Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and labelling at EU level of

Dibenzoyl peroxide; benzoyl peroxide

EC Number: 202-327-6
CAS Number: 94-36-0

CLH-O-0000007215-78-01/F

Adopted
1 December 2022

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: dibenzoyl peroxide; benzoyl peroxide
EC number: 202-327-6
CAS number: 94-36-0
Dossier submitter: Ireland

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
08.04.2022	Belgium		MemberState	1

Comment received
BE CA supports the proposed environmental classification of Aquatic Acute 1, H400 (M-factor = 10) and Aquatic Chronic 1, H410 (M-factor = 10) for Dibenzoyl peroxide; benzoyl peroxide.

Based on a weight-of-evidence approach, Dibenzoyl peroxide; benzoyl peroxide should be considered as rapidly degradable. Following the CLP guidance II.3.5., the OECD TG 301D study (Anonymous, 2015b) should be regarded as the determining study (key study) for ready biodegradability due to its good data quality and well-documented test conditions. No experimentally derived BCF is available for the substance, but based on the log Kow < 4 it can be concluded that Dibenzoyl peroxide; benzoyl peroxide does not meet the criterion for bioconcentration in aquatic organisms.

BE CA agrees that the acute classification should be based on the 96h-LC50 value for fish of 0.06 mg/L (Anonymous, 2010a), which leads to the environmental classification of Aquatic Acute 1, H400 (M-factor = 10) for Dibenzoyl peroxide; benzoyl peroxide.

BE CA further agrees that the chronic classification should be based on the 21d-EC10 value for aquatic invertebrates of 0.001 mg/L (Anonymous, 2015a). As the surrogate approach cannot be considered to be appropriate for this type of substance (rapidly degradable and low potential for bioaccumulation), the chronic classification according to the 21d-EC10 value is the most stringent outcome. This leads, together with the ready degradability of the substance, to the environmental classification of Aquatic Chronic 1, H410 (M-factor = 10) for Dibenzoyl peroxide; benzoyl peroxide. |

Dossier Submitter's Response
The IE CA would like to thank the BE CA for their support.

RAC's response
Thank you for your comment. Support for classification of the substance as Aquatic Acute 1, M-factor = 10 and Aquatic Chronic 1, M-factor = 10 is noted by RAC. RAC agrees.
RAC agree with commenting MS that in line with CLP guidance II.3.5. dibenzoyl peroxide should be considered as rapidly degradable base on OECD TG 301D study (Anonymous, 2015b). See ODD, section Assessment and comparison with the classification criteria.

RAC agrees that in line with the CLP guidance section 4.1.3.3 and Table 4.1.0. the surrogate method is not applicable for dibenzoyl peroxide as the substance is considered rapidly degradable and does not fulfil the criteria for bioaccumulation. |

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2022	United Kingdom		Individual	2
Comment received				
Hazardous to all aquatic life.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment MSDS_27581_PERVELOX_EVO_50_(GB)_REV6.pdf | | | | |
Dossier Submitter's Response				
The IE CA notes the information provided in the safety data sheet. No additional hazard data is provided and the results of the studies reported in section 12 of the safety data sheet are reflected in the CLH proposal.				
RAC's response				
Thank you for your comment. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
28.03.2022	United Kingdom	Health and Safety Executive	National Authority	3
Comment received				
dibenzoyl peroxide; benzoyl peroxide (EC: 202-327-6; 94-36-0):

In relation to the aquatic acute classification, we note the CLH report states that the following endpoints are based on mean measured concentrations:
• Oncorhynchus mykiss 96-h LC50 = 0.0602 mg/L (Anonymous, 2010a)
• Daphnia magna 48-h EC50 = 0.110 mg/L (Anonymous, 2010b)
However, the EU REACH registration states that these endpoints are based on initial measured concentrations. Please could the DS clarify whether these endpoints are based on initial measured concentrations or mean measured concentrations over the test period? Please could RAC also consider which basis (initial measured, or mean measured) is most relevant for the acute endpoints, noting the rapid hydrolysis of the test substance?

The key chronic endpoint used for the proposed classification is the Daphnia magna EC10 of 0.001 mg/L (95% C.I. 0.00010-0.0018 mg/L) based on reproduction. Whilst within the test guideline recommendation, we note that the coefficient of variation (CV) around the EC10 endpoint for mean number of living offspring produced per parent in the controls was 13.5%. As this control CV is above 10% and given the EC10 is below the NOEC (albeit it only slightly), the EC10 is likely to reflect considerable uncertainty regarding | | | | |

where a 10% difference compared to the mean living offspring truly lies – this is also demonstrated by the confidence intervals (which span two Chronic hazard classification ranges). Is there more information about the individual 10 control replicates to understand the background variation and the dose-response regression, for example were there any outliers? We wonder if the reproduction NOEC of 0.0011 mg/L from the same study, or an EC20, is more reliable and relevant to hazard classification in this instance. Using the NOEC would lead to an Aquatic Chronic 1 classification with an M-factor of 1 for this rapidly degradable substance.

Dossier Submitter's Response

The IE CA would like to thank the UK National Authority for their comments.

With respect to the comments on the acute aquatic toxicity studies, we checked again the information reported in the registration dossier for the two studies mentioned. For the acute toxicity studies with Oncorhynchus mykiss (Anonymous, 2010a) and Daphna magna (Anonymous, 2010b), the reported results are based on initial measured concentrations. The registration data states that in expired samples (at 24 hours for Anonymous 2010a and 48 hours for Anonymous 2010b), no measurable levels of dibenzoyl peroxide were found at any exposure concentration and for this reason, the results were expressed as initial measured concentrations. Although not specifically addressed in the comment, the same applies for the acute study with Pseudokirchneriella subcapitata (Anonymous, 2010c) in that no measurable levels were detected in expired samples at 72 hours and thus the results are expressed as initial concentrations.

With respect to the daphna magna reproduction test (Anonymous 2015a) and the suggestion that the NOEC may be more reliable and relevant to conclude on the chronic classification and M factor, we note that Table R-10.1 of ECHA Guidance R.10[1] states that the use of an EC10 from a long term study is preferred over a NOEC. Therefore, we consider the EC10 value to be more appropriate to derive the classification and M factor.

In this case both the EC10 (of 0.001 mg/l) and the NOEC (of 0.0011 mg/l) lead to a classification of aquatic chronic category 1. However, we agree that the choice of value impacts the M factor, with the NOEC falling within the range for a M factor of 1 and the EC10 within the range of an M factor of 10. In the comment it is noted that the CV around the EC10 was above 10 % and that this may lead to uncertainty in the EC10 value. We checked again the robust study summary reported in the registration dossier (we do not have access to the study report). No information is provided on the individual control replicates or on the dose-response regression and therefore it is not possible to provide any further information, including if there were any outliers in this group. We note that the 95% CI of the EC10 spans across three M factor levels, with only the current proposed M factor of 10 fully covered.

The EC10 and NOEC values as reported in the robust study summary are presented in the CLH report. We note the difference in the number of decimal places for each value: 0.001 mg/L and 0.0011 mg/l for the EC10 and NOEC, respectively. No information is provided in the study summary as to whether the EC10 value was rounded up.

RAC's response

Thank you for your comment.The change of mean measured concentrations to initial measured concentrations in acute toxicity study with *Oncorhynchus mykiss* (Anonymous, 2010a) and *Daphna magna* (Anonymous, 2010b) is noted by RAC.

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[1] ECHA (2017). Guidance on information requirements and chemical safety assessment, Chapter R.10 (version May 2008).

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2022	Czech Republic	<confidential>	Company-Importer	4
Comment received				
We do not have any toxicological and ecotoxicological studies to improve the proposal to give a support to the higher classification.				
Dossier Submitter's Response				
The IE CA notes your comment.				
RAC's response				
Thank you for your comment. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.03.2022	Netherlands		MemberState	5
Comment received				
Agree with the CLH proposal. No further comments.				
Dossier Submitter's Response				
The IE CA would like to thank the NL CA for their support.				
RAC's response				
Thank you for your comment. Support for classification of the substance as Aquatic Acute 1, M-factor = 10 and Aquatic Chronic 1, M-factor = 10 is noted by RAC. RAC agrees.				

PUBLIC ATTACHMENTS
1. MSDS_27581_PERVELOX_EVO_50_(GB)_REV6.pdf [Please refer to comment No. 2]