

CLH Response for 6:2 FTOH

The registrants of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC# 211-477-1; CAS# 647-42-7) present a response to the Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2 (CLH), issued by BAuA (Germany) in January 2021.

Whilst the registrants agree that action is needed at the European Community level due to the variation observed in existing self-classifications, it would be prudent to consider the results of an ongoing study that may significantly influence the outcome of the CLH process. In accordance with ECHA Decisions on Substance Evaluation SEV-D-2114457719-33-01/F and SEV-D-2114459081-54-01/F, a fish sexual development test is being conducted on this substance (as a transformation product of another substance under Evaluation), in accordance with OECD 234 (FSDT). This test is appropriate for assessing the chronic toxicity of a chemical substance to fish, providing measurements and observations consistent with OECD 210 (FELS), with additional ones relevant to endocrine modes of action.

The current version (version 2) of the CLH Report bases its proposal for harmonised classification and labelling for the environment on the following data:

Endpoint	Result
Rapid Degradability (CLP)	Not rapidly degradable
Bioaccumulation	Not bioaccumulative (BCF = 36-99)
Short-Term Toxicity to Fish	96 h LC ₅₀ = 4.84 mg/L (meas.) (OECD 203)
Short-Term Toxicity to Aquatic Invertebrates	48 h EC ₅₀ = 7.84 mg/L (meas.) (OECD 202)
Toxicity to Aquatic Algae	72 h E _r C ₅₀ = 14.8 mg/L (meas.); 72 h NOE _r C = 2.22 mg/L (OECD 201)
Long-Term Toxicity to Fish	<i>Presented Study (OECD 305) not suitable for assessment of chronic toxicity to fish</i>
Long-Term Toxicity to Aquatic Invertebrates	21 d NOEC = 2.16 mg/L (meas.) (OECD 211)

When classifying under CLP, the ideal approach for assessing chronic environmental hazards is to base the classification and labelling requirements on chronic toxicity data. However, as there are no suitable long-term toxicity data on fish, relevant toxicity data are available on species from only two trophic levels. To account for the increased uncertainty of a missing long-term toxicity data on fish, the CLP guidance requires an assessment of chronic toxicity classification based on both the available chronic data and also the short-term data, the resulting classification being in accordance with the most stringent outcome.

The registrants can agree with the general conclusions of the submitted CLH report that the OECD 305 study is not suitable for the assessment of chronic toxicity to fish and that a classification of Aquatic Chronic 2 is warranted, taking into account the available data that is considered to be valid. However, they would prefer to delay the CLH conclusion for this substance until the FSDT is completed. This approach will provide the option to conclude on chronic toxicity with reduced uncertainty, as chronic toxicity data will be available for all three trophic levels. This approach will also maintain the relevance of the CLH conclusion for a longer period of time, as self-classification may be required by the registrants when the OECD 234 study is completed, should the results indicate that the hazard is more severe. There is already an indication from the draft results of the OECD 234 study that the classification for environmental hazard may be more severe. We will be able to resolve this matter in due course, as the draft report is expected to be issued by the end of April 2021.

In conclusion, the registrants request that the CLH process is put on hold until the results of the OECD 234 study are available to allow a more comprehensive assessment of environmental classification.