

Committee for Risk Assessment
RAC

Annex 2

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

reaction mass of:
isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecyl phenol

isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol

isomers of

2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol.

***n* = 5 or 6**

EC Number: 401-680-5

CAS Number: -

CLH-O-0000001412-86-88/F

Adopted

4 December 2015

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public 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 public 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 public 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.

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Substance name: reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecylphenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol

EC number: 401-680-5

CAS number: -

Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
29.06.2015	France		MemberState	1
Comment received				
MSCA-FR proposes Aquatic chronic 4, H413 instead of the removal of Aquatic chronic 2, H411				
Dossier Submitter's Response				
See comment number 2				
RAC's response				
Noted				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
29.06.2015	France		MemberState	2
Comment received				
Aquatic chronic 4, H413 – may cause long lasting harmful effects to aquatic life is proposed by FR.				
<p>The substance is poorly soluble. Just one test (long term toxicity study on Daphnia, OECD 211) provides a true measure of the intrinsic toxicity (no chronic toxicity is recorded at levels up to the water solubility). No acute toxicity tests are carried out below the solubility limit. Moreover, the substance is not rapidly degradable.</p> <p>Finally, a BCF < 500 (111-132, lipid normalised) was determined using an aqueous exposure. Nevertheless due to the very low solubility of the substance, a dietary approach (OECD 305) could be considered as more relevant.</p>				
Given these uncertainties, a H413 classification must be proposed.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON REACTION MASS OF ISOMERS

Dossier Submitter's Response
<p>Thank you for your comment. Based on the criteria of the CLP regulation a poorly soluble substance should be classified as Aquatic Chronic 4 under following conditions:</p> <ul style="list-style-type: none"> - no acute toxicity in the range of its water solubility is recorded and - the substance is not rapidly degradable and - potential to bioaccumulate is indicated <p>The experimentally determined lipid normalised BCF values of 111-132 are below the cut-off value of the CLP regulation (BCF \geq 500). Hence, the substance has no potential to bioaccumulate and a classification as Aquatic Chronic 4 is not justified.</p>
RAC's response
Noted

ADDITIONAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2015	Netherlands	MPI Chemie BV	Company - Importer	1
Comment received				
At the moment we can only agree with the Proposal for Harmonised Classification and Labelling by the dossier submitter (BAuA)				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted				