COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 07.09.2021

Substance name: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol
CAS number: 647-42-7
EC number: 211-477-1
Dossier submitter: Germany

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
03.09.2021	France		MemberState	1
Comment received				
In the absence of a chronic aquatic toxicity fish study, FR is of the opinion that this OECD 234 study should be taking into account to characterise the long-term hazard in the aquatic environment. Based on the Guidance on the Application of the CLP Criteria, the NOEC value of 0.014mg/L for non-rapidly degradable substances will lead to a classification category Chronic 1 (Chronic NOEC <0,1 mg/L) and M factor=1 (0,01 < NOEC ≤ 0,1, non-rapidly degradable components). There are several deviations from the validity criteria in this study and this may not allow reaching the highest reliability score (Klimisch score 1 set by registrants on ECHA website). However, we consider the reliability of this study being acceptable and sufficient for classification purpose. In addition, considering the uncertainties around the validity criteria and the lack of chronic study on vertebrates (which may be the most sensitive species as seen in acute studies), a lower NOEC could be expected (and thus a higher M-factor).				

Date	Country	Organisation	Type of Organisation	Comment number
03.09.2021	Belgium	Chemours Netherlands BV	Company-Importer	2
Comment received				
The substance is not readily biodegradable. With the new study, adequate chronic data are available on three trophic levels (algae, daphnia, fish). and with the lowest NOEC value being 0.0137 mg/l (in OECD 234 test), we have reclassified the substance as Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects, with M-factor 1. The REACH registration dossier has been updated accordingly.				

Date	Country	Organisation	Type of Organisation	Comment number
06.09.2021	Finland		MemberState	3
Comment received				
FI CA has evaluated the relevance of FSDT (Fish Sexual Development Test) with Oryzias				

latipes in the targeted consultation of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (6:2 FTOH). The FI CA considers the study design adequate for the assessment of long-term aquatic toxicity for fish.

Based on the provided robust study summary, the results may affect the classification. However, a thorough evaluation of the study quality could not be conducted due to lack of details in the summary. Therefore, more information may be warranted on whether the validity criteria of OECD 234 were met (e.g. in terms of variation in measured concentrations). If the study is confirmed reliable, FI CA considers that the NOEC for hatching success based on geometric mean measured concentration should be used for the classification, due to problems maintaining and achieving the nominal concentrations in the test system.

In the initial CLH dossier, the classification of 6:2 FTOH was based on surrogate approach described in Table 4.1.0 (b) (iii) of the CLP Regulation, since no adequate long-term fish toxicity data was available. The surrogate approach was based on 96h-LC50 value of 4.84 mg/L for Pimephales promelas. The dossier submitter proposed a classification of Aquatic Chronic 2.

FI CA supports the reasoning that 6:2 FTOH should be considered not readily biodegradable, as there is no adequate information available on the biodegradation of the transformation products.

Based on the NOEC value of 0.0231 mg/L for hatching success in the new provided study, the proposed classification for the 6:2 FTOH would be Aquatic Chronic 1 (H410) with an assigned M-factor of 1, because the lowest valid NOEC is in the range of 0.01 < NOEC ≤ 0.1 mg/L for not rapidly degradable substances.

Date	Country	Organisation	Type of Organisation	Comment number
06.09.2021	United Kingdom	Heath and Safety Executive	National Authority	4

Comment received

The submitted study using 6:2 FTOH as the test substance has been conducted according to OECD TG 234 with Oryzias latipes as the test species. A robust study summary (RSS) is included in the registration dossier for the parent substance 6:2 FTMA (6:2 FTOH is a degradant for this substance) which indicates that the overall study NOEC is 0.0137 mg/L 6:2 FTOH (gmm) based on the VTG concentration in male fish for the 122-day study duration.

We note that effects on VTG have previously not been considered suitable for CLP because they may or may not result in long-term adverse apical effects on development or reproduction noting the CLP regulation (EC) No 1272/2008 states that "'chronic aquatic toxicity' means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism". This is consistent with chapter R.7b of the ECHA GD on REACH information requirements for specific endpoints (ECHA, 2017a) and a previously discussion at RAC / opinion for triadimenol, CAS: 55219-65-3 (ECHA, 2015 and ECHA, 2016).

From the table of results provided in the study summary, the lowest chronic fish toxicity endpoint that appears to be relevant for the purpose of hazard classification based on the above definition is the 122-d NOEC of 0.0231 mg/L (gmm) for hatching success. The NOEC

for survival and growth was at the next test concentration of 0.0537 mg/L (gmm) as statistically significant effects on these endpoints were observed at the highest test concentration (0.0953 mg/L (gmm). It would be useful to provide low ECx values (e.g. EC10 values) if these are available and reliable as these statistical endpoints are preferred over NOEC values for the purpose of hazard classification (ECHA, 2017b).

Based on the currently available data, the NOEC based on hatching success from this OECD TG 234 appears to be the lowest relevant chronic toxicity endpoint for the three trophic levels. If the substance is considered NRD, as in the original CLH proposal, this O. latipes 122-d NOEC of 0.0231 mg/L based on hatching success would lead to an Aquatic Chronic 1 classification with an M-factor of 1 for 6:2 FTOH. This classification following the standard approach is more stringent than the surrogate approach with the Pimephales promelas 96-h LC50 of 4.84 mg/L (mm) used in the original CLH proposal and therefore, should be favoured for the purpose of classification.

A reliability score of 1 for the study was assigned by the Registrant and the study was GLP compliant. Comparisons with the OECD TG 234 acceptance criteria indicate that the test is reliable and therefore relevant to CLP. It would be useful to take into account the review of the study by the eMS for the joint substance evaluation of the parent substances 6:2 FTA and 6:2 FTMA, although we note that this is not yet available on the ECHA public dissemination site.

We also note that the REACH registrant for 6:2 FTMA includes a self-classification for Aquatic Chronic 1 (M=1) based on what they state is the lowest NOEC value of 0.0162 mg/L from the new OECD TG 234 study with 6:2 FTOH. This endpoint was not included in the table of results for the study in the registration dossier above and we are unclear how it was calculated and whether there was perhaps a conversion for the parent substance? Please could the DS provide clarification on the basis for this endpoint and whether it is also relevant to consider for the CLH of 6:2 FTOH?

In relation to comments on the original CLH proposal, we submitted a comment to request information on the toxicity of the degradation products of 6:2 FTOH to support the NRD conclusion given that rapid primary degradation occurs. This information could further affect the environmental classification if the degradants are found to be more toxic than 6:2 FTOH.

ECHA (2015) RAC Opinion proposing harmonised classification and labelling at EU level of Triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1H-1,2,4-triazole-1-ethanol
ECHA (2016) Minutes of the 35th Meeting of the Committee for Risk Assessment (RAC-35)
ECHA (2017a) Guidance on information requirements and chemical safety assessment. Chapter R.7b: Endpoint Specific Guidance. Versions 4.0. European Chemicals Agency, Helsinki, Finland.
ECHA (2017b). Guidance on the application of the CLP criteria. Version 5.0. European Chemicals Agency, Helsinki, Finland.