low test concentrations, pendimethalin adsorbed to a considerate amount to the test vessel walls. The remaining test item in the aqueous phase showed no significant degradation although some degradation products could be detected in trace amounts in the chromatograms which were not visible in the sterile vessels. A half-life of pendimethalin in water can therefore only be extrapolated far beyond duration of the study and was calculated to be 193 days for the high dose system.
This study is conducted according to the Guidelines. Several limitations are reported, most important of which concerns the effect of the low dose rate on the quantification of metabolites. Further, some minor limitations were reported regarding sampling and study setup. Overall, these limitations did not impact the integrity of the study. However, it can be concluded that the applied test conditions as required by the Guideline OECD 309 were not suitable to investigate the biodegradation of strong adsorbing substances in aqueous environments, because –for this substance- binding on the walls of the vessels used in the experiment had a very strong influence that the biodegradation half-life could only be estimated from comparision of the sterile and non-sterile systems and even then the results exceeded the study duration. It is considered that this causes too much uncertainty for a reliable half-live to be determined. It is noted that the the 'ECHA Guidance on the Application of the CLP Criteria' (Annex II, 2.3.1) states that results from aquatic simulation tests (e.g. OECD 309) may be used directly for classification purposes. However, in this case it is questionable whether "ultimate degradation is correctly determined" as also requested in the 'ECHA Guidance on the Application of the CLP Criteria' (Annex II, 2.3.1). The study can be used as supporting evidence for the conclusion on rapid degradability.

The degradation of BAS 455 H - pendimethalin was investigated in two aerobic water/sediment systems (CA 7.2.2.3/1). The systems were treated with [(benzene U)-14C]-labelled pendimethalin at about 147 µg test item per test vessel (0.67 mg/L). Samples were taken in duplicates at 0, 3, 7, 16, 30, 62, 93/94 and 121 days after treatment (DAT). The water samples, methanol extracts of the sediment, ^{14}C-carbon dioxide and other volatile ^{14}C-labelled metabolites and the bound residue were analysed by liquid scintillation counting (LSC) and HPLC. Due to the limited solubility of pendimethalin in water, the content of radioactivity shifted immediately from the water phase to the sediment, reflected by the values of the radioactivity in the water phase of 48% total applied radioactivity (TAR) at the start (day 0) in both systems decreasing to <8% TAR at the end of the study. Simultaneously, the radioactivity of the sediments increased from 45% to a maximum of 75% and 89% TAR at day 121 in the system "Rückhaltebecken" and "Schaephysen", respectively. The degradation kinetics of pendimethalin were calculated at the time of the study according to Timme et al. The DT50 values of pendimethalin in the water phases were calculated to be 2-4 days (DT90 7-14 days). The DT50 values of pendimethalin for the whole systems were between 2-2.5 days (DT90 27-57 days). Since the kinetic evaluation was outdated a new evaluation of the study was conducted in recommendation of the FOCUS Kinetics workgroup (CA 7.2.2.3/5). The experimental data on pendimethalin in the both test systems were evaluated at Level P-I. A kinetic evaluation at Level P-II was not pursued. The results at Level P-I showed that degradation of pendimethalin in the total system and dissipation from the water phase were best described by SFO kinetics. The best-fit $DegT_{50}$ was 4.5 and 5.0 days in the total system, and the best-fit $DisT_{50}$ was 1.0 and 1.6 days in the water phase of the two systems.
This study is conducted before the Guideline OECD 308 was established, but was generally in line with this guideline. The temporary anaerobic conditions during the study are not considered a problem. These mimic the possible conditions that natuarually also might occur and are therefore acceptable.
Overall, these limitations did not impact the integrity of the study. Therefore, the study is considered reliable (Ri = 2). Endpoints can be used for classification purposes.

The degradation of BAS 455 H – pendimethalin under aerobic aquatic conditions was investigated in accordance with OECD 308 over a period of up to 100 days at 20 °C in the dark (CA 7.2.2.3/2). Two different natural systems of water and sediment taken from a pond-like side-arm of a river (Berghäuser Altrhein) and a small stream surrounded by a forest (Ranschgraben) were treated with [phenyl-U-^{14}C]-labelled pendimethalin at about 200 µg test item per test vessel. Duplicates test vessels were sampled at 0 and 6 h, and 1, 3, 7, 14, 28, 58, 79 and 100 days after treatment (DAT). Since the system Ranschgraben showed a considerable and inexplicable drop of pH during the experiment, data obtained after 14 days with this system were not used to evaluate the behaviour of pendimethalin in aqueous environments. The distribution of radioactivity was very similar for both water/sediment systems during the first two weeks after treatment, therefore it is justified to assume that the results obtained with Berghäuser Altrhein are also representative for system Ranschgraben. Pendimethalin quickly dissipated from the water phase (1-3% TAR at 14 DAT) and was adsorbed to the sediment. Numerous polar degradation products were formed in the water (up to 30), however, none of them exceeding 3% of the total applied radioactivity (TAR) at any investigated sampling time in both systems. Pendimethalin disappeared rapidly from the water phase with - at that time - DT_{50} values of 1.1 and 0.6 days and DT_{90} values of 4.9 and 12.0 days in the water phase of the systems Berghäuser Altrhein and Ranschgraben, respectively. The DT_{50} and the DT_{90} values of pendimethalin in the complete system amounted to 27.1 / 24.2 days and 89.9 / 80.3 days in the systems Berghäuser Altrhein / Ranschgraben. Since the kinetic evaluation was outdated a new evaluation of the study was conducted in recommendation of the FOCUS Kinetics workgroup (CA 7.2.2.3/6). The average total degradation half-life in water-sediment systems was 26.4 days.

This study is conducted in accordance with the Guideline OECD 308. Because for one of the systems only datapoints for the first 14 days are available, the study is considered reliable, but with Ri = 2. Endpoints can be used for classification purposes.

The degradation of ^{14}C- pendimethalin was investigated in accordance with OECD 308 in two aerobic water/sediment systems under dark conditions (CA 7.2.2.3/3). The systems were treated with 4-methyl-^{13}C phenyl-^{14}C-labelled pendimethalin at about 60 µg test item per test vessel. Samples for the experiment were taken at 0, 0.25, 1, 3, 7, 14, 28, 55, 78, and 100 days after treatment (DAT). The amount of non-extractable residues and volatiles was determined by LSC. After 100 days, pendimethalin was found in the water at levels of 1.4% TAR in system Berghäuser Altrhein and 2.1% TAR in system Ranschgraben. Several metabolites were detected in both systems, however none of them ever exceeded 2% TAR. The sediment pendimethalin reached its highest amount after 7 days with 80%-83% TAR. At the end of study amounts of 48% TAR and 44% TAR were found in the systems Berghauser Altrhein and Ranschgraben, respectively. The non-extractable (bound) residues reached average amounts of 39% TAR in the system Berghäuser Altrhein and 45% TAR in the system Ranschgraben. The bound residues were further characterised by NaOH extraction and humic substance fractionation. The highest amounts of radioactivity was always found in the insoluble humins and high molecular humic acids, indicating a tight incorporation into the organic matrix in the sediment. Overall, the degradation of pendimethalin was characterised by a very low mineralisation rate. The amount of $^{14}CO_2$ never exceeded 3.5% TAR in any of the samples over 100 days. Kinetic analysis and calculations of DT_{50} and DT_{90} values was performed following the recommendations of the FOCUS Kinetics workgroup. The DT50 for whole sediment was 101-103 days and the DT50 for water was 0.41-0.42 days.

This study is conducted in accordance with the Guideline OECD 308. Because no significant limitations are reported the study is considered reliable with Ri = 1. Endpoints can be used for classification purposes.

The aerobic soil degradation of pendimethalin was conducted using a 1:1 mixture of ^{13}C- and ^{14}C- labelled pendimethalin, with ^{14}C labelled uniformly on the benzene ring and ^{13}C labelled at the 3-methyl of the benzene ring (CA 7.1.1.1/1 and 7.1.2.1.1/6). The study was carried out in accordance with SETAC Part 1 section 1.1. Three soils were used for this study: a sandy loam soil (Norfolk) from North Carolina, a silt loam soil from Crowley (Louisiana) and a clay loam soil from Tensas (Mississippi). Only the soil in North Carolina was considered representative for European conditions. It was shown for the Louisiana and the Mississippi soil that they cannot be found in Europe because of the climatic weathering conditions that lead to these finally weathered soils. The material balance ranged from 94% to 105% total applied radioactivity (TAR) for the three soils. At the end of the experiment, up to 3.2, 4.9 and 7% TAR was trapped as organic volatiles in the Norfolk, Crowley and Tensas soils, respectively. Pendimethalin was degraded in all the three soils tested. Several minor degradation products were formed, each representing 0.1 to 4.8% of the applied radioactivity. Mineralisation was observed with levels of CO_2 reaching 1.7-2.4% after 120 days. However, the metabolic pattern was not properly identified, especially an unknown peak with the maximum amount of 4.8 % in the North Carolina soil at the end of the study. For this peak it was assumed that it may contain metabolite CL99900 (= M455H001) beside some others. The DT50 values based on current kinetic evaluation was 146 days.

This study predates Guideline OECD 307. Because this study lacks some clarity in metabolite identification the study is considered reliable, but with Ri = 2. Endpoints (for parent substance) can be used for classification purposes.

The rate of degradation of BAS 455 H - pendimethalin was investigated in three aerobic soils at a temperature of 20°C (CA 7.1.2.1.1/5 and 7.1.2.1.1/9). The study was carried out in accordance

with OECD 307. The soils were agricultural soils from Germany that had been collected from the field and sieved before use. The soil was treated with the test item pendimethalin at a nominal rate of 5.3 mg per kg dry soil which corresponds to a field application rate of 2 kg pendimethalin per hectare, calculated on the basis of an equal distribution in the top 2.5 cm soil layer and a soil density of 1.5 g/cm^3. Soil aliquots of 100 g (dry weight basis) were weighed into test vessels and placed into an incubation cabinet. The incubation was carried out in the dark in the laboratory under aerobic conditions at a soil moisture of 40% to 50% of the maximum water holding capacity and a temperature of 20°C. A closed incubation system with continuous aeration was used with an attached trapping system for the determination of volatile compounds. Trigger DT_{50} were 76.5 and 64.0 d, while modelling DT_{50} values normalised to reference conditions (20°C, pF2) were 57.8 and 53.6 d in soil LUFA 5M and LUFA 2.3, respectively.

This study is conducted in accordance with the Guideline OECD 308. No significant limitations are reported for this study. However, during the EU review process some question arose with regard to the effect of volatility of the active substance in the study. It is concluded based on these and other studies that the impact of volatility is limited. Therefore, the study conclusion is considered reliable with Ri = 2. Endpoints can be used for classification purposes.

The fate and behaviour of BAS 455H - pendimethalin was investigated in a German standard soil at 20 ºC and 50% of the maximum water holding capacity (approx. pF2) in the dark for 120 days (CA 7.1.1.1/4). The study was carried out in accordance with OECD 307. The nominal application rate was 5.3 mg/kg dry soil (corresponding to 2 kg test item/ha). A flow through system with humidified air was used. Absorption solutions for the determination of volatile compounds were set up to enable determination of a mass balance. Soil samples were taken 0, 1, 3, 7, 10, 14, 28, 63, 91 and 120 days after treatment (DAT), extracted, measured for radioactivity (LSC) and analysed by HPLC. Absorption solutions were removed at each sampling event and additionally 43, 77 and 105 DAT. Only one degradation product was detected above 5% of the total applied radioactivity (TAR), i.e. M455H001 occurred with a max of 6.9% of TAR at the end of incubation. With the HPLC system used, the detection limit for metabolites is 0.001 mg/kg. The degradation rate (SFO DT_{50}) of pendimethlin was calculated to be 97.0 days.

This study is conducted in accordance with the Guideline OECD 308. No significant limitations are reported for this study. Therefore, the study conclusion is considered reliable with Ri = 1. Endpoints can be used for classification purposes. Please note that this concerns only the endpoint (trigger value) for the parent substance.

The fate and behaviour of pendimethalin was investigated in a German standard soil adjusted to about 40% of the maximum water holding capacity (CA 7.1.1.1/3). The test item was applied at a concentration of 2 mg/kg dry soil, corresponding to a field concentration of 2 kg a.s./ha (considering the top 1 cm and a soil density of 1000 mg/kg). Duplicate samples were prepared for each timepoint and incubated at a temperature of 20 ± 2 ºC in the dark for 211 days. The metabolism was investigated by analysing the distribution of radioactivity by liquid scintillation counting (LSC) in the soil and gas phase (CO_2 and volatiles) of the test system. The mean recovery of radioactivity ranged from 94% to 95%. The content of pendimethalin and metabolites in the extracts was analysed by radio-HPLC. In total 7 metabolites (M1-M7) were observed in quantifiable amounts. None of them exceeded 2% of the initial dose. The DT50 values based on current kinetic evaluation was 58.5 days (SFO). A dramatic decline of the biomass by almost factor 3 was recorded at sampling day 120 and remained at low level until the end of the study. Therefore, the RMS conducted revised modelling where the datapoints from day 120 and later were left out, in accordance with the Guidance Document on Kinetics (FOCUS, 2014). The SFO model did not result in an acceptable fit, mainly because the residuals were not evenly spread around the x-axis. In line with the Guidance, the final endpoint for modelling 177.7 days (DFOP, slow phase) could also be used as trigger for further work (a

slight improvement of the spreading of the residuals over the FOMC kinetics is seen in the DFOP kinetics).

This study is conducted in accordance with the Guideline OECD 308. No significant limitations are reported for this study, the kinetics is calculated separately. Therefore, the study conclusion is considered reliable with Ri = 1. Endpoints can be used for classification purposes.

11.1.4.4 Photochemical degradation

A moderate photolytical degradation in aqueous media was demonstrated for pendimethalin during the last Annex I inclusion procedure with a half-life of 21 days of continuous irradiation. All detected metabolites were below 10% AR. However, since most of the data were non-GLP and incomplete, new studies on the direct photochemical degradation of pendimethalin were conducted. The older non-GLP, incomplete studies which were not considered reliable are not further discussed in the CLH dossier.
Additionally also a study where indirect photolysis was studied was submitted for the renewal.

The aqueous photolysis study with ^{14}C-labeled pendimethalin was performed in purified, de-ionized water containing 10% acetonitrile (CA 7.2.1.2/2). The study was carried in accordance with EEC 97/37 2.9.2 and 2.9.3. The test solutions with initial concentrations of 0.2 mg/L, 0.5 mg/L and 0.8 mg/L pendimethalin were exposed to a Xenon arc lamp (wavelength > 290 nm) for up to 164 hours in 30 mL quartz glass reaction vessels. The temperature was kept constant at 20°C. Samples were taken after irradiation periods of 0, 1, 2, 4, 6, 10, 16, 72 and 164 hours. Dark control samples were incubated under the same conditions except for irradiation. A DT_{50} value of 35 hours considering continuous irradiation was calculated from a rate constant k_D of approximately 2.4 * 10^{-6} s^{-1}, assuming pseudo-first order kinetics for the photodecomposition process. The only degradation product amounting for more than 10% of the initial concentration was 2,6-dinitro-3,4-dimethylaniline. The results of this study indicate that direct photolysis is an important process for decomposition of pendimethalin in surface water.
This study is conducted in accordance with the SETAC Guidance. Because the recovery was low for both the dark and irradiated samples the study is considered reliable, but with Ri = 2. the rate of degradation was not corrected for the samples with the recovery. Endpoint can be used for classification purposes.

The aqueous photolysis of BAS 455 H – pendimethalin was studied by using a solution of [phenyl-U-^{14}C]-labelled pendimethalin (0.1 mg/L) in sterile phosphate-buffer at pH 7 (CA 7.2.1.2/3). The study was carried out in accordance with EEC 94/37 2.9.2 and 2.9.3 The test solutions of pendimethalin were continuously exposed to a Xenon arc lamp (wavelength > 290 nm), emitting a light spectrum similar to sunlight (>290 nm) at an intensity of about 3 mW/cm^2 for 15 days. Temperature was kept constant at 22°C. Samples were taken at 0, 1, 3, 7, 9, 11 and 15 days after treatment. Dark control samples were incubated under the same conditions except for irradiation. All samples were measured for total radioactivity (LSC) and analysed by HPLC. Characterization and identification of the photolytic degradation products in aqueous samples was performed by co-chromatography with reference compounds via radio-HPLC and by MS-analysis.
The results showed that photolysis of [phenyl-U-^{14}C]- pendimethalin in sterile water at pH 7 resulted in a fast decline of pendimethalin to 7.8 % TAR after 15 days. No degradation occurred in the dark control samples. The half-life of pendimethalin under continuous irradiation in buffer pH 7 was calculated to be 5 days according to single first-order kinetics.
This study is conducted in accordance with the EEC guidelines. No significant limitations are reported for this study. Therefore, the study conclusion is considered reliable with Ri = 1. Endpoints can be used for classification purposes.

The study of the aqueous photolysis of BAS 455 H – pendimethalin and the calculation of its quantum yield was performed by using a solution of [phenyl-ring-U-C^{14}, 4-methyl-C13]-pendimethalin in sterile phosphate-buffer at pH 7 (CA 7.2.1.2/4). The study was carried out in accordance with FAO Guidelines. The test solutions were continuously exposed to a Xenon arc lamp (wavelength > 290 nm) for 15 days in 20 mL glass reaction vessels with a quartz glass covering. The temperature was kept constant at 22°C. Samples were taken at 0, 1, 3, 7, 9, 11 and 15 days after treatment. Dark control samples were incubated under the same conditions except for irradiation. For determination of the quantum yield of pendimethalin, a mixture of p-nitroacetophenone (PNAP) and pyridine was used as chemical actinometer. The vessel with the actinometer solution (18 mL) was irradiated under similar conditions as the other test vessels.Samples were analysed by LSC and HPLC.
The results showed that photolysis of [phenyl-ring-U-C^{14}, 4-methyl-C13]-pendimethalin in sterile water at pH 7 resulted in a fast decline of pendimethalin with 4.8% TAR remained after 15 days. No significant degradation occurred in the dark control samples. Continuous photolytic degradation of pendimethalin in aqueous solution at pH 7 was found in the course of the study. DT_{50} values for pendimethalin under irradiated and dark conditions were 4.1 and 154 days (non-GLP). The quantum yield calculation for pendimethalin was of 1.2 x 10^{-4}. The calculated half-life for the top layer of aqueous systems considering the quantum yield of pendimethalin varied between 2 and 5 days depending on the month of application.
This study is conducted in accordance with the (at that time) proposed OECD guideline. No significant limitations are reported for this study other than that the study was not carried out under GLP. Therefore, the study conclusion is considered reliable with Ri = 2. Endpoints can be used for classification purposes.

The indirect aqueous photolysis of BAS 455 H – pendimethalin in sterile natural water was studied in accordance with EEC 94/37 (CA 7.2.1.3/1). The test solutions containing [phenyl-U-^{14}C]-labelled pendimethalin (0.1 mg/L) were continuously exposed to a Xenon arc lamp (wavelength > 290 nm), emitting a light spectrum similar to sunlight (>290 nm) at an intensity of about 3 mW/cm^2 for 15 days. The temperature was kept constant at 22°C. Samples were taken at 0, 1, 3, 7, 9, 11 and 15 days after treatment. Dark control samples were incubated under the same conditions except for irradiation. All samples were measured for total radioactivity (LSC) and analysed by HPLC. Characterization and identification of the photolytic degradation products in aqueous samples was performed by co-chromatography with reference compounds via radio-HPLC and by MS-analysis. The results showed that photolysis of [phenyl-U-^{14}C]-pendimethalin in sterile natural water resulted in a fast decline of pendimethalin to 7.3 % TAR after 15 days. No degradation occurred in the dark control samples. Under continuous irradiation, pendimethalin was readily degraded in sterile natural water with half-life of 3 days according to a single first order kinetics.
This study is conducted in accordance with the FAO and EEC guidelines. No significant limitations are reported for this study. Therefore, the study conclusion is considered reliable with Ri = 1. Endpoints can be used for classification purposes.

Based on a 28-day biodegradability study pendimethalin was found to be not rapidly biodegradable. No information could be derived on BOD and COD data. Moreover, the water-sediment, soil degradation and hydrolysis studies did not provide in evidence of the degradation of the substance within a 28-day period. This is supported by the outcome of the 63 days OECD 309 water-sediment simulation study where the half-lives where so high that they could not be determined reliably.
Several direct and indirect photochemical degradation studies indicate a degradation of > 70% to carbon dioxide or NER within 16 days (DT50 is 5 days or lower) and metabolite 2,6-dinitro-3,4-dimethylaniline, which was formed > 10% of the active radiation was further degraded to unknown polar compounds and carbon dioxide.

However, in the ECHA GD on the application of the CLP criteria (2017) (Section II.2.3.9) it is stated that "Information on photochemical degradation e.g. OECD 1997 is difficult to use for classification purposes. The actual degree of photochemical degradation in the aquatic environment depends on local conditions e.g. water depth, suspended solids, turbidity as well as seasonal influences, and the hazard of the degradation products is usually not known." The information on photodegradation does therefore not alter the conclusion on the rapid biodegradability of the substance; **the substance is considered not rapidly biodegradable.**

11.2 Environmental transformation of metals or inorganic metals compounds

Not relevant for this dossier.

11.2.1 Summary of data/information on environmental transformation

Not relevant for this dossier.

11.3 Environmental fate and other relevant information

Volatility:

Pendimethalin has a vapour pressure of 1.39 x 10^{-3} Pa at 20°C (see Table 7) and therefore concluded to be semivolatile.

Adsorption/desorption from soil:

The adsorption and desorption behaviour of radiolabelled pendimethalin was investigated on four different soils (CA 7.1.3.1.1/1). The four soils covered a range of pH from 5.4 to 7.3, a range of organic carbon content from 1.26% to 4.10% and different textural classes. For the determination of the adsorption/desorption isotherm, five different concentrations (nominal 150, 100, 50, 20 and 10 µg/L of the test item in 0.01 M $CaCl_2$) were used. As determined in preliminary experiments, the appropriate ratio of soil versus test solution was 1/50, and the adsorption equilibrium time was 24 hours. Radioactivity in the aqueous supernatants and soil extracts was determined by liquid scintillation counting (LSC). To check if metabolites of pendimethalin were formed during the test, HPLC-analysis with UV- and radioactive detection was used. The amount of test substance adsorbed to soil was calculated as the difference between the amount of test substance initially present in solution and the amount remaining at the end of the experiment (indirect method). The following adsorption parameters were measured and evaluated for the test item pendimethalin in each soil: distribution coefficients K_d and K_{OC} at five concentration levels, the Freundlich adsorption coefficient K_F, the Freundlich exponent 1/n, and the corresponding K_{FOC} values. Freundlich adsorption coefficients K_F of 124 to 367 mL/g were determined corresponding to K_{FOC} values ranging from approximately 9000 to 12600 mL/g. Freundlich exponents 1/n ranged from 0.92 to 0.98. The determination of desorption isotherms was performed for each soil in one step. The desorption coefficient K_{Fdes} at five concentration levels ranged from 140 to 381 mL/g for the four soils corresponding to K_{FOCdes} values ranging from approximately 9000 mL/g to 18400 mL/g. The values show that pendimethalin was sorbed very strongly to the soils. Desorption kinetics and isotherms experiments showed that adsorption was not reversible.

This study is conducted in accordance with the OECD 106 guideline. The order of concentrations tested for the adsorption isotherm is small (one order of magnitude). Therefore, the study conclusion is considered reliable, but with Ri = 2. Endpoints can be used for classification purposes.

In a second study the aim was to determine the adsorption / desorption behavior of pendimethalin in five European soils in the laboratory (CA 7.1.3.1.1/2). The soils covered a range of pH ($CaCl_2$) from 5.6 to 7.4, a range of organic carbon content from 0.60% to 1.85%, and four different USDA textural classes: one sand, two sandy loams, one silt loam and one sandy clay loam. For the determination of the adsorption isotherm, five different nominal concentrations (1, 3, 10, 30 and 100 µg/L) of the test item in 0.01 M $CaCl_2$ solution were used. The ratio of soil versus test solution was 1/20, and the measurements were performed at the adsorption equilibrium time of 24 h. Desorption tests were performed in two steps on the samples used for the previous adsorption tests by adding 0.01 M $CaCl_2$ solution to the samples without the test item. HPLC-MS/MS was used to determine the amount of pendimethalin in $CaCl_2$ solution after extraction with pentane, and in the soil after extraction with methanol. Distribution coefficients K_d and K_{oc} at five concentration levels, the Freundlich adsorption coefficient K_f, the Freundlich exponent 1/n, and the corresponding $K_{f,oc}$ values were determined. Resulting $K_{f,oc}$ values ranged from 10258 mL/g to 27578 mL/g, with Freundlich exponent 1/n values between 0.904 and 0.961.

This study is conducted in accordance with the OECD 106 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes.

11.4 Bioaccumulation

Table 17: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
USEPA (1979) Fed Reg V44, no53, ASTM E-35.21 draft nos. 6 and 8 (1977 and 1978); Hamelink (1977) *Current bioconcentration test methods and theory*. Aquatic toxicology and hazard evaluation 634: 149-161.	No reliable endpoint	Study does not meet the validaty criteria in accordance with OECD 305. Study not acceptable for classification purposes.	CA 8.2.2.3/01 PN-519-002
OECD 305 (1996), OPPTTS 850.1730, Rainbrow trout (*Oncorhynchus mykiss)*	BCF_{KLG} (growth and lipid corrected): 931 L/kg BCFss: 903 L/kg	R= 1	CA 8.2.2.3/05 2013c/1224090
OECD 305 (1996), zebra fish (*Danio rerio*)	BCFk whole fish: 2900 L/kg, normalized to 5% fat content 1179 L/kg wwt BCFssl (steady stat, lipid corrected): 963-1180 L/kg wwt.	Fish were not fed during exposure. However, overall the endpoints of the study were considered acceptable as weight of evidence. RI = 2	CA 8.2.2.3/08 2003a/ 1033759
Bioaccumulation in fish in outdoor mesocosm enclosures	Maximum BCF 337, 207 and 97.3 L/kg, respectively, based on actual concentration, TWA concentration and initial	RI = 1	CA 8.2.2.3/07 2010a/ 1230332

Method	Results	Remarks	Reference
(*Leuciscus idus melanotus*)	nominal concentration in water; mean BCF based on actual concentration in water 199 L/kg		

11.4.1 Estimated bioaccumulation

No data available.

11.4.2 Measured partition coefficient and bioaccumulation test data

The bioaccumulation potential of 14C pendimethalin was determined for the bluegill sunfish, *Lepomis macrochirus* (CA 8.2.2.3/01). The validaty criteria for OECD 305 were not met due to the variation in the tested concentration (2.2 µg/L to 4.2 µg/L). No reliable endpoints could be drawn from the study and study was not considered acceptable for classification purposes.

Rainbow trout (*Oncorhynchus mykiss*, 4.9-6.9 cm and 1.6-2.4 g/fish at the start) were exposed to [phenyl-U-^{14}C] BAS 455 H (pendimethalin) in the water for 28 days in a flow-through system (~5 volume exchanges per day), followed by 16 days of depuration in clean water (CA 8.2.2.3/05). The study was carried out in accordance with OECD 305. All fish samples were separated into edible and inedible parts prior to analysis by combustion/LSC. The lipid content of 3 control fish was determined at the start and end of uptake and at the end of depuration. Water samples were removed for LSC measurement prior to feeding from treated and control aquaria on day -1, 0, 1, 2, 4, 7, 14, 21 and 28 of uptake and 1, 2, 3, 4 and 5 of depuration. Five fish were sampled from treated and control aquaria prior to feeding on day 1, 2, 4, 7, 14, 21, and 28 of uptake and 1, 2, 4, 8 and 16 of depuration. Length and weight of all sampled fish was measured. The actual measured concentration (LSC) of the saturated stock solution (0.147 mg/L) was below the water solubility (0.33 mg/L at 20°C; List of Endpoints review report pendimethalin (2003)), and radioactivity concentrations in centrifuged and uncentrifuged samples of the stock were essentially the same, indicating that the stock contained no undissolved test substance.
Fish growth rate in the control and the test group was 0.0086 and 0.0119/day, respectively. As these growth rates were statistically significantly different, the value of 0.0119/day was used as k_g value for growth-corrected calculations. The lipid content of 3 control fish was 2.4%, 4.8% and 7.0%, respectively, on day 1, 28 and 44, the value of 4.8% at the end of uptake was used for calculation of the lipid corrected BCF. All validity criteria specified in OECD 305 were satisfied. BCF_{KLG} (growth and lipid corrected) based on total radioactivity was found to be 931 L/kg.

This study is conducted in accordance with the OECD 305 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

Zebra fish (*Danio rerio*) were exposed to [phenyl-^{14}C]-pendimethalin for 14 days in a flow-through system (5 exchanges per day), followed by 21 days of depuration in clean water (CA 8.2.2.3/08). The study was carried out in accordance with OECD 305. Fish were not fed during exposure and fed at 1-2% of body weight daily during depuration.Mean fish weight of the sampled fish (n=4-6 per sampling day) was 347 mg during the uptake phase and 314 mg during the depuration phase. Radioactivity in water and in extracts was quantified by LSC and in extracted fish samples by combustion followed by LSC.
No adverse effects on fish or fish mortality were observed during the study. Fish lipid content in control fish was fairly stable during the study (lipid % per sampling day in range 7.4-18.4% during uptake (mean 12.3%, SD 3.1%) and in the range 11.9-26.2% during the first 8 hours of

depuration (mean 17.7%, SD 6.1%). The modelled BCF values show a good agreement with the steady steady BCF values, confirming the reliability of the study results. The overall kinetic BCF was 2900 L/kg (rounded to 2 significant figures). When corrected for fat content (12.3% during uptake phase), the kinetic BCF normalised to 1% fat content is 236 L/kg, and the kinetic BCF normalised to 5% fat content (fat content recommended by OECD 305 (2012)) is 1179 L/kg. It was noted during review that the reported normalisation was not correct: based on BCF 2800 L/kg, a normalised BCF (1% fat content) of 22800 L/kg was reported, this should be 228 L/kg.
The fish were not fed during uptake, which is rather unusual. However, no adverse effects on fish and fish mortality were recorded, and there were no remarkable differences in fish weight and fat content between the uptake and depuration phase. That said, it is possible that the lack of feeding during the test resulted in changes in metabolism (generally, periods of starvation can result in slower metabolism). It is not known the effect these potential changes might have on the calculated BCF (though if, indeed, metabolism was slowed, it could be a worst-case.
BCF_K value for pendimethalin in whole fish 2900 L/kg wwt, BCF_K normalised to 5% fat 1179 L/kg wwt; CT_{50} for pendimethalin in whole fish 2.5-4.4 days. CT_{90} values 8.3-15 days, 96-97% clearance within 21 days of depuration.
BCF_{SSL} (steady state, lipid corrected) is estimated by RMS to be 963-1180 L/kg wwt. However, considering the lack of feeding and the lack of growth-correction, this endpoint does have some restrictions.

This study is conducted in accordance with the OECD 305 guideline with the exception that the fish were not fed during exposure. However, overall the endpoints of the study were considered acceptable as weight of evidence, with Ri = 2. Endpoints can be used for classification purposes

A study was conducted to investigate the bioaccumulation of pendimethalin in fish under realistic exposure conditions in outdoor mesocosm enclosures in Germany following a single application at 10 µg/L in June 2009 (CA 8.2.2.3/07). A 4 x 3 m pond (depth 120 cm, sublayer 10-15 cm clay) was established in April 2008 in Neu-Ulrichstein, 35315 Hombergh/Ohm, Germany.
The fish exhibited normal behaviour throughout the study. In each enclosure one fish died. Gross pathology of the two fish that died showed infection with common ecto-parasites and damage around the gill or the caudal fin. In addition, one fish was missing in each enclosure at the final sampling for unknown reasons. Fish weight increased by 2-3%, but fish length by about 4-5%, and as a result k-factors decreased during the study (from 1.60 at the start to 1.42-1.47 at the end). No effect of pendimethalin on fish growth could be observed. The abundance of macrozoobenthos decreased during the in-life phase by about 50%, with a slightly stronger decrease in the treated enclosure. This effect was mainly caused by the decreasing abundance of Asellus aquaticus and Gastropoda, which are both natural food items of golden orfe.
The maximum BCF in fish 337, 207 and 97.3 L/kg, respectively, based on actual concentration, TWA concentration and initial nominal concentration in water; mean BCF based on actual concentration in water 199 L/kg.
The study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes.

Based upon the three reliable BCF studies showing BCFs exceding 500 L/kg, it can be concluded that for classification purposes pendimethalin should be considered to have a potential to bioaccumulate.

11.5 Acute aquatic hazard

Table 18: Summary of relevant information on acute aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
Acute, 96 hr (static, with and without sediment) None-guideline	*Oncorhynchus mykiss* (Rainbow trout)	pendimethalin (batch AC12053-136A, purity 94.6%)	LC50 without sediment: **0.196 mg a.s./L** (mean measured)	RI = 2	CA 8.2.1/03/ PN-511-006
Acute, 96 hr (flow through) OECD 203	*Pimephales promelas* (Fathead minnow)	Pendimethalin (batch COD-001337, purity 93.3%)	LC50 > 0.240 mg a.s./L (mean measured)	RI =1	CA 8.2.1/04/ 2010/1155847
Acute, 48 hr (static) OECD 202	*Daphnia magna*	Pendimethalin (batch 20703, purity 98.4%)	EC50**: 0.147 mg a.s./L** (mean measured)	RI = 1	CA 8.2.4.1-02/ PN-521-012
Acute, 48 hr (static) EEC method C.2.	*Daphnia magna*	Pendimethalin (Batch AC12053-136A, purity 94.6%)	EC50: Without sediment: > 1.0 (nominal) / 0.701 mg as/L (mean measured) With sediment: >1.0 (nominal) / 0.606 mg as/L (mean measured)	RI = 1	CA 8.2.4.1-05/ PN-521-017
Acute, 72 hr OECD 201 (2006)	*Selenastrum capricornutum* [a]	Pendimethalin (Batrch 0261, purity 94.5%)	72 h E_rC_{50}: **9.3 µg/L** Mean measured	RI = 1	CA 8.2.6-02/ PN-521-005 CA 8.2.6/07/ 2013a/1160822 (amendment)
120 hr EPA, 1971	*Selenastrum capricornutum*	Pendimethalin (Batch AC-6539-77A, purity 92.98%)	72-h ErC50 >55 µg/L Mean measured	RI = 1	CA 8.2.6-03/ PN-521-006 CA 8.2.6/08 2013b/1160823 (amendment)
Acute, 72 hr OECD 201	*Selenastrum capricornutum*	Pendimethalin (Batch AC12053-136A, purity 94.6%)	72 h ErC50: 24.3 µg/L (mean measured)	RI = 1	CA, 8.2.6/11 PN-521-016
120 hr EPA 1971	*Anabaena flos-aquae*	Pendimethalin (batch AC-6539-77A, purity 92.98%)	EyC50: >0.174 mg/L (mean measured)	RI = 1	CA 8.2.6-04 PN-521-010
14-d study OECD	*Lemna gibba*	Pendimethalin (batch AC12053-136A, purity	ErC50: 22 µg/L	RI = 1	CA 8.2.7/01/ PN-521-007

221 (2006)		94.6%)			8.2.7/02/ 2013a/1160824 (amendment)
7-d study OECD 221 (draft 2002)	*Lemna gibba*	Pendimethalin (batch 115, purity 97.5%)	7-day ErC50 = 15.6 µg a.s./L (initially measured)	RI = 1	CA 8.2.8/01/ TLA91811
Public literature	*Lemna minor*	Pendimetalin, purity 98.0%	EC50 (4d exp.) 85 µg/L EC50 (7d exp.): 177 µg/L	Non-GLP, public literature study RI = 2	CA 8.2.7/03

[a] The current name of this species is *Raphidocelis subcapitata* and formerly also known as *Pseudokirchneriella subcapitata*.

11.5.1 Acute (short-term) toxicity to fish

The 96-hour LC50 of pendimethalin (94.6% purity, batch AC12053-136A) was determined in rainbow trout (*Oncorhynchus mykiss*) in both the presence and absence of natural sediment under static conditions (CA 8.2.1/03). No guideline was reported. The NOEC was also determined. Mortality was the toxic endpoint. Evidence of abnormal behaviours was also recorded. The nominal test concentrations were 1000, 500, 250, 125, 63 and 32 µg/l of pendimethalin. The fish were observed after 1, 3, 6, 24, 48, 72 and 96 hour for mortality and sub-lethal effects. The analytical results for aquaria with sediment showed that measured water concentrations were between 105 and 134% of nominal concentrations at the start of the test, between 52 and 65% after 6 hours and between 0.6 to 5.6% at the end of the exposure.For aquaria without sediment, the measured concentrations were between 90 to 110% of nominal concentrations at the start of the test, between 39 and 57% after 6 hours and between 0.9 to 3.4% of nominal concentrations at the end of exposure. The toxicity of pendimethalin to rainbow trout was based on nominal initial concentration. The results of the test showed that the LC50 96 hours with sediment was 932 µg/l and the NOEC was 125 µg/l (nominal). The results for no sediment vessels showed a LC50 96 hour of 890 µg/l and a NOEC of 125 µg/l. No significant difference in toxicity of pendimethalin to rainbow trout with sediment or without sediment was recorded. However, from the study report it can be read that concentrations in the test media without sediment fell <80% during the study. Based on the measured concentrations on LC50 96 hours without sediment of 195.7 µg/L was derived. For the endpoint in the presence of sediment no measured concentration was available and hence the endpoint in the presence of sediment cannot be used for classification purposes. The study conclusion is considered reliable, with Ri = 2.

In a flow-through acute toxicity study in Fathead minnow (*Pimephales promelas*) the 96-hour LC50 of pendimethalin (93.3% purity, batch COD-001337) was determined in accordance with OECD 203 (CA 8.2.1/04). The test concentrations were Control, 6.25%, 12.5%, 25%, 50% and 100% of a saturated stock solution, corresponding to mean measured concentrations of 0, 0.015, 0.036, 0.055, 0.119 and 0.240 mg pendimethalin/L. Assessment of mortality and symptoms of toxicity were assessed within 1 hour after start of exposure and 6, 24, 48, 72 and 96 hours after start of exposure. After 96 hours of exposure no mortality was observed in the control and at concentrations of up to 0.055 mg pendimethalin/L, whereas 5% and 10% mortality was observed at 0.119 mg a.s./L and 0.240 mg a.s./L. Even though the mortalities in the 0.240 mg a.s./L treatment were marginal, they were preceeded by observeable toxic signs (after 24 and 48 h) and thus considered test substance related. However, the mortality at 0.119 mg/L is not considered to be a toxicologically relevant effect. After 96 hours of exposure no symptoms of toxicity were observed for surviving fish at any of the test item concentration. The LC_{50} (96 h)

for pendimethalin was determined to be > 0.240 mg a.s./L based on mean measured concentrations.

This study is conducted in accordance with the OECD 203 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

In a static acute toxicity study, *Daphnia magna* were exposed to seven measured concentrations of the test substance pendimethalin in a static system over 48 hours (CA 8.2.4.1-02). The study was carried out in accordance with. Acetone was used as a slolvent. The test parameter was the cumulative immobilization of the daphnids after 24 and 48 hours. The EC50 value was based on measured concentrations of pendimethalin. The mean analytical concentrations were 0, 0.029, 0.06, 0.12, 0.21, 0.39, 0.8 and 1.68 mg as./L. Because there was no renewal, test concentrations were calculated as the average of the 0 and 48 hour analyses. The pendimethalin concentration measured after 48 h of static exposure ranged between 75 and 92% of those reported for time 0, with an average value of 82%. The EC 50 value (48 hours) was 0.147 mg a.s./L.

This study is conducted in accordance with the OECD 202 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

In a second study in *Daphnia magna* the 48-hour EC50 of pendimethalin (batch AC 12053-136A, purity 94.6%) was determined in both the presence and absence of natural sediment under static test conditions (CA 8.2.4.1-05). The study was carried out in accordance with EEC method C.2. Immobilisation was used as toxic endpoint, but abnormal behaviour was also recorded. The nominal test concentrations were 1000, 500, 250, 125 and 63 µg/l of pendimethalin. Based on the mean measured water concentrations the EC50s were 606.3 µg/L (including sediment) and 700.86 µg/L (without sediment).

This study is conducted in accordance with the EEC method C.2. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

11.5.3 Acute (short-term) and chronic toxicity to algae or other aquatic plants

An algal growth inhibition test was conducted to determine the 24-, 48- and 72-hour EC50 values of pendimethalin for the freshwater alga *Selenastrum capricornutum* (current name *Raphidocelis subcapitata*) (CA 8.2.6-02). The study was carried out in accordance with OECD 201. The tested concentration range of pendimethalin (Batch No. 0.261, purity 94.5%) was 1 to 128 µg/L. Mean measured concentration ranged from 0.51 to 54.18 µg/L. Biomass was determined by cell counts at 24, 48 and 72 hours. The calculated endpoints based on mean measured concentrations were ErC50 9.3 µg/L and EyC50 3.8 µg/L. The NOEC was determined to be 7.59 µg/L. The EyC10 was 0.74 µg/L and ErC10 was 2.8 µg/L.

This study is conducted in accordance with the OECD 201 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

In a second alga growth inhibition test in *Selenastrum capricornutum* pendimethalin (batch AC 6539-77A, purity 92.98%) was tested at . 2.00, 6.25, 12.5, 25.0, 50.0 and 100 µg/L (CA 8.2.6-03). The study was conducted in accordance with EPA, 1971 guideline. The test was conducted for 5 days under static, non-renewal conditions. Standing crop values were determined by electronic particle counting on test days 3, 4 and 5. Three replicates were tested for each concentration. The measured concentrations (average of day 0 and day 5 analysis) were 0.795, 3.02, 4.85, 13.4, 26.2 and 51.7 µg/L. The EC50 values were ErC50 > 55 µg/L and EyC50 4.3 µg/L. The NOEC was determined to be 3.0 µg/L.

This study is conducted in accordance with the EPA, 1971 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

In an acute toxicity study in *Selenastrum capricornutum* pendimethalin (batch AC12053-136A() was tested at nominal concentraitons of 50, 25, 12.5, 6.3, 3.2 and 1.6 µg/l (CA 8.2.6/11). The study was conducted in accordance with OECD 201 Pendimethalin concentration analysis was performed at the start and at the end of the 72 h exposure period. The effect of the test substance on survival and growth was evaluated. The results of the test showed that the EC50 72 hours for growth rate was 33.7 µg/l (24.3 µg/l based on measured concentrations) and the EC50 72 hours for yield was 18 µg/l (12.7 µg/l based on measured concentrations). The NOEC for both effects was 6.3 µg/l (4.1 µg/l based on measured concentrations).

This study is conducted in accordance with the OECD 201 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

A test was conducted to evaluate the effect of pendimethalin (batch AC-6539-77A, purity 92.98%) on blue-green alga (*Anabaena flos-aquae*) (CA 8.2.6-04). The study was carried out in accordance with EPA 1971 test guideline. The criterion for effect was inhibition of growth in comparision to controls after 5 days of exposure. The nominal test concentrations were 17.5, 35.0, 70.0, 140 and 280 µg/L. Tree replicates were tested for each test substance concentration and control. The highest concentration was slightly above the maximum water solubility limit of the test substance (275 µg/L). The test was conducted for 5 days under static non-renewal conditions. The measured concentrations were 11.7, 24.2, 47.0, 98.0 and 174 µg/L. The effect of pendimethalin on standing crop ranged from 4.1% inhibition at 47.0 µg/L to 19.6% inhibition at 174 µg/L. Therefore the EyC50 was determined to be >0.174 mg/L. The NOEC was determined to be 174 µg/l.
This study is conducted in accordance with the EPA, 1971 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

The acute toxicity of pendimethalin (batch 6539-77A, purity: 92.98%) has been determined for duckweed, *Lemna. gibba* G3 in accordance with OECD 221 (CA 8.2.7/01). Nominal test concentrations were 0, 2.5, 5, 10, 20 and 40 µg/L. The actual concentrations of pendimethalin were measured on test days 0 and 14 in all treatments and the controls. The measured concentrations represented 102-114% of nominal at the start and 5-25% of nominal at the end of exposure. The ErC50 value was 22 µg/L and the EyC50 value was 8.4 µg/L. The NOEC was

not reported, but an EC_{10} for growth rate of 4.15 µg/l and and EC_{10} for yield of 2.27 µg/l were calculated.
This study is conducted in accordance with the OECD 221 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

In a second study in *Lemna gibba* pendimethalin (batch 115, purity 97.5%) was tested at concentrations of 1.00, 3.00, 7.54, 28.9 and 65.0 µg/L in accordance with OECD 221 (CA 8.2.8/01). Static exposure over 7 days was carried out. Three replicates were investigated for the the test concentrations and six replicates for the control. Frond numbers were assessed on days 0, 2, 5 and 7. Inhibition of log biomass growth, specific growth rate and log biomass dry weight were determined.
The NOEC for yield and growth rate was 3.7 µg a.s./L. Based on biomass, the NOEC was 10 µg a.s./L for both yield and growth rate. The 7-day ErC50 was 15.6 µg a.s./L (Initially measured concentration) and the 7-day EyC50 was 6.4 µg a.s./L (initially measured concentration).

This study is conducted in accordance with the OECD 221 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

In a public literature study six herbicides, including pendimethalin, were evaluated for their effect on *Lemna minor* (CA 8.2.7/03). Frond measures were taken every day for 7 days. For each herbicide six or eight concentrations increasing in steps of a factor two plus a control were used. The EC50 values for *Lemna minor* after a short-term exposure pulse of pendimethalin over 3 hours followed by a 4 day and 7 day recovery period were determined to be 0.551 mg a.s./L and 0.549 mg a.s./L, respectively. Longer term exposure over 4 days and 7 days resulted in ErC50 values of 0.085 mg a.s./L and 0.177 mg a.s./L, respectively. The study conclusion is considered reliable, with Ri = 2. Endpoints can be used for classification purposes

11.5.4 Acute (short-term) toxicity to other aquatic organisms

No other relevant studies.

11.6 Long-term aquatic hazard

Table 19: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
Full life cycle toxicity test (up to 288 days) US EPA 1971, US EPA 1975	Fathead minnow *(Pimephales promelas*)	Pendimethalin (batch AC-2603-47, purity 98.3%)	NOEC: 6.3 µg/L (measured) EC_{10}: **7.2 µg/L** (measured) BCF: 1810 L/kg	RI = 1	CA 8.2.2.2/01 PN-513-001
Full life cycle	Zebrafish *(Danio rerio)*	Pendimethalin (batch D-1346,	NOEC: 20 µg/L (nominal)	RI = 1	CA 8.2.2.2/02 2012/1364165

toxicity test (up to 172 days) OECD 210		purity 95.03%)	EC_{10}: 53 µg/L		
Full life cycle toxicity test (up to 184 days) OECD 210	Zebrafish *(Danio rerio)*	Pendimethalin (batch AC 12053-136A, purity 94.6%)	NOEC: 50 µg/L (nominal) EC_{10}: not possible to calculate	RI = 1	CA 8.2.2.2/03 2011/1020765
Flow-through test (21 days) in house protocol	*Daphnia magna*	Pendimethalin (batch no. not reported)	NOEC: **14.5 µg/L** (mean measured) EC_{10}: not possible to calculate	RI = 2	CA 8.2.5.1-01 PN-523-001
Semi-static test (21 days) OECD 211 (1998)	*Daphnia magna*	Pendimethalin (batch 115, purity 97.5%)	Reproduction NOEC: 17.3 µg/L EC_{10}: not calculated	RI = 1	CA 8.2.5/01 DRE91811
30 days Draft BBA guideline	*Chironomus riparius*	Pendimethalin, Lot AC 5213-72A, purity 92.4%	NOEC: 0.138 mg/L (initial measured) 0.082 mg/L (mean measured) NOEC (219 mg a.s./kg sed dw; mean measured) EC_{10}: not possible to calculate	spiked water RI = 2	CA 8.2.5.4-01/ PN-549-002
static test (28 days) BBA guideline proposal (Streloke & Köpp, 1995)	*Chironomus riparius*	Pendimethalin technical, batch no.: 115, purity: 97.5 %;	NOEC: ≥0.261 mg a.s./L (initial measured) NOEC: ≥0.0011 mg a.s./L (mean measured) EC_{10}: not possible to calculate	spiked water RI = 1	CA 8.2.7/1 IZA91811
static test (28 days) OECD 218 (draft): Sediment-water chironomid toxicity test using	*Chironomus riparius*	Pendimethalin (BAS 455 H, Reg. no. 900 072), batch no. FH2933, purity 94.9%	NOEC: 227.3 mg a.s./kg sed dw; initial measured NOEC: (0.1099 mg a.s./L; initial measured, 0.080 mg a.s./L; mean measured)	spiked sediment RI = 1	CA 8.2.5.4-02 2008/1010543

spiked sediment (Feb. 2004)			EC_{10}: not possible to calculate		
Acute, 72 hr OECD 201 (2006)	*Selenastrum capricornutum* [a]	Pendimethalin (Batrch 0261, purity 94.5%)	NOErC 7.59 µg/L ErC_{10}: 2.8 µg/L EyC_{10}: 0.74 µg/L	RI = 1	CA 8.2.6-02/ PN-521-005 CA 8.2.6/07/ 2013a/1160822 (amendment)
120 hr EPA, 1971	*Selenastrum capricornutum*	Pendimethalin (Batch AC-6539-77A, purity 92.98%)	NOEC 3.0 µg/L ErC_{10}: **1.8 µg/L** EyC_{10}: 0.47 µg/L	RI = 1	CA 8.2.6-03/ PN-521-006 CA 8.2.6/08 2013b/1160823 (amendment)
Acute, 72 hr OECD 201	*Selenastrum capricornutum*	Pendimethalin (Batch AC12053-136A, purity 94.6%)	NOEC: 4.1 µg/L (mean measured) EC_{10}: not calculated	RI = 1	CA, 8.2.6/11 PN-521-016
120 hr EPA 1971	*Anabaena flos-aquae*	Pendimethalin (batch AC-6539-77A, purity 92.98%)	NOEC: 174 µg/L EC_{10}: not possible to calculate	RI = 1	CA 8.2.6-04 PN-521-010
14-d study OECD 221 (2006)	*Lemna gibba*	Pendimethalin (batch AC12053-136A, purity 94.6%)	ErC_{10} = 4.15 µg/l EyC_{10} = 2.27 µg/l	RI = 1	CA 8.2.7/01/ PN-521-007 8.2.7/02/ 2013a/1160824 (amendment)
7-d study OECD 221 (draft 2002)	*Lemna gibba*	Pendimethalin (batch 115, purity 97.5%)	NOEC = 3.7 µg a.s./L (initially measured) ErC_{10}: 2.9 µg a.s./L EyC_{10}: 4.2 µg a.s./L	RI = 1	CA 8.2.8/01/ TLA91811

[1] Indicate if the results are based on the measured or on the nominal concentration

11.6.1 Chronic toxicity to fish

The chronic toxicity of ^{14}C pendimethalin has been determined for the fathead minnow, *Pimephales promelas*, in a full life cycle test carried out in accordance with US EPA 1971, US EPA 1975 (CA 8.2.2.2/01). Effects on hatchability of eggs, survival, growth, and reproduction of first generation fish, and on egg hatchability, survival, and growth of their offspring were evaluated. The bioaccumulation and depuration of pendimethalin were also studied. During the first 14 days of the test measured concentrations ranged between 33% - 40% of nominal concentrations, which were 6.3, 13, 25, 50 and 100 µg/L nominal. After the change to DMSO, the nominal concentrations were lowered by 50% and set at half the initial values (i.e. 3.1, 6.3, 13, 25 and 50 µg/L), and the mean measured concentrations accounted for 64% - 90% of these nominal concentrations. Measured concentrations corresponding to 33% - 40% of nominal concentrations 6.3, 13, 25, 50 and 100 µg/L are roughly equivalent to measured concentrations corresponding to 64% - 90% of nominal concentrations 3.1, 6.3, 13, 25 and 50 µg/L. Statistically significant reductions of survival of F1 fry were noted at the two highest treatment levels (mean measured concentrations 22 and 36 µg/L), and these effects are considered to be biologically relevant since there was also a reduction (not statistically significant) of F2 fry

spawned from solvent control eggs at the highest concentration of 40 µg/L. compared to the pooled controls. Hatchability was reduced by 9% and 15% at 22 and 43 µg/L, respectively. These reductions of 9% and 15% are considered to be biologically relevant, although they were not statistically significant at the 95% level when compared to the controls, probably due to the relatively large variation of hatchability at these two treatment levels compared to all lower treatment levels and the controls. In addition, a statistically significant reduction of the number of eggs per female of 56% compared to the pooled control was determined at 9.8 µg/L. As a consequence, the NOEC is 6.3 µg/L.
This study is conducted in accordance with the US EPA, 1971 and US EPA 1975 guidelines. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

11.6.2 Chronic toxicity to aquatic invertebrates

The chronic (21 days reproduction inhibition) toxicity of pendimethalin (batch number not reported) has been determined for the water flea, *Daphnia magna* (CA 8.2.5.1-01). The study was carried out following an in-house protocol. Groups of daphnids were exposed in a flow-through system to technical pendimethalin, dissolved in acetone, in a flow-through test system. Mortality, number of young produced and mean brood sizes produced were recorded. Concentrations of pendimethalin in each dose level were determined on test days 0, 1, 3, 7, 10, 14, 17, and 21. The calculated 21 day reproduction no observed effect concentration (NOEC) was 14.5 µg/L, while 100% mortality was reported for all higher concentrations. The test differed slightly from the current daphnid chronic toxicity test in that fewer daphnids were used per dose than typical for a flow-through exposure system. However, the study conclusion is considered reliable, with Ri = 2. Endpoints can be used for classification purposes

The chronic (21 days) toxicity of pendimethalin (batch 115, purity 97.5%) was determined for *Daphnia magna* (CA 8.2.5/01*)*. The study was carried out in accordance with OECD 211. The mean measured test concentrations were of 125, 54.3, 17.3, 7.12 and 2.28 µg a.i./L. Observations included immobilisation, size and general condition of the parental generation, number and first appearance of juveniles. The results were expressed in terms of mean measured concentrations. One and five parent animals appeared pale at mean measured concentrations of 7.12 and 54.3 µg a.i./L, respectively. The mean length was significantly reduced at 54.3 µg/L. An immobilisation rate of 100 % was observed at 125 µg a.i./L after 5 days of exposure, whereas no immobilisation occurred at any other test level. The reduction in reproduction was significantly different at 54.3 and 125 µg a.i./L when compared to the control ($p < 0.05$). No biologically significant numbers of aborted eggs were observed at any tested concentration. In contrast, biological significant numbers of stillborn juveniles were reached at 54.3 µg a.i./L. The NOEC was 17.3 µg/L.

This study is conducted in accordance with the OECD 211 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

A 30-day toxicity study has been performed for the effect of pendimethalin (purity 92.4%) on larvae of the chironomid midge, *C. riparius* (CA 8.2.5.4-01). The study was carried out following the BBA Guideline proposal. The water solubility of the substance was exceeded, producing low and non-linear recoveries. In the highest nominal treatment groups, the test substance was observed to form an insoluble crystalline surface film at the time of dosing. The crystalline film then precipitated, remaining as crystals on the surface of the sediment. Therefore, at the higher nominal concentrations, lower amounts of the material actually went into solution, resulting in the lower actual water concentrations at the higher treatments. The measured water concentrations decreased in all treatments at the day-10 and day-30 observation

periods. A NOEC of 0.138 mg/L was derived (initial measured). Based on the mean measured concentration a NOEC of 0.082 mg/L is derived. The study conclusion is considered reliable, with Ri = 2. Endpoints can be used for classification purposes

A 28-day static test study has been performed for the effect of pendimethalin (purity 97.5%) on the development of *C. riparius* (CA 8.2.7/1). The test concentration of 0.3 mg/L (nominal initial concentration) was based on a preliminary range-finding study and represents the maximum water solubility of pendimethalin. At the limit test concentration, no statistical significant difference was noted for the emergence rate, transformed emergence rate, mortality and the development rate when compared to the pooled control. Thus, the overall No-Effect-Level (NOEC) was 0.3 mg/L (initial measured). The mean measured concentration declined over the study duration. The geomean of the concentration in the water column over 28 days is calculated as 1.1 µg a.s/L. Therefore the endpoint, based on the geomean concentration is NOEC ≥ 1.1 µg a.s/L. The study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

Another 28-day static test evaluated the effect of pendimethalin (purity 94.9%) on the development of *C. riparius* (CA 8.2.5.4-02). The study was carried out in accordance with OECD 218 (draft, Feb. 2004). The test concentrations were 15, 30, 60, 120 and 240 mg a.s./kg dry sediment. Recoveries in the sediment were in a range between 92.0% - 106.8% of the nominal concentrations at test initiation. The following initial concentrations were measured: 14.3, 31.4, 64.1, 110.4 and 227.3 mg pendimethalin/kg dry sediment. At test termination the detected concentrations ranged from 74.4% - 94.6% of the nominal values (12.5, 25.4, 56.7, 96.4 and 178.5 mg a.s./kg dry sediment). First emerged midges were observed on DAI 16 (= day after insertion of larvae). In the control and all test item treatments 13 to 20 midges emerged. No statistically significant differences were found for the emergence rates (ANOVA with $Chi^2$2x2 Table Test with Bonferroni correction, $\alpha = 0.05$) and development rates (ANOVA followed by Williams Multiple Sequential t-test procedure, $\alpha = 0.05$) at any test item concentration when compared to the solvent control. Therfore, the NOEC was 227.3 mg a.s./kg dry sediment (initially measured). The overlying water concentration was 0.1099 mg a.s./L (initially measured).

This study is conducted in accordance with the OECD 218 guideline. No limitations are reported. Therefore, the study conclusion is considered reliable, with Ri = 1. Endpoints can be used for classification purposes

11.6.3 Chronic toxicity to algae or other aquatic plants

See short-term toxicity for summaries.

11.6.4 Chronic toxicity to other aquatic organisms

No further data relevant for classification.

11.7 Comparison with the CLP criteria

11.7.1 Acute aquatic hazard

The criteria for Category Acute 1 in line with Table 4.1.0 from the Guidance on the Application of the CLP Criteria are:

96 hr LC50 (for fish) ≤ 1 mg/l and/or

48 hr EC50 (for crustacea)	≤ 1 mg/l and/or
72 or 96 hr ErC50 (for algae or other aquatic plants)	≤ 1 mg/l.

Acute toxicity data is available for all three taxa. For fish, invertebrates, algae and aquatic plants, the lowest LC/EC50 values are 0.196 mg/L in Rainbow trout, 0.147 mg/L in *Daphnia magna*, 0.0093 mg/L in *Selenastrium carpricornutum* and 0.0156 mg/L in *Lemna gibba*, respectively. Based on the ErC50 of 0.0093 mg/L in *Selenastrium carpricornutum* pendimethalin should be classified as Category Acute 1 (H400). The corresponding M-factor is 100.

11.7.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Based on a 28-day biodegradability study pendimethalin was found to be not rapidly biodegradable. No information could be derived on BOD and COD data. Moreover, the water-sediment, soil degradation and hydrolysis studies did not provide in evidence of the degradation of the substance within a 28-day period. This is supported by the outcome of the 63 days OECD 309 water-sediment simulation study where the half-lives where so high that they could not be determined reliably.
Several direct and indirect photochemical degradation studies indicate a rapid degradation Howewer, because the actual degree of photochemical degradation in the aquatic environment depends on local conditions and cannot be used for classification purposes, the information on photodegradation does therefore not alter the conclusion on the rapid degradability of the substance; **the substance is considered not rapidly degradable.**
The BCF ranged between 97.3-1179 L/kg for different species. Overall, it is concluded that pendimethalin, for which adequate chronic toxicity data is available, is not rapidly degradable and has a potential to bioaccumulate therefore the following criteria apply:

Category Chronic 1:

Chronic NOEC or ECx (for fish)	≤0.1 mg/l and/or
Chronic NOEC or ECx (for crustacea)	≤0.1 mg/l and/or
Chronic NOEC or ECx (for algae or other aquatic plants)	≤0.1 mg/l.

Category Chronic 2:

Chronic NOEC or ECx (for fish)	> 0.1 to ≤1 mg/l and/or
Chronic NOEC or ECx (for crustacea)	> 0.1 to ≤1 mg/l and/or
Chronic NOEC or ECx (for algae or other aquatic plants)	> 0.1 to ≤1 mg/l.

Chronic toxicity data is available for all three taxa. For fish, invertebrates, algae and aquatic plants, the lowest NOEC/EC10 values are 0.0072 mg/L in Fathead minnow, 0.0145 mg/L in *Daphnia magna* and 0.0018 mg/L in *Selenastrum capriconutum*, respectively. Based on the ErC10 of 0.0018 mg/L for *Selenastrum capriconutum* exposed to pendimethalin via spiked water, Category 1 (H410) should be assigned. The corresponding M-factor for chronic ecotoxicity is 10.

11.8 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

Acute (short-term) aquatic hazard: category Acute 1, M-factor: 100.

Long-term aquatic hazard: category Chronic 1, M-factor: 10.

12 EVALUATION OF ADDITIONAL HAZARDS

12.1 Hazardous to the ozone layer

No data.

12.1.1 Short summary and overall relevance of the provided information on ozone layer hazard

No data.

12.1.2 Comparison with the CLP criteria

Not relevant.

12.1.3 Conclusion on classification and labelling for hazardous to the ozone layer

No classification proposed. Data lacking.

13 ADDITIONAL LABELLING

None.

14 REFERENCES

A full reference list of the studies from the DAR is included in Annex 1. In addition, to these studies the following references were used:

1. EFSA (2016). Peer review of the pesticide risk assessment of the active substance pendimethalin. EFSA Journal 14(3):4420.

2. ECHA (2017). Guidance on the Application of the CLP Criteria, Version 5.0 – July 2017.

3.FOCUS (2014). Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Version 1.1, January 2014. annexes

The study summaries from the DAR of pendimethalin have been included in Annex I.