

Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

Nonylphenol, branched and linear, ethoxylated
(with 352 g/mol ≤ average molecular weight
< 704 g/mol) [includes ortho-, meta-, para- isomers
or any combination thereof]

EC Number: 230-770-5; 248-743-1; 247-555-7;
248-293-6 and others

CAS Number: 127087-87-0; 9016-45-9; 7311-27-5;
27942-27-4; 26264-02-8; 27177-05-5;
14409-72-4 and others

CLH-O-0000007026-79-01/F

Adopted
16 September 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (WITH 352 G/MOL ≤ AVERAGE MOLECULAR WEIGHT < 704 G/MOL) [INCLUDES ORTHO-, META-, PARA- ISOMERS OR ANY COMBINATION THEREOF]

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]

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Dossier submitter: The Netherlands

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
01.10.2020	France		MemberState	1
Comment received				
NPE _n (n = ≤ 3 to < 11) is considered as not ready biodegradable Chronic toxicity data is available for fish, invertebrates and algae. On the basis of the available valid data, fish is the most sensitive species with NOEC values of in the range 0.1 – 1 mg/L. Therefore, the group NPE _n (n = ≤ 3 to < 11) fulfils the criteria for classification as Category Chronic 2.				
France supports the classification proposal for the group NPE _n (n = ≤ 3 to < 11) as Aquatic Chronic 2, H411				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comments				

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Date	Country	Organisation	Type of Organisation	Comment number
02.10.2020	United Kingdom	HSE	National Authority	2
Comment received				
<p>nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] EC: 230-770-5; 248-743-1; 247-555-7; 248-293-6 and others; CAS: 127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others)</p> <p>1) The Aquatic Chronic 2 classification is based on a 100-day NOEC of 0.114 mg/L for the survival of <i>Oryzias latipes</i> exposed to NPE-4 (Balch and Metcalfe, 2006). However, the recent 2018 Substance Evaluation (SEv) for nonylphenol, branched, ethoxylated (EC 500-315-8, CAS 127087-87-0) and the REACH registration dossier for nonylphenol, branched, ethoxylated (1 - 2.5 moles ethoxylated, CAS 68412-54-4, EC 500-209-1) considered that there were no effects on survival in the study with NPE-4 at any concentration, leading to a 100 d NOEC of = ≥0.380 mg/L (mm). As this is the key endpoint for the proposed chronic classification, please could the DS clarify the basis of this endpoint and consider the endpoint review in the SEv report?</p> <p>2) All other aquatic chronic toxicity values that are considered valid by the DS for the CLH report are above 1 mg/L and would not result in a classification for aquatic chronic toxicity given that the substance is NRD. However, the surrogate approach would be applicable using the LC50 values for <i>Lepomis macrochirus</i> and <i>Pimephales promelas</i> since there are no reliable chronic toxicity data for these fish species. These LC50 values are in the range of >1 to ≤10 mg/L, leading to an Aquatic Chronic 2 classification.</p>				
Dossier Submitter's Response				
<p>We thank the UK for their comments and support.</p> <p>Sub 1)</p> <p>The Balch and Metcalfe (2006) study, cited in the SEv for nonylphenol, branched, ethoxylated and in the REACH registration dossier on the ECHA dissemination website, state that no effects on survival were observed at any doses (<i>Oz. latipes</i>, NPE-4), so the 100-d NOEC was ≥ 1mg/L (nominal) (≥0.380 mg/L based on measured concentrations). However, the chemical safety report mentions the following '<i>Fish survival during the 100-day exposure period was greater than 70% in all treatments, except those tested at 380 µg/L of NPE-4. Survival was only 20% in the 380 µg/L of NPE-4</i>' and the NOEC value for survival for NPE-4 is 0.114 mg/L.</p> <p>We reviewed the original study report to clarify these inconsistencies (Balch and Metcalfe, 2006). Japanese medaka (<i>Oryzias latipes</i>) were exposed to NPE-4 of 10, 30, 100, 300 and 1000 µg/L for 100 days. During the 100-day exposure period, fish survival was greater than 70% in all treatments, excluding those tested at 1000 µg/L of NP4EO. Survival was only 20% in the 1000 µg/L NPE-4. Therefore, there were effects on survival at the highest concentration of NPE-4. Therefore, we believe that the 100-day NOEC of 0.114 mg/L based on survival should be used for classification purposes.</p>				

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Sub 2)

Acute data are available for the following fish species: *Lepomis macrochirus* and *Pimephales promelas* (LC50 ranges from 1.3 to 7.9 mg/L). For long-term data is available for *O. lapites* (NOEC ranges 0.54 mg/L; > 0.38 mg/L and 0.114 mg/L). Taking into consideration that no chronic toxicity data are available for *Lepomis macrochirus* and *Pimephales promelas* we agree with the UK's suggestion that the surrogate method can be applied. Because there is no chronic data on *Lepomis macrochirus* to confirm that it will (or not be) more sensitive than *O. lapites*. The use of the surrogate approach as set out in Table 4.1.0 (b)(i) and 4.1.0(b)(iii) of the CLP guidance leads to a classification of Aquatic Chronic 2. This supports the proposed classification for medium-chain NPEs.

RAC's response

Regarding the Balch and Metcalfe (2006) study, RAC agrees with the DS that the use of the 100-day NOEC of 0.114 mg/L based on Japanese medaka survival is adequate for classification purpose. Since mortality is observed in the highest concentration tested, this NOEC has not resulted from a concentration limit. RAC took note of the proposal to use the surrogate approach and that this method results in the same classification as the DS proposal.