Annex I to the CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification:

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol

EC Number: **211-477-1**

CAS Number: **647-42-7**

Index Number: **n.a.**

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Version number: **2.0**

Date: **January 2021**

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1 ENVIRONMENTAL HAZARDS

1.1 Degradation

1.1.1 Ready biodegradability (screening studies)

[Study 1: (ECHA Registration dossier: Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, 2010)]

Study reference:

Kurume Laboratory, Chemicals Evaluation and Research Institute (2010): Biodegradation study of 13F-EtOH by microorganisms. Report no. 15463 (report date: 2010-07-01)

Detailed study summary and results:

The ready biodegradability of 6:2 FTOH was evaluated in a closed bottle test (OECD TG 301 D). The initial concentration of 6:2 FTOH used in this study was 100 mg/L (test material). Activated sludge was used as inoculum. Further details on inoculum as well as test conditions were not given in the registration dossier. After 28 days an average biodegratation of 5% (average of three replicates) was determined.

Test type:

OECD Guideline 301 D, GLP not specified

Test substance:

• equivalent

Materials and methods:

• Details on inoculum: activated sludge (adaption not specified)

• Duration of test: 28 days

• Initial test substance concentration: 100 mg/L based on test mat.

Results:

• Degradation: 5 % (based on test material analysis) after 28 days (average of three replicates: 5%, 6% and 4%)

[Study 2: (ECHA Registration dossier: DR. U. NOACK-LABORATORIUM, 2000)]

Study reference:

DR. U. NOACK-LABORATORIUM (2000): Fluowet EA 600 Ready Biodegradability, Modified Sturm Test. Report no. AST75701 (report date 2000-11-15)

Detailed study summary and results:

A test according to OECD TG 301 B (CO2 Evolution Test) was performed. 40 mg/L of the test material was used as initital concentration. Domestic activated sludge was used as inoculum. Further details on the study

are not published. After 28 days 21% CO2 evolution and 0% CO2 evolution were observed in two replicates. The difference of the biodegratation values of the two replicates is > 20%, therefore, the study should be considered as not valid.

Test type:

OECD Guideline 301 B, GLP

Test substance:

• equivalent

Materials and methods:

• Details on inoculum: activated sludge, domestic (adaption not specified)

• Duration of test: 28 days

• Initial test substance concentration: 40 mg/L based on test mat.

Results:

• Degradation: 21 % (CO2 evolution) after 28 days; 0 % (CO2 evolution) after 28 days

1.1.2 Aquatic simulation tests

[Study 1: Zhao et al. 2013, aerobic river sediment system)]

Study reference:

Zhao L., Folsom P.W., Wolstenholme B.W., Sun H., Wang N., and Buck R.C. (2013): 6:2 fluorotelomer alcohol biotransformation in an aerobic river sediment system. Chemosphere 90 (2), 203-209. DOI: 10.1016/j.chemosphere.2012.06.035

Detailed study summary and results:

In an aerobic river sediment system similar biotransformation products as in soil and activated sludge were detected.. The recovery of 6:2 FTOH and quantifiable transformation products ranged 71-88 mol% of initially applied 6:2 FTOH. The lower mass balance compared to sterile control (86-98 mol%) could be explained by formation of bound residues. The 6:2 FTOH primary degradation half-life in sediment system was estimated to be 1.8 days. After 100 days 22.4 mol% 5:3 polyfluorinated acid, 10.4 mol% perfluoropentanoic acid, 8.4 mol% perfluorohexanoic acid, and 1.5 mol% perfluorobutanoic acid were detected.

Test type:

OECD Guideline 308, GLP not specified

Test substance:

• equivalent (>97% purity)

Materials and methods:

• Details on water/sediment sample: The river sediment was collected from Brandywine Creek, PA at

the position of Latitude 39° 51 min 34 s, longitude 75° 35 min 55 s,and 78 m above sea level. River water was collected from the same location. The collected sediment was sandy loam (67% sand, 24% silt, and 9% clay) with 5.3% organic matter or 3.1% organic carbon content. The pH of the sediment was 6.9 and the cation exchange capacity (CEC) was 86 mmol/kg sediment.

• Duration of test: 100 d

• The biotransformation was conducted in 119-mL glass serum bottles. Twenty grams wet sediment containing 9.3 g dry weight and 10.7 mL river water, 25 mL pure river water, and 5 mL mineral media were added sequentially into each test vessel. The mineral medium solution contained 85 mg/L of KH2PO4, 218 mg/L of K2HPO4, 334 mg/ L of Na2HPO4·2H2O, 5 mg/ L of NH4Cl, 36.4 mg/L of CaCl2·2H2O, 22.5 mg/ L of MgSO4·7H2O, and 0.25 mg/L of FeCl3·6H2O with a pH of 7.0. For the sterile control, autoclaved sediment and river water were used instead and triple antibiotics (kanamycin, chloramphenicol, and cycloheximide) were added to the sterile sediment to a final concentration of 200 mg/kg sediment. The sample bottles containing live and sterile sediment were crimp-sealed with butyl rubber stoppers and aluminum caps and incubated at room temperature for 5 d before dosing 6:2 FTOH to initiate the experiment. After the pre-incubation, each bottle was inverted and 10 µL of 6:2 FTOH stock solution (5000 mg/ L) made in 50% ethanol (v/v, ethanol:water = 1:1) was injected into the sediment with a 10-µL glass microsyringe. The initial 6:2 FTOH dosing concentration was determined based on the LC/MS/MS detection limit that would allow low levels (1–2% of initially applied 6:2 FTOH) of transformation products to be quantified and environmentally relevant. Some of the live sediment sample bottles after pre-incubation were only dosed with 10 µL of 50% ethanol into each bottle as live matrix control for monitoring headspace O2 content during the biotransformation and also serving as background blank for LC/MS/MS analysis. After dosing with 6:2 FTOH or 50% ethanol, the bottle was gently shaken to disperse the dosed solution throughout the sediment system.. Two C18 SPE cartridges) pre-activated with acetonitrile (CH3CN), were coupled with two 18-gauge needles, which were pushed into the headspace of each sample bottle. These two cartridges enabled air exchange between headspace and ambient air and also captured 6:2 FTOH and other volatile intermediates during biotransformation. After dosing with 6:2 FTOH or 50% ethanol and connecting with C18 cartridges, the sample bottles were kept static for 10–15 min to settle the sediment before the bottles were shaken continuously at about 35 rpm on an orbital shaker at room temperature. The 35 rpm low-velocity motion ensured aqueous phase aeration but did not disturb the settled sediment phase.

• Sampling and sample preparation: At each sampling time (days 0, 2, 7, 14, 28, 56, and 100), three live, three sterile control, and two live matrix control bottles were sacrificed for sampling and processing to analyze 6:2 FTOH and transformation products. The day 0 sample bottles were processed within 15 min after dosing with 6:2 FTOH stock solution or 50% ethanol. At each sampling time except day 0, the O2 content in the headspace of the live matrix control bottles (dosed with only 50% Ethanol) was measured using a headspace Oxygen Analyzer Model 905 to estimate the aerobic condition of the live sediment system. The C18 cartridges were disconnected from all the three live, three sterile control, and two live matrix control bottles and each was eluted with 5 mL CH3CN for LC/MS/MS analysis. Each of the butyl rubber

stoppers from the bottles was removed and transferred to a glass vial containing 5 mL CH3CN to extract 6:2 FTOH and other volatile products. The aqueous phase from each bottle was decanted to a glass bottle containing 60 mL CH3CN for extraction of 6:2 FTOH and transformation products. Forty milliliters of CH3CN was added to the remaining sediment of each bottle, which was immediately crimp-sealed with a fresh butyl rubber stop and aluminum cap for the extraction. All extractions were carried out at 50°C for 2–5 d on an orbital shaker kept at 200 rpm. The extract solution (first extract) from each of the sediment sample bottles was decanted to a glass container after centrifugation at ~1000 rpm (162g) with a Sorval GSA rotor for 15–20 min. The remaining sediment was extracted again with 40 mL CH3CN plus 40 µL of 5 MNaOH at 50 °C overnight and the extract solution (2nd extract) was decanted to a glass container after the centrifugation. All the processed sample solutions described above were filtrated through nylon filters (0.45 lmpore) and stored at ~10 °C before subject to LC/MS/MS analysis.

Results:

• primary degradation DT_{50} = 1.8d

• transformation products and transient intermediates after 100 d: 5:3 acid [F(CF2)5CH2CH2COOH] (22.4 mol%), perfluoropentanoic acid (10.4 mol%), perfluorohexanoic acid (8.4 mol%), perfluorobutanoic acid (1.5 mol%), 6:2 FTCA [F(CF2)6CH2COOH] (<1 mol%), 6:2 FTUCA [F(CF2)5CF=CHCOOH] (<1 mol%), 4:3 acid [F(CF2)4CH2CH2COOH] (2.7 mol%), 5:2 ketone [F(CF2)5C(O)CH3] (1.5 mol%), and 5:2 sFTOH [F(CF2)5CH(OH)CH3] (20.2 mol%)

• In sterile sediment control samples, only 6:2 FTOH was detected and ranged between 86 and 98 mol% of day 0 concentration over 100 d. The recovery of 6:2 FTOH and quantifiable transformation products in live samples ranged 71–88 mol% of initially applied 6:2 FTOH over 100 d. The bound residues formed between live sediment and 6:2 FTOH or 5:3 acid catalyzed by microbial enzymes may explain the slightly lower recovery in live sediment system versus sterile controls.

• partition of sedimentdosed 6:2 FTOH and formed transformation products: sterile controls: 51 mol% remained in the sediment phase, 3.4 mol% was partitioned to the aqueous phase, and 32 mol% was volatized to the headspace on day 100; live samples: 39 mol% remained in the sediment phase, 16 mol% was partitioned to the aqueous phase, and 15 mol% was volatized to the headspace on day 100.

1.1.3 Other degradability studies

[Study 1: Liu et al. 2010b; mixed aerobic bacterial culture]

Study reference:

Liu J., Wang N., Szostek B., Buck R.C., Panciroli P.K., Folsom P.W., Sulecki L.M., and Bellin C.A. (2010b): 6-2 Fluorotelomer alcohol aerobic biodegradation in soil and mixed bacterial culture. Chemosphere 78 (4), 437-444. DOI: 10.1016/j.chemosphere.2009.10.044

Detailed study summary and results:

The biodegradability of 6:2 FTOH (2.8 µg/ml and 20 µg/ml) was investigated with a mixed aerobic bacterial culture developed from activated sludge from an industrial wastewater treatment plant. The sludge was previously exposed to fluorinated chemicals. The concentration of 6:2 FTOH decreased to 1.6-2.8% after 7 days (primary biodegradation). Metabolite concentrations reached steady state after 14-28 days (metabolites: 6:2 fluorotelomer unsatured acid, 5:2 secondary alcohol (5:2 sFTOH), 6:2 fluorotelomer satured acid; 5:3 polyfluorinated acid, perfluorohexanoic acid, perfluorobutanoic acid and perfluoropentanoic acid). Adsorption of the transient metabolites to rubber septa cannot be excluded. Due to the adaption of the inoculum the study should no be used for classification and labelling purposes.

Test type:

OECD Guideline 302 A, GLP not specified

Test substance:

• equivalent (99% purity)

Materials and methods:

• Details on inoculum: mixed bacterial culture from activated sludge (industrial), activated sludge was adapted;

• Duration of test: 90 days

• Initial test substance concentration: 2.8 µg/ml based on test mat.

• The test vessels were 120-mL glass serum bottles sealed with natural rubber septa and the vessels were incubated on an orbital shaker at 150 rpm at 20–25 °C. The incubation was initiated by aseptically adding 30 mL of the mixed bacterial culture to each test vessel then dosing with 6 µL of 6:2 FTOH stock solution prepared in ethanol. Sterile treatments were prepared by autoclaving the culture and dosing with the triple antibiotics (kanamycin, chloramphenicol and cycloheximide) at 100 mg/L final concentration each to further inhibit microbial or enzymatic activities. Three treatments of duplicate vessels were prepared: (1) untreated (matrix) live culture with 6 µL ethanol; (2) 6:2 FTOH treated live culture; and (3) 6:2 FTOH treated sterile culture. At each sampling time point, a total of six test vessels were sacrificed for sample processing and extraction of 6:2 FTOH and potential metabolites. The O2 content was also measured at each time point in untreated live culture to approximate O2 content in treated live sample bottles.

• sampling and sample preparation: In mixed bacterial culture, test vessels were extracted and analysed at 0, 2, 7, 14, 28, 60, and 90 d. Prior to vessel opening, the pH was measured with a miniaturized pH probe pierced through the sample vessel rubber septa. Without breaking the seal, ~1.0 mL of the headspace gas was sampled with a gas-tight syringe and analyzed for the oxygen content with a 4900 Micro-GC Then, without breaking the seal, 5 mL of culture was drawn out with a syringe for fluoride measurement, using a previously described method.. Finally, the entire sample vessel was extracted with 30 mL of acetonitrile injected with a syringe through the septum. The vessel was first shaken at room temperature for 1–2 h, the seals were removed and the rubber septum was pushed into the bottle to be extracted together with the culture by acetonitrile. The vessels were then recrimped with a new septum and shaken at 50 °C for 2–7 d.

After extraction, 20 mL of the total acetonitrile extract was filtered through a 0.45 µm nylon filter and stored frozen (~ -20 °C) until chemical analysis by LC/MS/MS.

Results:

• Degradation: 6:2 FTOH concentration decreased rapidly and stabilized after day 7 at 1.6-2.8% of the total 6:2 FTOH mass applied at day 0 (7.7 nmol/mL). No metabolism was observed in untreated and sterilized control test systems. Metabolite concentrations reached steady-state after 14–28 d. At day 28, 6:2 fluorotelomer unsatured acid (6:2 FTUCA) (25%) and 5:2 sFTOH (17%) were the two dominant metabolites with 6:2 fluorotelomer satured acid (6:2 FTCA) (5.7%), 5-3 acid (5.5%), perfluorohexanoic acid (PFHxA, 5.1%), and perfluorobutanoic acid (PFBA) and perfluoropentanoic acid (PFPeA) each less than 0.5% yield. 6:2 FTUCA, 5:2 sFTOH and 6:2 FTCA are not terminal metabolites and they would be expected eventually to be converted to terminal metabolites such as PFPeA, PFHxA, and 5-3 acid. 6-2 FTOH degradation virtually ceased after 14–28 d.

[Study 2: Liu et al. 2010a, flow through soil incubation system]

Study reference:

Liu J., Wang N., Buck R.C., Wolstenholme B.W., Folsom P.W., Sulecki L.M., and Bellin C.A. (2010a): Aerobic biodegradation of [14C] 6:2 fluorotelomer alcohol in a flow-through soil incubation system. Chemosphere 80 (7), 716-723. DOI: 10.1016/j.chemosphere.2010.05.027

Detailed study summary and results:

The aerobic biodegradation of 6:2 FTOH was performed in a flow through soil incubation system. After 1.3 days, 50% of 14C labelled 6:2 FTOH disappeared from soil, because of microbial degradation and volatilisation. The overall mass balance during the 84-day incubation averaged 77% and 87% for the live and sterile treatments, respectively. 16% [14C] 5:2 sFTOH, 14% [14C] 6:2 FTOH and 6% [14C] CO2 were measured in the airflow after 84 days. In soil the following stable transformation products were detected after 84 days: 5:3 polyfluorinated acid (12%), perfluorohexanoic acid (4.5%), perfluoropentanoic acid (4.2%), and perfluorobutanoic acid (0.8%). In soil-bound residues, the major transformation product was 5:3 polyfluorinated acid, which may not be available for further biodegradation in soil.

Test type:

Flow through Soil simulation test

Test substance:

• equivalent (purity 99%)

Materials and methods:

• Details on soil sample: Sassafras soil

• Duration of test: 84 d

• Seven identical systems were constructed to make three replicates of live soil, three replicates of sterile soil and one soil matrix. The soil matrix sample was used for LC/MS/MS analysis of background levels of 6:2 FTOH and its potential transformation products over 84 d. The incubation was initiated by adding 200 lL

working solution (972µL [1,2-14C] 6:2 FTOH test substance diluted with 2.028 mL absolute ethanol) into the soil microcosms in the 500-mL vessel (live and sterile) and manually mixed with a sterile spatula. The initial 14C dosed was experimentally determined to be 5.3 x 105 dpm (disintegrations per minute) g^{-1} soil (oven-dry mass), which corresponds to 8 nmol/g or 2.9 µg/g (including both 14C-labeled and unlabeled 6:2 FTOH). The system maintenance included keeping constant air flow rate, replacing the soda lime traps when needed, and changing the NaOH traps every four weeks.

• Sampling and sample preparation: At each designated sampling time (days 0, 1, 4, 7, 14, 29, 56, 84), a soil aliquot of ~5.0 g was removed from each vessel for three sequential extractions performed in a 20-mL glass bottle. The soil was first extracted with 15 mL acetonitrile (CH3CN) for 2–7 d at 50°C, centrifuged at 657g for 20 min and the supernatant was removed for analysis. For the second and third extractions, the soil was shaken overnight with 15 mL 90/10 (v/v) CH3CN/250 mM NaOH solution at 50 °C, neutralized with 80 µL of 5 M HCl and centrifuged at 657g for 20 min. All soil extracts were stored at below -10 °C in the dark before chemical analysis. The bottle septum was replaced after each soil sampling and extracted with 5 mL CH3CN at 50 °C for 2–7 d. On each sampling day, the C18 cartridges were removed from the soil vessel outlet and replaced with fresh cartridges. The removed cartridges were eluted with 5 mL CH3CN individually for the first 7 d, then in tandem for the later sampling days. Periodically, 0.5 mL of aqueous NaOH solution from each trap was withdrawn from each trap and counted for radioactivity.

• Analytical methods: Radioactivity was determined using a Beckman LS5000 TD liquid scintillation counter. The soil CH3CN extracts and C18 cartridge eluent were analysed using a liquid chromatography/accurate radioisotope counting (LC/ARC) system. The first soil extracts were treated with NaOH and Envicarb™ activated carbon before LC/ARC and LC/MS/ MS analysis to recover 6:2 FTOH and transformation products that were conjugated to dissolved soil components

Results:

• Half of the [1,2-14C] 6:2 FTOH disappeared from soil in 1.3 d, undergoing simultaneous microbial degradation and partitioning of volatile transformation product(s) and the 6:2 FTOH precursor into the air phase.

• The overall 14C (radioactivity) mass balance in live and sterile treatments was 77–87% over 84-d incubation. In the live test system, 36% of total 14C dosed was captured in the airflow (headspace), 25% as soil-bound residues recovered via thermal combustion, and 16% as soil extractable. After 84 d, [14C] 5:2 sFTOH [F(CF2)5CH(OH)14CH3] was the dominant transformation product with 16% molar yield and primarily detected in the airflow. The airflow also contained [1,2-14C] 6:2 FTOH and 14CO2 at 14% and 6% of total 14C dosed, respectively. The other significant stable transformation products, all detected in soil, were 5:3 acid [F(CF2)5CH2CH2COOH, 12%], PFHxA [F(CF2)5COOH, 4.5%] and PFPeA [F(CF2)4COOH, 4.2%]. Soil-bound residues as well as conjugates between fluorinated transformation products and dissolved soil components were only observed in the live test system and absent in the sterile soil, suggesting that such binding and complexation are microbially or enzymatically driven processes. At

day 84, 5:3 acid is postulated to be the major transformation product in soil-bound residues, which may not be available for further biodegradation in soil environment.

[Study 3: Liu et al. 2010b; soil]

Study reference:

Liu J., Wang N., Szostek B., Buck R.C., Panciroli P.K., Folsom P.W., Sulecki L.M., and Bellin C.A. (2010b): 6-2 Fluorotelomer alcohol aerobic biodegradation in soil and mixed bacterial culture. Chemosphere 78 (4), 437-444. DOI: 10.1016/j.chemosphere.2009.10.044

Detailed study summary and results:

The authors investigated the aerobic biodegradation of 6:2 FTOH (without ^{14}C-labelling) in soil (closed system). 6:2 FTOH primary degradation half-life was 1.6 days. The overall mass balance in aerobic soil was ~67% after 180 days (e.g. due to irreversible bond to soil). After 180 days the following substances were accounted: 30 % perfluoropentanoic acid, 8.1% perfluorohexanoic acid, 1.8% perfluorobutanoic acid, 15% 5:3 polyfluorinated acid, 1 % 4:3 polyfluorinated acid, 3 % 6:2 FTOH, and 7.1% 5:2 sFTOH.

Test type:

OECD Guideline 307, GLP not specified

Test substance:

• equivalent (99% purity)

Materials and methods:

• Details on soil sample: Sassafras soil from a forested area undisturbed for at least 40 years in Newark, Delaware; The soil was a sandy loam (52% sand, 34% silt, and 14% clay) with 3.8% organic matter (OM), pH of 5.8 (1:1 soil:water) and microbial biomass carbon of 150 µg/ g dry soil

• Duration of test: 180 days

• 6:2 FTOH was initially dosed at 2.9µg/ g soil (or 8.0 nmol/ g). Parent and metabolites were measured in three compartments: volatile analytes in the headspace, volatile analytes absorbed onto the rubber septa, and study analytes in soil by exhaustive solvent extraction of the entire test vessel. 120-mL glass serum bottles were incubated statically in dark at 20–25 °C for 180 d. Approximately 10 g dry weight equivalent of sieved Sassafras soil was added to each vessel, and dosed with 10 µL of 6:-2 FTOH stock solution prepared in ethanol. For each sampling time point, four treatments of triplicate vessels were prepared: (1) untreated (matrix) live soil with 10 lL ethanol; (2) 6:2 FTOH treated live soil; (3) 6:2 FTOH treated sterile soil; and (4) sterile soil treated with selected metabolites.

• sampling and sample preparation: T*est vessels were sacrificed at each time point for extraction and sample analysis at 0, 2, 7, 14, 28 60, 90, 120, and 180 d. The O2 content was also measured at each time point in untreated live soil to approximate O2 content in treated live sample bottles. Prior to opening the soil test vessels, the headspace gas of a sample bottle was pumped out through two needles inserted through the septum using an air pump at a rate of 1.5 L/ min for 1 min. The outlet air went through two C18 cartridges in series to capture volatile fluorinated compound(s). Each cartridge was eluted with 5 mL acetonitrile and*

subject to chemical analysis. The rubber septum was then removed and extracted in 5 mL acetonitrile at 50 °C for 2–7 d. The soil was subjected to two sequential extractions in the test vessel sealed with a new rubber septum to enhance recovery of 6:2 FTOH and potential metabolites. For the first extraction, 20 mL acetonitrile was added to the soil of each bottle, and the vessels were shaken at 50 °C for 2–7 d and then centrifuged at 1000 rpm for 20 min to collect the supernatants (extracts). For the second extraction, 18 mL acetonitrile and 2 mL of 250 mM NaOH were added to the soil of each bottle. The final concentration of acetonitrile was 90% and NaOH was 25 mM. The vessels were shaken at 50 °C overnight. 0.5 mL of 1 M HCl was then added to each bottle to neutralize the extract and the vessels were centrifuged at 1000 rpm for 20 min to collect the neutralized supernatants.All the extracts, from C18 cartridge, septa and soils, were stored under frozen conditions (~ -20°C) and later analyzed by LC/MS/MS.

Results:

• treated sterile control: ~87–113% 6:2 FTOH mass balance over 180 d; treated live soil samples: ~67% 6:2 FTOH mass balance after 180 days (metabolites irreversibly bound to soil and and non-extractable)

• half-life (primary degradation) = 1.6 d

• metabolites after 180 d: perfluoropentanoic acid (30%), 5:3 acid (15%), perfluorohexanoic acid (8.1%), 5-2 sFTOH (7.1%), perfluorobutanoic acid (1.8%), 4:3 acid (~1%), 5:2 sFTOH (7%)

1.2 Bioaccumulation

1.2.1 Bioaccumulation test on fish

[Study 1: (ECHA Registration dossier, Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, 2002)]

Study reference:

Kurume Laboratory, Chemical Evaluation and Research Institute (2002): Bioconcentration study of C6-2 alcohol in carp. Report no.: 43771 (report date: 2002-01-31)

Detailed study summary and results:

A fish bioconcentration test according to OECD TG 305 was conducted for 28 days on Cyprinus carpio with two exposure levels (1 and 10 µg/L nominal; 0.835 and 9.11 µg/L measured) of the test substance (registration dossier Kurume, 2002). The test temperature ranged from 24.6 to 25.9°C and the pH from 7.6 to 7.9. The lipid content was 2.95% at the start of the exposure and 2.26% at the end of the exposure. After 28 days whole body w.w. BCF values of ≤ 36 (exposure level 1 µg/L) and 46 (exposure level 10 µg/L) were determined (steady state).

Test type:

OECD Guideline 305, GLP; derivation: no post-exposure (depuration) phase

Test substance:

• equivalent (purity 99.8 wt%)

Materials and methods:

• Sampling intervals/frequency for test organisms: The test fish of Level 1 and 2 were analysed five times in duration of exposure. Four fish were taken out at each sampling time and divided into two groups, then both were analysed individually. Because one fish was too small to take out the stored sample for the measurement of lipid content, two fish a group were employed.

The control fish were analysed before the experimental starting and after the experimental completion. Four fish were taken out at each sampling time and divided into two groups, and then each was analysed individually. In addition, two fish were taken out and three groups (two fish per group) were used for measurement of lipid contents.

• Sampling intervals/frequency for test medium samples: The test water of each level was analysed once before first analysis of test fish and at the same time as analysis of test fish thereafter. The number of each sample was one .

• Details on sampling and analysis of test organisms and test media samples: Analysis of test item in test water and test fish was performed with gas chromatography-mass spectrometry (GC-MS) analysis. If the test item was bioaccumulated in the test fish, the test item had a possibility to be metabolised in the fish body. Therefore, C5F11COOH (hereafter mentioned as "carboxylic acid") which was an estimated metabolite of the test item in the test fish was analysed at the same time. Analysis of the carboxylic acid in the test fish was performed with the liquid chromatography - tandem mass spectrometry (LC/MS/MS).

• Details on pretreatment: Extraction: Test fish were extracted (polytron on ice) with acetonitrile/isopropyl alcohol (7/3 V V) then centrifuged and filtered.

• Identification and quantification of test substance/product:

- Separation method: Test item in water and fish - Gas chromatograph-mass spectrometer Shimadzu Corporation. type QP-5000; Carboxylic acid - Liquid chromatograph-mass spectrometer Agilent type HP-1100 Micromass type Quattro Ultima

- Conditions (column, mobile phase, etc.): Test item in water and fish - INNOWAX 30 m x 0.25 mm I.D.; Carboxylic acid - L-column ODS 15 cm x 2.1 mm LD.

- Detection method: Test item in water and fish - Electron ionisation (El); Carboxylic acid – Ionisation mode Electrospray, Detection ion Negative,

Detection mode Selected reaction monitoring

• Vehicle: yes

• Test organisms: Cyprinus carpio

- Source: Sugishirna fish farm, Japan

- Age at study initiation: Yearling fish

- Length at study initiation: 6.6 - 6.8 cm

- Health status: The fish were checked visually at receipt and those showing any abnormalities were removed.

- Description of housing/holding area: 100-L glass tank

- Feeding during test: yes

- Food type: Feed for fry of carp

Proteins content ≥ 43.0 %

Lipid content ≥ 3.0 %

- Amount: Amount corresponding to about 2 % of total body weight was fed twice a day in halves.

The fish were starved for 24 hours before sampling.

- Acclimation period: flow-through system for 41 days

- Acclimation conditions (same as test or not): same

• Study design:

- Route of exposure: aqueous

- Test type:flow-through

- Water / sediment media type: natural water: freshwater

- Total exposure / uptake duration: 28d

• Test conditions:

- Hardness: 58.6 mg/L

- Test temperature: 24.6 - 25.9 °C

- pH: 7.6 - 7.9

- Dissolved oxygen: 7.0 -8.0 mg/L

- TOC: 1.6 mg/L

- Salinity: fresh water

Details on test conditions

TEST SYSTEM

- Test vessel: 100-L glass tank

- Type of flow-through: 0.02 mL/min for stock solution and 1600 mL/min for dilution water, 2304 L/day of test water, was supplied.

- Renewal rate of test solution: 2304 L/day of test water

- No. of organisms per vessel: test - 29; control - 12

- No. of vessels per concentration (replicates): 1

- No. of vessels per control / vehicle control (replicates): 1

TEST MEDIUM / WATER PARAMETERS

- Source/preparation of dilution water: Groundwater from the premises of Kurume Laboratory.

It was confirmed that the dilution water met the ministerial ordinance of the Ministry of Health and Welfare (December 21, 1992), water quality criteria for fisheries (Shadanhozin Nihon Suisansigen Hogokyokai, March 1983), OECD Guidelines for Testing of Chemicals, "Fish, Early-life Stage Toxicity

Test" (Guideline 210, July 17, 1992) and environmental quality standards for water pollutants No.14 (Revised February 22, 1999, Environment Agency) or OECD Guidelines for Testing of Chemicals, " Bioconcentration: Flow-through Fish Test (Guideline 305, June 14, 1996)".

- nominal and measured concentrations:

Nominal concentrations: High exposure level (Level 1) - 10 µg/L, Low exposure level (Level 2) - 1 µg/L

Mean Measured: High exposure level (Level 1) - 9.11 µg/L, Low exposure level (Level 2) - 0.835 µg/L

Results:

• lipid content: 2.95% (start of exposure); 2.26% (end of exposure)

• BCF = 46 (whole body w.w.), high exposure level; time of plateau: 28 d; calculation basis: steady state

• BCF ≤ 36 (whole body w.w.), low exposure level; time of plateau: 28 d; calculation basis: steady state

• BCF of metabolite carboxylic acid ≤ 1.1 (whole body w.w.) at high exposure level and ≤ 12 (whole body w.w.) at low exposure level

[Study 2: (ECHA Registration dossier, Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, 2007)]

Study reference:

Kurume Laboratory, Chemical Evaluation and Research Institute (2007): Bioconcentration study of 13F-EtOH in carp. Report no.: 44807 (report date: 2007-03-19)

Detailed study summary and results:

A bioconcentration test according to OECD TG 305 (deviation: no post-exposure (depuration) phase) was conducted for 28 days on Cyprinus carpio with two exposure levels (1 and 10 µg/L nominal) of the test substance (registration dossier Kurume, 2007). After 28 days whole body w.w. BCF values of 24 - 99 (exposure level 1 µg/L) and 8.4 - 58 (exposure level 10 µg/L) were determined.

Test type:

OECD Guideline 305, GLP not specified; derivation: no post-exposure (depuration) phase

Test substance:

• equivalent

Materials and methods:

• Test organisms: Cyprinus carpio

• Study design:

- Route of exposure: aqueous

- Test type:flow-through

- Water / sediment media type: natural water: freshwater

- Total exposure / uptake duration: 28d

• Test conditions:

- Nominal concentrations: High exposure level (Level 1) - 10 µg/L, Low exposure level (Level 2) - 1 µg/L

Results:

• BCF = 8.4-58 (whole body w.w.), high exposure level; time of plateau: 28 d; calculation basis: steady state

• BCF = 24 -99 (whole body w.w.), low exposure level; time of plateau: 28 d; calculation basis: steady state

1.3 Acute toxicity

1.3.1 Short-term toxicity to fish

[Study 1: Anonymous 1, 2007]

Study reference:

H-28078: Static-Renewal, Acute, 96-Hour Toxicity Test with Fathead Minnow, Pimephales

study report

Detailed study summary and results:

The 96-hour acute toxicity test with fathead minnow, Pimephales promelas, according to OECD TG 203 was conducted in a static test-type. The test concentrations were analytically monitored by LC/MS analysis (nominal test concentrations: 0, 1.0, 2.0, 4.0, 8.0, and 16.0 mg/L; mean measured: 0, 0.751, 1.61, 3.12, 7.52 and 16.4 mg/L). For the test 5 organisms per replicate and 2 replicates were used. The photoperiod was 16 hours light per day (light intensity: 126-710 lux). The test temperature ranged from 21.4 to 21.6°C, the pH from 7.0 to 7.3 and the dissolved oxygen concentration from 5.4 to 8.5 mg/L. No control mortality or behavioural abnormalities occurred. The fish in the control had a standard length of 2.2 to 2.8 cm and a wet weight, blotted dry, of 0.140 to 0.304 g. The validity criteria were fulfilled. The test resulted in an 96h-LC_{50} of 4.84 mg/L (mean measured concentrations) and an 96h-LC_{100} of 7.52 mg/L (mean measured). At 3.12 mg/L (mean measured) and below no mortality occurred.

Test type:

OECD Guideline 203 (Fish, Acute Toxicity Test) (no deviations; GLP, analytical monitoring: LC/MS)

Test substance:

• equivalent

• Degree of purity: 99.7%

Materials and methods:

• Test species and origin: Pimephales promelas

• Age at study initiation: >112 days

• Test conditions: Dissolved oxygen: 5.4 - 8.5 mg/L; pH: 7.0 - 7.3; Total Alkalinity: 49 mg/L as CaCO3, EDTA Hardness: 116 mg/L as CaCO3; Test temperature: 21.4 to 21.6°C; Photoperiod: 16 hours light and 8 hours darkness, which included 30 minutes of transitional light (3-125 Lux) preceding and following the 16-hour light interval. Light intensity: approximately 126-710 Lux; static test type; no vehicle

• Tested doses: 0, 1.0, 2.0, 4.0, 8.0, and 16.0 mg/L

• Test duration/total exposure duration: 96 h

• Test design: - Test vessel: 4-L Erlenmeyer flasks; - Renewal rate of test solution (frequency/flow rate): renewed at day 2 (48 hours); - No. of organisms per vessel: 5; - No. of vessels per concentration (replicates): 2; - No. of vessels per control (replicates): 2

Results:

• Observations in the controls: Mortality of control: none; Behavioural abnormalities: none observed; Observations on body length and weight: Fish in the dilution water control ranged from 2.2 to 2.8 cm in standard length and 0.140 to 0.304 g in wet weight, blotted dry, at test end.

• Observations in the test system: Mortality of mean measured test concentrations: 100% mortality at 7.52, and 16.4 mg/L; Behavioural abnormalities: none

• Monitoring of test concentrations: Measured concentrations: 0, 0.751, 1.61, 3.12, 7.52 and 16.4 mg/L

• LC50 at 96 hours: 4.84 mg/L (meas.) (95% confidence interval of 3.12 to 7.52 mg/L); NOEC at 96 hours: 3.12 mg/L (meas., mortality); LC100 at 96 hours: 7.52 mg/L (meas.)

[Study 2: (Anonymous 2, 2005)]

Study reference:

C6-2AL: ACUTE TOXICITY TO RAINBOW TROUT (Oncorhynchus mykiss) / study report

Detailed study summary and results:

The 96-hour acute toxicity test was conducted with Oncorhynchus mykiss according to OECD TG 203 in a semi-static test-type. The test concentrations were analytically monitored. The test concentrations ranged from 1.3 to 13 mg/L (nominal). The validity criteria were fulfilled according to the registrant. The resulting 96h-LC_{50} was 9 mg/L (nominal). The reliability was difficult to access because of to little details provided in the registration dossier.

Test type:

OECD Guideline 203 (Fish, Acute Toxicity Test) (no deviations; analytical monitoring)

Test substance:

• equivalent

• Degree of purity: 99.7%

Materials and methods:

• Test species and origin: Oryzias latipes

• Test conditions: semi-static test type

• Tested doses: at start of exposure 2.00 to 10.0 mg/L (measured)

• Test duration/total exposure duration: 96 h

• Test design: -

Results:

• LC50 at 96 hours: 9.0 mg/L (nominal) (95% confidence interval of 7.7 - 10 mg/L); NOEC at 96 hours: 2.3 mg/L (nominal, mortality)

[Study 3: (Anonymous 3, 2007)]

Study reference:

A 96-hour Acute Toxicity Study of 13F-EtOH with Medaka / study report

Detailed study summary and results:

The 96-hour acute toxicity study was conducted with ricefish, Oryzias latipes, according to OECD TG 203 in a semi-static test-type. The test concentrations were analytically monitored and ranged from 2 to 10 mg/L (measured). The validity criteria were fulfilled according to the registrant. The test resulted in an 96h-LC_{50} of 5.78 mg/L (mean measured concentrations) and an 96h-NOEC of 3.06 mg/L (mean measured).

Test type:

OECD Guideline 203 (Fish, Acute Toxicity Test) (no deviations; analytical monitoring)

Test substance:

• equivalent

• Degree of purity: not reported

Materials and methods:

• Test species and origin: Oryzias latipes

• Test conditions: semi-static test type

• Tested doses: 2.00 to 10.0 mg/L (measured).

• Test duration/total exposure duration: 96 h

• Test design: -

Results:

• LC50 at 96 hours: 5.78 mg/L (geom.mean meas.) (95% confidence interval of 4.92 – 6.89 mg/L); NOEC at 96 hours: 3.06 mg/L (geom.mean meas., mortality)

1.3.2 Short-term toxicity to aquatic invertebrates

[Study 1: (ECHA Registration dossier: DuPont Haskell Global Centers for Health & Environmental Sciences, 2007)]

Study reference:

H-28078: Static, Acute, 48-Hour Toxicity Test with Daphnia magna / DuPont Haskell Global Centers for Health & Environmental Sciences / study report

Detailed study summary and results:

The acute toxicity test with Daphnia manga was conducted according to OECD TG 202 under GLP with analytical monitoring (LC/MS/MS) in a static test-type. The test temperature ranged from 20.1 to 20.4°C and the pH from 7.2 to 7.6. Nominal test concentrations were 0, 0.625, 1.25, 2.50, 5.00, and 10.0 mg/L and the

mean measured concentrations were 0, 0.600, 1.23, 2.39, 4.90, and 9.29 mg/L. For the test system 10 organisms were used per test vessel and two replicates per concentration. The photoperiod was 16 hours light per day (495-534 lux). The resulting 48h-EC50 (endpoint: immobility) was 7.84 mg/L and the 48h-NOEC was 2.39 mg/L based on mean measured concentrations. Lethargy was observed in surviving daphnids in the 2.39, 4.90, and 9.29 mg/L mean measured concentrations at the end of the study. The validity criteria were fulfilled.

Test type:

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test))(no deviations, GLP, analytical monitoring: LC/MS/MS LOD= 0.007 mg/L LOQ= 0.375 mg/L, no vehicle)

Test substance:

• test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity: 99.7%

• Impurities (or a note that the impurities do not affect the classification)

Materials and methods:

• Test species and origin: Daphnia magna

• Species life stage: < 24h; collected from the 3rd and 6th broods of 14- and 20-day old parent daphnids

• Test conditions:

- *Hardness: Total alkalinity (dilution water control) 47 mg/L as CaCO3; hardness (dilution water control) 137 mg/L as $CaCO_3$;*
- *Test temperature: 20.1 to 20.4°C (dilution water control;*
- *pH 7.2 to 7.6 (dilution water control); static test type*

• Test duration/total exposure duration: 48h

• Test design:

- *test concentrations 0, 0.625, 1.25, 2.50, 5.00, and 10.0 mg/L (nominal) or 0, 0.623, 1.25, 2.49, 4.99, and 9.97 mg/L (nominal, adjusted for purity);*
- *Test vessel: Glass vials (44-mL). The test chambers were covered with modified lids containing a septum during the test. The modified lids were used to ensure zero-headspace in the test chambers. A zero-headspace chamber was used to ensure the maintenance of test concentrations for the duration of the study.*
- *No. of organisms per vessel: 10*
- *No. of vessels per concentration (replicates): 2*
- *No. of vessels per control (replicates): 2*
- *Photoperiod: A photoperiod of 16 hours light and 8 hours darkness was employed, which included 30 minutes of transitional light (15-19 Lux) preceding and following the 16-hour light interval.*
- *Light intensity: 495-534*

Results:

• Observations in the test system: Behavioural abnormalities: Lethargy was observed in surviving daphnids in the 2.39 (3 of 20), 4.90 (3 of 15), and 9.29 mg/L (5 of 7) mean, measured test concentrations at the end of the study.

• Monitoring of test concentrations: 0, 0.600, 1.23, 2.39, 4.90, and 9.29 mg/L (mean measured)

• EC50 at 48 hours: 7.84 mg/L (95% confidence interval 6.75 to 9.39 mg/L); NOEC at 48 hours: 2.39 mg/L; EC100 at 48 hours: 9.29 mg/L

[Study 2: (ECHA Registration dossier: Safepharm Laboratories Ltd., UK, 2005)]

Study reference:

C6-2AL: ACUTE TOXICITY TO DAPHNIA MAGNA / Safepharm Laboratories Limited / study report

Detailed study summary and results:

The acute toxicity test with Daphnia manga was conducted according to OECD TG 202 under GLP with analytical monitoring under static test conditions. The test concentrations ranged from 0.14 to 14 mg/L (nominal). The resulting 48h-EC_{50} (endpoint: immobility) was 8.3 mg/L and the 48h-NOEC was 2.5 mg/L based on nominal concentrations. According to the registrant, the validity criteria were fulfilled.

Test type:

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) (no deviations, GLP, analytical monitoring, no vehicle)

Test substance:

• test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity: 99.8 %

Materials and methods:

• Test species and origin: Daphnia magna

• Test conditions: static test system

• Test duration/total exposure duration: 48h

• Test design: test concentrations ranged from 0.14 to 14 mg/L (nominal).

Results:

• EC50 at 48 hours: 8.3 mg/L (95% confidence interval: 7.1 – 9.8 mg/L); NOEC at 48 hours: 2.5 mg/L

[Study 3: (ECHA Registration dossier: Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, 2007)]

Study reference:

A 48-hour Acute Immobilization Study of 13F-EtOH with Daphnia magna / Kurume Laboratory / study Report

Detailed study summary and results:

The acute toxicity test with Daphnia manga was conducted according to OECD TG 202 with analytical monitoring in a static test-type. The test concentrations ranged from 1.30 to 15.5 mg/L (nominal). The resulting 48h-EC_{50} (endpoint: immobility) was 8.2 mg/L and the 48h-NOEC was 1.33 mg/L based on mean measured concentrations. According to the registrant, the validity criteria were fulfilled.

Test type:

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) (no deviations; GLP not specified; analytical monitoring; no vehicle)

Test substance:

• Test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity: not reported

Materials and methods:

• Test species and origin: Daphnia magna

• Species life stage

• Test conditions: static test system

• Test duration/total exposure duration: 48 hours

• Test design: test concentrations at the start of exposure ranged from 1.30 to 15.5 mg/L (measured)

Results:

• EC50 at 48 hours: 8.2 mg/L (meas. geom. mean) (95% confidence interval: 7.16 – 9.46 mg/L); NOEC at 48 hours: 1.33 mg/L

1.3.3 Algal growth inhibition tests

[Study 1: (ECHA Registration dossier: DuPont Haskell Global Centers for Health & Environmental Sciences, 2007)]

Study reference:

H-28078: Static, 72-Hour Growth Inhibition Toxicity Test with the Green Alga, Pseudokirchneriella su / DuPont Haskell Global Centers for Health & Environmental Sciences / study report

Detailed study summary and results:

The toxicity study with Pseudokirchneriella subcapitata was conducted according to OECD TG 201 under GLP with analytical monitoring (LC/MS) in a static test-type. The test temperature ranged from 23.8 to 24.0 °C and the pH value from 7.97 to 9.97. Nominal test concentrations were 0.200, 0.640, 2.00, 6.60, and 21.0 mg/L and the mean measured concentrations were 0.154, 0.623, 2.22, 7.10, and 23.5 mg/L. Four replicates were used per concentration (3 for the test and 1 for analytical sampling). The photoperiod was 24 hours light per day (6670 to 6980 lux). The resulting 72h-E_rC_{50} was 14.8 mg/L (measured). The NOE_rC was 2.22 mg/L (measured). All validity criteria were fulfilled.

Test type:

OECD Guideline 201 (Alga, Growth Inhibition Test) before 23 March 2006 (no deviations; GLP; analytical monitoring: LC/MS; no vehicle)

Test substance:

• Test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity

Materials and methods:

• Test species: Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

• Initial cell concentration: 10000 cells/mL

• Test conditions:

- *Static test type*
- *Test temperature 23.8 to 24.0 °C*
- *pH 7.97 to 9.97 (e.g. temperature, lighting, test medium, pH, test system, solubilising agent, etc.)*
- *Adjustment of pH: nutrient medium pH was adjusted to 7.49*
- *Photoperiod: 24 hrs light*
- *Light intensity and quality: 6670 to 6980 lux*

• Test duration/total exposure duration: 72 hours

• Test design:

- *test concentrations: 0.200, 0.640, 2.00, 6.60, and 21.0 mg/L, number/type of controls, number of replicates, etc)*
- *No. of vessels per concentration (replicates): 4 (3 used for test, 1 for analytical sample)*
- *No. of vessels per control (replicates): 4 (3 used for test, 1 for analytical sample)*

Results:

• Observations in the controls: control end cells density mean 430000 cells/mL

• Details on the determination of algal biomass: Growth was determined by counting the number of cells in an approximate 10-µL sample from each vial at approximately 24, 48, and 72 hours after the definitive test initiation. The counts were conducted using a haemocytometer and a compound microscope.

• Growth curves: exponential growth in the control (for algal test): Healthy cell counts increased in the blank control by at least a factor of 16 in 72 hours and the coefficient of variation of average specific growth rates during the whole test period (0-72 hour) in blank control replicates did not exceed 7%, thereby satisfying the appropriate test acceptance criteria

• Monitoring of test concentrations: 0, 0.154, 0.623, 2.22, 7.10, and 23.5 mg/L (mean measured)

• ErC50 at 72 hours: 14.8 mg/L (meas.; 95 confidence interval 9.85 to 19.8 mg/L), EbC50 at 72 hours: 7.3 mg/L (cell count; meas.; 95 confidence interval 5.16 – 10.3 mg/L), NOErC at 72 hours: 2.22 mg/L (meas.); NOEbC at 72 hours: 0.623 mg/L (meas.)

[Study 2: (ECHA Registration dossier: Safepharm Laboratories Ltd., UK, 2005)]

Study reference:

C6-2AL: ALGAL INHIBITION TEST / Safepharm Laboratories Limited / study report

Detailed study summary and results:

The toxicity study with Desmodesmus subspicatus was conducted according to OECD TG 201 under GLP with analytical monitoring in a static test-type. Mean measured concentrations ranged from 1.13 to 13 mg/L (1.3, 2.3, 3.1, 6.7 and 13). The resulting 72h-E_rC_{50} was 7.8 mg/L (measured). The NOE_rC was 1.3 mg/L (measured). All validity criteria were fulfilled according to the registrant.

Test type:

OECD Guideline 201 (Alga, Growth Inhibition Test) before 23 March 2006 (no deviations; GLP; analytical monitoring; no vehicle)

Test substance:

• Test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity: 99.8%

Materials and methods:

• Test species: Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)

• Test conditions: the culture solution contained additional sodium bicarbonate to provide a source of CO2 required for algal growth in sealed test vessels; static test type

• Test duration/total exposure duration: 72 hours

• Test design: mean measured concentrations ranged from 1.13 to 13 mg/L (1.3, 2.3, 3.1, 6.7 and 13)

Results:

• ErC50 at 72 hours: 7.8 mg/L (meas.; 95% confidence interval 6.8 – 8.9 mg/L), EbC50 at 72 hours: 3.8 mg/L (meas.; 95% confidence interval 3.4 – 4.3 mg/L), NOErC at 72 hours: 1.3 mg/L

[Study 3: (ECHA Registration dossier: Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan, 2007)]

Study reference:

Algae Growth Inhibition Study of 13F-EtOH with Pseudokirchneriella subcapitata / Kurume Laboratory / study report

Detailed study summary and results:

The toxicity study with Pseudokirchneriella subcapitata was conducted according to OECD TG 201 with analytical monitoring in a static test-type. Mean measured concentrations ranged from 0.0966 to 9.45 mg/L. The resulting 72h-E_rC_{50} was greater than 5.19 mg/L (mean measured). The NOE_rC was 1.47 mg/L (measured). All validity criteria were fulfilled according to the registrant.

Test type:

OECD Guideline 201 (Alga, Growth Inhibition Test) before 23 March 2006 (no deviations; GLP: not specified; analytical monitoring)

Test substance:

• Test material used in the study is equivalent to the substance identified in the C&L dossier.

• Degree of purity: not reported

Materials and methods:

• Test species: Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

• Test duration/total exposure duration: 72 hours

• Test design: test concentrations: five exposure levels, ranging from 0.0966 to 9.45 mg/L measured at study start; static test type (e.g. test concentrations, number/type of controls, number of replicates, etc)

Results:

• ErC50 at 72 hours: > 5.19 mg/L (meas), NOErC at 72 hours: 1.47 mg/L (meas.)

1.4 Chronic toxicity

1.4.1 Chronic toxicity to aquatic invertebrates

[Study 1: (ECHA Registration dossier: DuPont Haskell Global Centers for Health & Environmental Sciences, 2007)]

Study reference:

H-29849: 21-Day Chronic Static-Renewal, Zero Headspace Toxicity Test with the Cladoceran, Daphnia m / DuPont Haskell Global Centers for Health & Environmental Sciences / study report

Detailed study summary and results:

One long-term toxicity test to the aquatic invertebrate Daphnia magna is available conducted according to OECD TG 211 under GLP with analytical monitoring (LC/MS/MS) in a semi-static test-type. The test temperature ranged from 20.6 to 21.6 °C, the pH value from 7.6 to 8.1 and the dissolved oxygen concentration from 5.4 to 9.0 µg/L. The nominal test concentrations amounted to 0, 0.65, 1.3, 2.5, 5, and 10 mg/L and the mean measured concentrations amounted to 0, 0.557, 1.11, 2.16, 4.46, and 8.57 mg/L. Two organisms per test vessel werever used and the control was composed of 5 replicates. The number of replicates for the test concentrations was not described in the RSS but it would be likely that this replicate number was also used for the test concentrations. The photoperiod was 16 hours light per day (17-40 lux). The test resulted in a NOEC of 2.16 mg/L (based on mean measured concentrations) (basis for the effect: adult survival, total live young per female, total immobile young per surviving female and length and weight of surviving females at day 21). According to the registrant all validity criteria were fulfilled.

Test type:

EPA OTS 797.1330 (Daphnid Chronic Toxicity Test) as well as OECD Guideline 211 (Daphnia magna Reproduction Test) (no deviations; GLP; analytical monitoring LC/MS/MS; no vehicle)

Test substance

• Test material used in the study is equivalent to the substance identified in the C&L dossier

• Degree of purity: 99.94%

• Impurities: 1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 10-heptadecafluoro- (CAS 678-39-7) - 0.0143 wt%; Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo- (CAS 2043-53-0) - 0.0015 wt%; Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-8-iodo- (CAS 2043-57-4) - 0.0127 wt%; Unknowns - 0.0315 wt%

Materials and methods:

• Test species and origin: Daphnia magna (Parent Daphnia magna were reared at Haskell Laboratory in 1000-mL Pyrex beakers which contained 1000 mL of filtered fish tank water at approximately 20°C. Each beaker contained 8-10 adults.)

• Species life stage: age of parental stock = 24 days

• Test conditions: semi-static test system;

- *Food type: during test: green algae (Pseudokirchneriella subcapitata) and yeast, cereal leaves and trout chow (YCT) mixture; Amount: during test: 62,500 cells/mL and 3 mL/L YCT on renewal days, 62,500 cells/mL on nonrenewal days; Frequency: daily;*
- *hardness: Total alkalinity range: 80 - 88 mg/L as CaCO3; EDTA hardness range: 117 - 131 mg/L as CaCO3*
- *Test temperature: range of 20.6 - 21.6ºC*
- *pH: range of 7.6 - 8.1*
- *Dissolved oxygen: range of 5.4 - 9.0 µg/L*

• Preliminary test

• Test duration

• Test design:

- *test concentrations 0, 0.65, 1.3, 2.5, 5 and 10 mg/L (nominal),*
- *Test vessel: Glass bottles (250 mL) containing approximately 250 mL of test solution capped with a Mininert™ valve closure*
- *Renewal rate of test solution: renewed every Monday, Wednesday, and Friday*
- *No. of organisms per vessel: 2*
- *No. of vessels per concentration (replicates):*
- *No. of vessels per control (replicates): 5 number of controls, number of replicates, number of animals, etc.)*
- *Photoperiod: 16 hours light, 8 hours dark with approximately 25-30 minutes of transitional light preceding and following the 16 hour light interval*
- *Light intensity: approximately 17 - 40 Lux*

Results:

• Monitoring of test concentrations: 0, 0.557, 1.11, 2.16, 4.46, and 8.57 mg/L

• *NOEC of 21 days: 2.16 mg/L (arithm. mean meas.; endpoints: adult survival, total live young per female, total immobile young per surviving female and length and weight of surviving females at day 21), EC50 of 21 days: 3.87 mg/L (arithm. Mean meas.; mortality); LOEC of 21 days: 3.1 mg/L (arithm. Mean meas.)*

1.4.2 Chronic toxicity to algae or aquatic plants

[See short-term toxicity]