

Committee for Risk Assessment
RAC

Annex 2

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

5-chloro-2-(4-chlorophenoxy)phenol

EC Number: 429-290-0
CAS Number: 3380-30-1

CLH-O-0000001412-86-69/F

Adopted
09 September 2015

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 5-CHLORO-2-(4-CHLOROPHENOXY)PHENOL

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 attachments including confidential documents received during the public consultation have been provided in full to the dossier submitter, to RAC members and to the Commission (after adoption of the RAC opinion). 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.

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Substance name: 5-chloro-2-(4-chlorophenoxy)phenol

CAS number: 3380-30-1

EC number: 429-290-0

Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
23.04.2015	France		MemberState	1
Comment received				
Page 4 and 12: Purity reported is not in line with purity set in final AR of Biocide dossier. CLH report should be amended on this point.				
Dossier Submitter's Response				
We agree to amend the CLH report with the purity set in the final AR. The original data resulted in purity of 99.1% (w/w). Due to certain deficiencies of the original data the TM IV 2013 concluded that a new 5-batch analysis for DCPD has to be submitted. The study has been submitted in June 2014. Based on the new data the purity for DCPD amounts to 99.5 % (w/w). A more detailed summary of the new 5-batch analysis and a comparison with data previously submitted can be found in the confidential document "Doc IIA Confidential.doc"				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2015	Germany		MemberState	2
Comment received				
The CLH Dossier does not address endpoints concerning human health and physical hazards. Therefore no comments are provided on those sections. In general we agree to the proposed environmental classification and derivation of M-factors.				
<i>ECHA note: Confidential comments on the Substance Identification as reported in the IUCLID dossier were provided with the comment above [Attachment 1]</i>				
- <i>Comment of the German CA on confidential information provided in the CLH-Dossier: 5-Chloro-2-(4-chlorophenoxy)phenol (CAS-Nr. 3380-30-1)</i>				
Dossier Submitter's Response				
Thank you for your comment and agreement. With regard to the confidential comment,				

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please see our response added to <i>Attachment 1</i>
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
23.04.2015	France		MemberState	3
Comment received				
We agree with the current proposal for consideration by RAC: CLP regulation: Aquatic acute 1 (M=10); Aquatic chronic 1 (M=10); H400 – very toxic to aquatic life; H410 – very toxic to aquatic life with long lasting effects.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2015	Germany		MemberState	4
Comment received				
In general we agree to the proposed environmental classification and derivation of M-factors. Please consider following comment on the CLH report. Chapter 5.2.3, Summary and discussion of aquatic bioaccumulation: The stated BCF value for the metabolite methyl-DCPP is wrong. Please amend the value as stated in the assessment report. In the latest version from November 2014 BCF values between 10517 and 17505 are stated.				
Dossier Submitter's Response				
Thank you for your comment. Please note that experimental BCF values for the metabolite were amended after the submission of the CLH report. We agree that the information should be considered and added to the report: "The metabolite methyl-DCPP has a calculated log Kow value of 4.6. An experimental study with <i>Danio rerio</i> revealed high Bioconcentration factors: Kinetic BCF values of 23804 and 16738 were obtained, resulting in lipid corrected values of 17505 and 12129. Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517 were obtained. Based on the criteria for PBT/vPvB substances, methyl-DCPP has to be regarded as very bioaccumulative (vB)."				
RAC's response				
Dossier Submitter's text is included in the opinion.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
23.04.2015	France		MemberState	5
Comment received				

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Page 6: For end points: hazard from liquid, gaz and aerosol, the term "data lacking" is confusing. FR would rather use the term not relevant, but it's not available in ECHA template. Anyway, "Conclusive but not sufficient for classification" would be more adequate as DCP is a solid.

Dossier Submitter's Response

We agree that "data lacking" might be confusing in this case, because there is not data simply because it is not relevant. On the other hand "Conclusive but not sufficient for classification" might insinuate that there is some data but not considered for some reason, which is also not true. We tend to use "data lacking" which is slightly closer to the real situation in our opinion.

RAC's response

Noted.

CONFIDENTIAL ATTACHMENT RECEIVED

- Comment of the German CA on confidential information provided in the CLH-Dossier: 5-Chloro-2-(4-chlorophenoxy)phenol (CAS-Nr. 3380-30-1). Submitted by the German MSCA on 24.02.2015. (Filename: comment-DE-CA-identity-confidential_CONF.docx) *[Please refer to comment 2]*

CONFIDENTIAL ATTACHMENTS added by Dossier Submitter

- Doc IIA Confidential.doc *[Please refer to comment 1]*
- AT response to DE-CA comment on identity Confidential.doc *[Please refer to comment 2]*