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 06.10.2020

Substance name: Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]
CAS number: 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others
EC number: 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; and others
Dossier submitter: The Netherlands

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
02.10.2020	United Kingdom	HSE	National Authority	1

Comment received

nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]. (EC: 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5 and others CAS: 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others
The lowest acute endpoint for Mysidopsis bahia used to derive the proposed Aquatic Acute classification does not meet the validity criteria for ≤10% control mortality. The CLH DS considers the level of mortality in the control acceptable because lower levels of mortality occurred for mysids exposed to low concentrations of NPE-1.5. We think the control mortality could impact the reliability of the study. According to the registration dossier for nonylphenol, branched, ethoxylated (1 - 2.5 moles ethoxylated, CAS 68412-54-4, EC 500-209-1), it is not specified whether the study is GLP compliant. Test concentrations were also not reported. Raw data are not included in this registration dossier for us to further assess the study reliability. Overall, we are unclear if the study should be considered Klimisch 2, and a score of 4 (or 3) may be more appropriate.

We note other acute invertebrate and fish studies, which are considered valid by the DS for the CLH report, are within the same concentration range from 0.1-1 mg/L and support the Aquatic Acute 1 classification with an M-factor of 1.

While the study summaries indicate that test concentrations were measured, it would be useful for the DS to clarify whether the endpoints are based on mean measured concentrations. With the exception of the study with Cerio daphnia dubia (Anonymous, 2007), analytical verification information is not available in the CLH report. The REACH registration dossier for nonylphenol, branched, ethoxylated (1 - 2.5 moles ethoxylated, CAS 68412-54-4, EC 500-209-1) states that the endpoint for Cerio daphnia dubia is based on

initial measured concentrations. To support the use of initial measured concentrations, it would be useful to see the measured concentrations in the old solutions before renewal.

An additional toxicity test with Cerio daphnia dubia (England, 1995) not included in the CLH report is referred to in the Substance Evaluation (SEv) report (2018) for nonylphenol, branched, ethoxylated (EC 500-315-8, CAS 127087-87-0). The acute endpoint from this study is a 96-h EC50 of 0.626 mg/L based on immobilisation following exposure to NPE-1.5 and thus would support the Aquatic Acute 1 classification with an M-factor of 1 for short-chain NPEs. A chronic toxicity endpoint from the same study by England (1995) is also included in the SEv. We note that the SEv report (2018) was not included in the list of data sources in section 6 of the CLH report. The SEv is a recent EU regulatory assessment and includes relevant information which should be referenced?

We note that some study details for the algal toxicity study could not be found by the DS for the CLH report. As this study is the only toxicity study for algae/aquatic plants for short-chain NPEs, please can the DS clarify whether the control growth met the validity criteria, or if this information is not available? We recognise this study will not impact the classification since algae appear to be the least sensitive trophic group based on the available information.

Date	Country	Organisation	Type of Organisation	Comment number
01.10.2020	France		MemberState	2
Comment received				
Screening studies show that short chain NPEn (n=1 or 2) are not ready biodegradable. Acute and chronic data on short chain NPE with 1 to 2 ethoxy groups are available for fish, invertebrates and algae. The lowest LC50 value obtained in mysids (0.11 mg/L). allow to classify the group as Acute Cat 1 and M factor of 1. Regarding to the available information on chronic studies, the lowest long term toxicity is reported with Americamyis bahia with a NOEC value of 0.0077 mg/L. Therefore, the group fulfil criteria for classification as chronic category 1 with a M-factor of 10. France supports the classification proposal for short chain NPE as Aquatic Acute 1, M1 and Aquatic Chronic 1, H410, M=10				