CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification:

Octamethylcyclotetrasiloxane; D4

EC Number: **209-136-7**

CAS Number: **556-67-2**

Index Number: **014-018-00-1**

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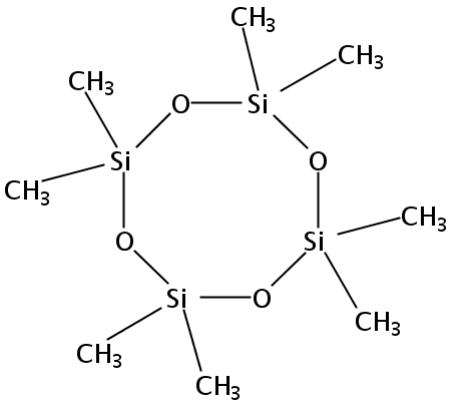
CONTENTS

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)	Octamethylcyclotetrasiloxan
Other names (usual name, trade name, abbreviation)	D4
ISO common name (if available and appropriate)	-
EC number (if available and appropriate)	209-136-7
EC name (if available and appropriate)	octamethylcyclotetrasiloxane
CAS number (if available)	556-67-2
Other identity code (if available)	
Molecular formula	$C_8H_{24}O_4Si_4$
Structural formula	
SMILES notation (if available)	C[Si]1(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O1
Molecular weight or molecular weight range	296.62 g/mol

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)	
Octamethylcyclotetrasiloxane	For typical concentration and concentration ranges see confidential annex.	Repr. 2 Aquatic Chronic 4	H361f *** H413	Repr. 2 Aquatic Chronic 4 Flam. Liq. 3 Aquatic Chronic 2 Aquatic Chronic 1 Not Classified Acute Tox. 1 Acute Tox. 3 Acute Tox. 4 Acute Tox. 4	H361f *** H413 H226 H411 H410 - H330 H311 H302 H312

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
Please refer to confidential annex.				

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 4:

	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	014-018-00-1	octamethylcyclo-tetrasiloxane	209-136-7	556-67-2	Repr. 2 Aquatic Chronic 4	H361f*** H413	GHS08 Wng	H361f *** H413			
Dossier submitters proposal		octamethylcyclo-tetrasiloxane; D4			**Modify**: Aquatic Chronic 4 to Aquatic Chronic 1	**Modify**: H413 to H410	**Add**: GHS09	**Modify**: H413 to H410		**Add**: M=10	
Resulting Annex VI entry if agreed by RAC and COM					Repr. 2 Aquatic Chronic 1	H361f*** H410	GHS08 GHS09 Wng	H361f *** H410		M=10	

Table 5: 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	Data conclusive but not sufficient for classification	No
Acute toxicity via dermal route	Data conclusive but not sufficient for classification	No
Acute toxicity via inhalation route	Data conclusive but not sufficient for classification	No
Skin corrosion/irritation	Data conclusive but not sufficient for classification	No
Serious eye damage/eye irritation	Data conclusive but not sufficient for classification	No
Respiratory sensitisation	Data lacking	No
Skin sensitisation	Data conclusive but not sufficient for classification	No
Germ cell mutagenicity	Data conclusive but not sufficient for classification	No
Carcinogenicity	Data conclusive but not sufficient for classification	No
Reproductive toxicity	No change of the harmonised classification as Repr. 2 (H361f***)	No
Specific target organ toxicity-single exposure	Hazard class not assessed in this dossier	No
Specific target organ toxicity-repeated exposure	Data conclusive but not sufficient for classification	No
Aspiration hazard	Hazard class not assessed in this dossier	No
Hazardous to the aquatic environment	Harmonised classification proposed	**Yes**
Hazardous to the ozone layer	Hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

D4 has been classified as Repr. Cat. 3; R62 and R53 and added to Annex I of Directive 67/548/EEC in 2001 by the 28.ATP. With implementation of the CLP Regulation, D4 was classified and labelled with Repr. 2 (H361f***) and Aquatic Chronic 4 (H413).

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

- Change in existing entry due to changes in the criteria
- Differences in self-classification
- Disagreement by the dossier submitter with current self-classification

5 IDENTIFIED USES

The following information is taken from the InfoCard of D4 on the ECHA-website (ECHA, 2016b):

This substance is used in the following products: washing & cleaning products, polishes and waxes, cosmetics and personal care products, lubricants and greases, textile treatment products and dyes, leather treatment products, semiconductors and non-metal-surface treatment products. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging. This substance is used for the manufacture of: chemicals, rubber products, plastic products, mineral products (e.g. plasters, cement) and electrical, electronic and optical equipment.

6 DATA SOURCES

- Registration dossiers (ECHA, 2016a)
- MSC opinion and Annexes (ECHA, 2015)
- PBT/vPvB evaluation factsheet (Environment Agency, 2013)

7 PHYSICOCHEMICAL PROPERTIES

Table 6: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	liquid	Visual observation	
Melting/freezing point	17.7 °C	J. Amer. Chem. Soc., 75, 2227	Handbook data
Boiling point	175 °C	J Amer. Chem. Soc., 68, 358	Handbook data
Relative density	0.95g/cm³ at 25 °C	AIChE DIPPR Database	Handbook data
Vapour pressure	132 Pa at 25 °C	AIChE DIPPR Database	Handbook data
Surface tension			In accordance with Column 2 of REACH Annex VII, the surface tension study does not need to be conducted as the water solubility of the substance is less than 1 mg/l.
Water solubility	0.0562 mg/L At 23 °C and pH ca. 7	Environmental Toxicology and Chemistry, Vol. 15, No. 8, pp. 1263–1265	Measured
Partition coefficient n-octanol/water	6.488 at 25.1 °C	REACH registration dossier: Study according to OECD Guideline 123 (Partition Coefficient (1-Octanol / Water), Slow-Stirring Method), report date 2007. [ECHA (2016a)]	Measured
Granulometry			In accordance with Column 2 of REACH Annex VII, the granulometry study does not need to be conducted as the substance is marketed and used in a non-solid form.
Stability in organic solvents and identity of relevant degradation products			In accordance with Column 1 of REACH Annex IX this test is only required if stability of the substance is condered to be critical.
Dissociation constant			In accordance with section 1 of REACH Annex XI, the study does not need to be conducted because there are no ionizable groups present in the molecule.
Viscosity	1.6 mm²/s (kinematic) at 20 °C		QSAR MPBPVP v1.43 (EPIWIN 2009 and Stein 1994)

8 EVALUATION OF PHYSICAL HAZARDS

Not addressed in this dossier.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not addressed in this dossier.

10 EVALUATION OF HEALTH HAZARDS

During the preparation of the CLH dossier the registration data and the 'Opinion on cyclomethicone D4/D5 (22 June 2010)' of the SCCS (Scientific Committee on Consumer Safety) (SCCS/1241/10, 2010) for carcinogenicity, mutagenicity, reproductive toxicity and respiratory sensitisation were checked which is evaluated with reliability 4 (secondary source). However, it was concluded that the registrants' and SCCS evaluation of the reliabilities of the studies is appropriate.

As a result of this evaluation the dossier submitter concludes that no additional classification regarding human health or change of the current harmonized classification as Repr. 2, H361f*** is required. Therefore no data are presented in Section 10 'Evaluation of health hazards'.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Table 7: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
OECD Guideline 111 (Hydrolysis as a function of pH)	pH 4: half-life = 4.76 hours (at 9.5 °C) half-life = 1.77 hours (at 24.6 °C) half-life = 0.885 hours (at 35.1 °C) pH 7: half-life = 542 hours (at 9.5 °C) half-life = 91.4 hours (at 24.6 °C) half-life = 144 hours (at 24.6 °C) half-life = 69.3 hours (at 24.8 °C) half-life = 24.9 hours (at 35 °C) pH 9: half-life = 6.37 hours (at 9.5 °C) half-life = 5.61 hours (at 9.5 °C) half-life = 0.902 hours (at 24.6 °C) half-life = 1.01 hours (at 24.3 °C) half-life = 0.190 hours (at 34.5 °C) half-life = 0.218 hours (at 34.6 °C) degradation product: dimethylsilanediol (CAS: 1066-42-8) 12°C, pH 7; half-life = 16.7 days (freshwater) 9°C, pH 8; half-life = 2.9 days (marine water)	Rel. 1 GLP-study	(ECHA, 2015, 2016a)
OECD Guideline 111 (Hydrolysis as a function of pH)	25°C pH 4 half-life = 33 hours pH 7 half-life = 69 hours pH 9 half-life = 0.56 hours	Rel. 4 – secondary source - No GLP-study - tested at only one temperature - not further considered for C&L	(ECHA, 2016a)
OECD Guideline 310 (CO2 in sealed vessels – Headspace Test)	3.7 % CO_2 evolution after 29 days	Rel. 1 GLP-study	(ECHA, 2015, 2016a)
OECD Guideline 308 (Aerobic and anaerobic transformation in	24°C half-life = 242 days (aerobic conditions)	Rel. 4 – secondary source) GLP-study	(ECHA, 2015)

Method	Results	Remarks	Reference
aquatic sediment system)			

11.1.1 Ready biodegradability

Ready biodegradation of D4 was investigated in a study conducted according to OECD Guideline 310 using 10 mg solids/L inoculum (activated sludge, sewage, soil) and 10 mg/L test substance. After 29 days 3.7 % CO_2 evolution was observed. CO_2 evolution of the reference substance (sodium benzoat) was 87.73 % after 14 days. 50.76 % CO_2 evolution at day 14 was shown in the toxicity control. In conclusion, D4 is not readily biodegradable.

11.1.2 BOD_5/COD

No data available.

11.1.3 Hydrolysis

The hydrolysis of D4 was tested according to OECD Guideline 111 at pH 4,7, and 9. The average half-life for pH7 at 25°C was calculated by the registrant to be 3.9 days (ECHA, 2016a). Nevertheless, based on Annex II of the guidance on the application of CLP criteria, the degree of degradation depends not only on the intrinsic degradability but also on the environmental conditions. Hydrolysis was tested in clean water test system. D4 is highly adsorptive to organic matter, which is preventing the hydrolytic degradation in natural waters. Furthermore, the average surface water temperature of 12°C is a more realistic environmental condition in Europe than 25°C. The half-life for the lower temperature was estimated to be 16.7 days (pH 7) (ECHA, 2015).

11.1.4 Other convincing scientific evidence

No data available.

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

Not relevant for this dossier.

11.1.4.2 Inherent and enhanced ready biodegradability tests

No data available.

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

Sediment:
Based on OECD Guideline 308 sediment simulation studies, D4 has an estimated degradation half-life of 242 days in aerobic sediment at 24°C (expected to be longer at lower temperatures) (ECHA, 2015). Low degradation in sediment is also supported by sediment core data from Lake Pepin, USA (monitoring data, (ECHA, 2015)).

Soil:
The available data do not allow a reliable soil degradation half-life to be derived.

11.1.4.4 Photochemical degradation

Not relevant for this dossier.

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

In a reliable study according to OECD Guideline 106 a mean log Koc of 4.22 (average of three different soils; 24.8°C) was observed. It is therefore likely that D4 will adsorb strongly to organic matter in sediment and soil. The Henry´s law constant of 1.21 x 10^6 Pa*m^3/mol at 21.7 °C indicates a high potential for volatilization from water (ECHA, 2016a).

11.4 Bioaccumulation

Table 8: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
OECD Guideline 123	Log Kow = 6.488 at 25.1 °C	Rel. 2 GLP-study	(ECHA, 2015, 2016a)
EPA OTS 797.1520 (*Pimephales promelas*) ^{14}C measurement	BCF = 12400 L/kg (steady state) BCF = 13400 L/kg (kinetic) Re-analysis of the data: BCF = 19000 L/kg (kinetic) BCF = 14900 L/kg (kinetic, lipid normalised)	Rel. 1 GLP-study	(ECHA, 2015, 2016a)
OECD Guideline 305 (Cyprinus carpio	BCF = 3129 L/kg (steady state, 2.52 µg/L) BCF = 3000 L/kg (steady state, 0.22 µg/L) (lipid content close to 5%)	Rel. 2 GLP-study	(ECHA, 2015, 2016a)
OECD Guideline 305 (Cyprinus carpio)	BCF = 3329 L/kg (steady state, 2.4 µg/L treatment level) BCF = 3967 L/kg (steady state, 0.23 µg/L treatment level) BCF = 4106 L/kg (kinetic, 2.4 µg/L) BCF = 5540 L/kg (kinetic, 0.23 µg/L) (lipid content close to 5%)	Rel. 2 GLP-study	(ECHA, 2015, 2016a)

11.4.1 Estimated bioaccumulation

Not data available.

11.4.2 Measured partition coefficient and bioaccumulation test data

A log Kow of 6.488 was determined at 25.1°C according to OECD Guideline 123 (ECHA, 2016a).

The bioconcentration factor (BCF) of D4 was measured (based on ^{14}C measurements) for *Pimephales promelas* using EPA OTS 797.1520 (ECHA, 2015, 2016a). The study included a preliminary test with 6 days exposure followed by 14 days of depuration and a definitive test with 28 days of exposure and 14 days of depuration. A steady-state BCF of 12400 L/kg after 28 days and a kinetic BCF of 13400 L/kg was reported. The data of the study were re-analyzed to take the variable exposure concentrations during the tests into account (concentration in the range of 0.2 to 0.5 µg/L) (Smit et al., 2012). The re-analysis resulted in a kinetic lipid-normalized BCF of 14900 L/kg (lipid content = 6.4 %).

Furthermore, two bioconcentration studies with *Cyprinus carpio* are available (ECHA, 2015, 2016a). Both studies were carried out according to OECD Guideline 305 and had an exposure period of 60 days followed

by a depuration period of 15 days in the first study and 12 days in the second. The lipid content in both studies were close to 5 %.

The first study was carried out using two exposure concentrations (0.22 µg/L and 2.52 µg/L) in a continuous-flow system. The concentration in the fish was found to reach steady state within 39 days. The steady-state BCF values were 3129 L/kg for the higher exposure level and 3000 L/kg for the lower exposure level.

The second study with *Cyprinus carpio* was carried out using 0.23 µg/L and 2.4 µg/L D4. Steady state was found to have been reached by day 46. The mean BCF at steady state was 3329 L/kg at the 2.4 µg/L treatment level and 3967 L/kg at the 0.23 µg/Ltreatment level. Based on the uptake rate constant (k_1) of 407 L/kg/day and the overall depuration rate constant (k_2) of 0.0991 day^{-1}, a kinetic BCF of 4106 L/kg was estimated for the 2.4 µg/L treatment level. For the 0.23 µg/L treatment level a kinetic BCF of 5540 L/kg was determined (k_1 = 467 L/kg/day, k_2 = 0.0843 day^{-1}).

Based on measured BCF values and log Kow, D4 has a high bioaccumulation potential.

11.5 Acute aquatic hazard

Only the most reliable studies are included in the report. There are other studies available from the registration dossier (ECHA, 2016a).

Table 9: Summary of relevant information on acute aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
EPA 797.1400	*Oncorhynchus mykiss*	CAS 556-67-2	96h-LC_{50} > 22 µg/L (mean measured) 96h-NOEC ≥ 22 µg/L (mean measured) 14d-NOEC = 4.4 µg/L (mean measured)	Prolonged acute tox. study Rel. 1 GLP-study	(Sousa et al., 1995)
EPA 797.1300	*Daphnia magna*	CAS 556-67-2	48h-EC_{50} > 15 µg/L (mean measured)	Rel. 1 GLP-study	(Sousa et al., 1995)
EPA 797.1050	*Selenastrum capricornutum (*new: *Pseudokirchneriella subcapitata)*	CAS 556-67-2	96h-ErC_{50} > 22 µg/L (initially measured) (corresponds to 6 µg/L mean measured)	Rel. 2 GLP-study	(ECHA, 2016a)

11.5.1 Acute (short-term) toxicity to fish

(Sousa et al., 1995) conducted two reliable (prolonged) acute toxicity tests to fish, one with *Oncorhynchus mykiss* and one with *Cyprinodon variegatus*. As there were no effects with the latter one, only the test with *O.mykiss* will be described here. The test was performed according to EPA Guideline 797.1400 at 12 ± 2 °C. Sealed glass vessels were used as D4 is volatile. Five concentrations (2.9, 4.4, 6.9, 12 and 22 µg/L measured) were used with two replicates each and ten organisms per vessel (flow-through). No vehicle was used. The biomass loading rate was 0.17 g/L. A photoperiod of 16 h light per day with a light intensity of 55 to 210 footcandles was obtained. Up to day 7 no effects were observed. Therefore, the 96h-EC_{50} was > 22 µg/L. At day 14 20 % of the organisms in test concentration 6.9 µg/L died. Therefore, the 14d-NOEC for survival is 4.4 µg/L.

With *C.variegatus* concentrations up to 6.3 µg/L (maximum achievable concentration) were tested in the (prolonged) acute toxicity test and no effects were observed. Therefore the 14d-NOEC is 6.3 µg/L.

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

(Sousa et al., 1995) also conducted two reliable tests with aquatic invertebrates (freshwater: *Daphnia magna* and marine: *Mysidopsis bahia*, new name: *Americamysis bahia*). They were performed according to EPA 797.1300 and EPA 797.1930. The *D.magna* test was a flow-through test with a duration of 48 hours and analytical monitoring. The test concentrations were 1.7, 2.9, 3.7, 7.8 and 15 µg/L (measured). No vehicle

was used. There was no effect observed up to the highest test concentration. Therefore, the 48h-EC_{50} was > 15 µg/L.

With *Americamysis bahia* the test was conducted 96 hours (flow-through) without vehicle with test concentrations of 1.3, 2.2, 3.7, 6.9 and 9.1 µg/L (measured). No effects up to the highest test concentration were observed. Therefore, the 96h-LC_{50} was > 9.1 µg/L.

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

In (ECHA, 2016a) an toxicity test to algae is reported. The test was performed according to EPA Guideline 797.1050 with *Selenastrum capricornutum* (new: *Pseudokirchneriella subcapitata*). It was a limit test with sealed test vessels without headspace. The limit concentration was 22 µg/L (initially measured) (corresponds to 6 µg/L mean measured concentration). No vehicle was used. The test was valid as the criteria of the guideline OECD 201 (biomass concentration in the control cultures should have increased by a factor of at least 16 within 72h) was fulfilled (increased cell density by a factor of 16.5 after 72 h in the control group). The cell density was decreased 18 % in the treatment compared with the control group. The cell density in both (test system and control system) was lower than expected. In the test also an open-system reference control system was included which demonstrated that the restricted gaseous exchange in the sealed system caused a reduction in growth rate.

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

Not data available.

11.6 Long-term aquatic hazard

Table 10: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
40 CFR 797.1600	*Oncorhynchus mykiss*	CAS 556-67-2	93d-NOEC ≥ 4.4 µg/L (mean measured)	Rel. 1 GLP-study	(ECHA, 2016a; Sousa et al., 1995)
EPA 797.1400	*Oncorhynchus mykiss*	CAS 556-67-2	14d-NOEC = 4.4 µg/L 14d-LOEC = 6.9 µg/L (both mean measured)	Prolonged acute tox. study Rel. 1 GLP-study	(Sousa et al., 1995)
EPA 797.1330	*Daphnia magna*	CAS 556-67-2	21d-NOEC = 7.9 µg/L (mean measured)	Rel. 1 GLP-study	(Sousa et al., 1995)
EPA 797.1050	*Selenastrum capricornutum (*new: *Pseudokirchneriella subcapitata)*	CAS 556-67-2	96h-NOErC < 22 µg/L (initially measured) (corresponds to 6 µg/L mean measured)	Rel. 2 GLP-study	(ECHA, 2016a)

11.6.1 Chronic toxicity to fish

Additionally to the prolonged acute toxicity study with *O.mykiss*, (Sousa et al., 1995) also conducted a reliable long-term (93 day) fish early life stage toxicity study . The test was performed according to Guideline 40 CFR 797.1600 with analytical monitoring and without the use of a vehicle. It was a flow-through test with five concentrations (0.25, 0.53, 1.1, 1.9 and 4.4 µg/L, measured). The resulting NOEC from the FELS test was ≥ 4.4 µg/L (measured). This was the highest test concentration. In a prolonged acute toxicity study with *Oncorhynchus mykiss* also conducted by (Sousa et al., 1995) mortality occurred at a next higher concentration of 6.9 µg/L. It cannot be ruled out that effects might have been observed at higher concentrations than tested in the FELS test. Generally, a longer-term test with early life stages is preferable to a prolonged acute test for the purposes of chronic toxicity assessment. However, the two studies did not overlap in test concentration, so the true level of toxicity to fish over the long-term is unclear.

Overall, the long-term NOEC for fish is assumed to be around 4--6 µg/L, although there is some uncertainty in the actual value and the reasons for the differences between the two studies.

11.6.2 Chronic toxicity to aquatic invertebrates

(Sousa et al., 1995) carried out a reliable 21 day reproduction study with *Daphnia magna* using a flow-through system with no head space (to minimise loss of D4 through volatilisation). The D4 tested was > 99 % pure and stock solutions of the substance were prepared by slow-stirring dilution water with a floating layer (approximately 6 mm thick) of D4. This method of stock-solution preparation gives reproducible results and can achieve a maximum concentration of ca. 15 µg/L in hard freshwater. Five exposure concentrations were used (measured concentrations were 1.7, 1.8, 4.2, 7.9, and 15 µg/L). This study showed a statistically significant (p = 0.05) reduction in the survival at the highest concentration tested (survival in the 15 µg/L was 77 %) compared with the control population (survival was 93 %) after 21 days. The 21-day NOECsurvival was therefore 7.9 µg/L. For the reproduction endpoint, the mean cumulative number of offspring per female daphnid was 111 in the control, 107, 92, 123, 151, and 167 in the 1.7, 1.8, 4.2, 7.9 and 15 µg/L treatment groups, respectively. There were no statistically significant (p = 0.05) differences between the control response and the treatment response in the 1.7, 1.8, and 4.2 µg/L groups, but the mean cumulative number of offspring per female was significantly higher in the 7.9 µg/L treatment group than in the control groups (the data for the 15 µg/L treatment group were not included in the statistical analysis as a reduction in daphnid survival occurred in this group). Therefore it is concluded that concentrations of D4 ≤ 7.9 µg/L do not adversely affect the reproduction of *D. magna*.

11.6.3 Chronic toxicity to algae or other aquatic plants

As described above (chapter 11.5.3), there is one toxicity study with algae reported in (ECHA, 2016a). As it is a limit test, the validity of the study is restricted. The resulting NOEC is < 22 µg/L (initially measured) (corresponds to 6 µg/L mean measured).

11.6.4 Chronic toxicity to other aquatic organisms

Not data available.

11.7 Comparison with the CLP criteria

11.7.1 Acute aquatic hazard

Table 11: Comparison with critera for acute aquatic hazards

	Criteria for environmental hazards	D4	Conclusion
Acute Aquatic Toxicity	Cat. 1: $LC_{50}/EC_{50}/ErC_{50} \leq 1$ mg/L	Fish: 96h-LC_{50} > 0.022 mg/L (mean measured) Invertebrates: 48h-EC_{50} > 0.015 mg/L (mean measured) Algae: 96h-ErC_{50} > 0.022 mg/L (initally measured)	**No classification**

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

Table 12: Comparison with critera for long-term aquatic hazards

	Criteria for environmental hazards	D4	Conclusion
Rapid Degradation	Half-life hydrolysis < 16 days Readily biodegradable in a 28-day test for ready biodegradability (> 70% DOC removal or > 60% theoretical oxygen demand, theoretical carbon dioxide) Supporting information: Half-life aquatic sediment < 16 days	Half-life hydrolysis = 16.7 days (pH7, 12°C) 3.7 % after 29 days (CO_2 evolution) => not readily biodegradable Half-life = 242 days	**Not rapidly degradable**
Bioaccumulation	Log Kow ≥ 4 BCF ≥ 500	Log Kow = 6.488 BCF = 3000-14900	**High potential for bioaccumulation**
Aquatic Toxicity	Non-rapidly degradable substances: Cat. 1: NOEC ≤ 0.1 mg/L Cat. 2: NOEC ≤ 1 mg/L	Fish: 14d-NOEC = 0.0044 mg/L (mean measured) Invertebrates: 21d-NOEC = 0.0079 mg/L (mean measured) Algae: 96h-NOErC < 0.022 mg/L (initially measured)	**Aquatic chronic 1, H410, M=10** (based on 21d-$NOEC_{Daphnia}$ = 0.0079 mg/L suppored by 14d-$NOEC_{fish}$= 0.0044 mg/L)

11.8 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

D4 is not rapidly degradable and fulfills therefore with a NOEC ≤ 0.1 mg/L the classification criteria for hazardous to the aquatic environment “Aquatic Chronic 1”. The hazard statement code is H410. With the NOECs of 0.0044 mg/L (for fish) and 0.0079 mg/L (for aquatic invertebrates) a M-factor of 10 has to be assigned.

12 EVALUATION OF ADDITIONAL HAZARDS

Not addressed in this dossier.

13 ADDITIONAL LABELLING

None

14 REFERENCES

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15 ANNEXES

Annex I (confidental)