

**Committee for Risk Assessment**  
**RAC**

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

**3,3'-dicyclohexyl-1,1'-methylenebis (4,1-  
phenylene)diurea**

**EC number: 406-370-3**  
**CAS number: 58890-25-8**

CLH-O-0000001412-86-87/F

**Adopted**  
**4 December 2015**

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 3,3'-DICYCLOHEXYL-1,1'-METHYLENEBIS(4,1-PHENYLENE)DIUREA**

**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: 3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea**

**CAS number: 58890-25-8**

**EC number: 406-370-3**

**Dossier submitter: Germany**

**GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2015	France		MemberState	1
Comment received				
MSCA-FR is not supporting the proposition of removal the classification of Aquatic Chronic 4 for Complex soap TH 28 and skin sens. 1 H317.				
Dossier Submitter's Response				
<u>Response to comment number 1</u>				
<p><u>Skin sensitisation:</u> The registered compound 'Complex soap TH 28' with a purity of 95 % has not shown skin sensitizing properties in a guideline-compliant mouse Local Lymph Node Assay (LLNA, according to OECD TG 429/EU B.42). Based on these results the removal of the current classification and labelling according to CLP Regulation with Skin Sens. 1 (H317) for the registered compound 'Complex soap TH 28' is proposed.</p> <p><u>Hazardous to the Aquatic Environment:</u> From a present-day perspective and considering the comments made in the public consultation the removal of the classification of Aquatic Chronic 4 is not further supported.</p> <p>A more detailed response can be found under the specific endpoint (response to comments number 2 and 3).</p>				
RAC's response:				
<p><u>Skin sensitisation:</u> Regarding skin sensitization the basis of former skin sensitization classification is unclear. The compound 'Complex soap TH 28' was notified under the former NONS Regulation (Directive 92/32/EEC). According to the information in the CLH dossier, the notified compound has not been tested for skin sensitisation under NONS. RAC agrees with DS on the removal of skin sensitization classification.</p> <p><u>Hazardous to the Aquatic Environment:</u> RAC agrees with MSCA FR not removing Aquatic Chronic 4.</p>				

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**OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2015	France		MemberState	2
Comment received				
<p>Skin sensitisation, page 20                      MSCA-FR questioned if skin sensitisation data are sufficiently complete to remove the current classification as Skin sens. 1 –H317. In fact, there is no information on what basis the substance has initially been classified as skin sens. 1 –H317.</p>				
Dossier Submitter's Response				
<p>Response to comment number 2, Skin sensitisation:                      The skin sensitisation data on the registered compound 'Complex soap TH 28' are sufficiently complete to remove the current classification as Skin Sens. 1 (H317).</p> <p>The skin sensitisation potential of the registered compound 'Complex soap TH 28' with a purity of 95 % was tested in a Local Lymph Node Assay (LLNA) performed in CBA/J@Rj mice according to OECD TG 429/EU B.42. No skin sensitisation properties were observed in mice in this study according to CLP criteria.</p> <p>The compound 'Complex soap TH 28' was notified under the former NONS Regulation (Directive 92/32/EEC).</p> <p>The new information on the negative test results refers to the substance as registered ('Complex soap TH 28'), with data from a guideline-compliant mouse LLNA, performed in 2009. This information confirmed that the previous classification is no longer justified and a declassification of the classification with Skin Sens. 1 (H317) is warranted.</p>				
RAC's response:				
Agreed.				

**OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment**

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2015	United Kingdom		MemberState	3
Comment received				
<p>We do not support the removal of Aquatic Chronic 4. We do not feel there is sufficient chronic data or reliable water solubility information to support not classified for the environment.</p> <p>The new water solubility information was not conducted to GLP and there is insufficient detail to consider the data adequate for classification. The study did not employ a substance specific method and as noted in Table 8, may have overestimated the pure substance water solubility. While we note the purity is <math>\geq 95\%</math>, small amounts of soluble impurities can cause large errors in measured solubility, especially within a low solubility range (Reference OECD Test Guideline 106, (2015)). We also note the EPIWIN QSAR submitted with the CLH Report indicates a water solubility <math>\ll 1\text{mg/l}</math>. Overall, we do not consider there is reliable data to consider the water solubility <math>&gt;1\text{mg/l}</math>.</p> <p>The substance is considered not rapidly degradable and has a QSAR logKow of 6.91 indicating a logKow <math>\geq 4</math>. The CLH Report presents acute data indicating L(EC)50 values</p>				

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above test media solubility. The current dataset does not include reliable chronic data for all trophic levels.

Given the new water solubility data does not reliably demonstrate the substance water solubility is >1mg/l, the Aquatic Chronic 4 criteria in CLP, Annex I, Section 4.1, Table 4.1.0 are met.

ECHA (2013) states 'In case of classification of a substance as Chronic 4, sufficient evidence should be provided that the NOEC or equivalent ECx for each taxonomic group is greater than 1 mg/l or greater than the water solubility of the substances under consideration.' On this basis, we do not consider the data demonstrates no chronic toxicity for fish, crustacea and algae/aquatic plants above the water solubility or > 1mg/l.

References:

ECHA (2013) Guidance on the Application of the CLP Criteria. Version 4.0 – November 2013.

**Dossier Submitter's Response**

Response to comment number 3, Hazardous to the Aquatic Environment:

From a present-day perspective we agree entirely with the point of view in comment 3. As described there, 'Complex soap TH28' is not rapidly degradable, has a logPow above 4, and not for all trophic levels but only for algae reliable chronic data is available. Therefore we agree that the removal of Aquatic Chronic 4 is not adequate.

RAC's response:

RAC agrees with the insufficiency of chronic data from only one trophic level (algae NOEC) in addition to not rapid degradation and a potential to bioaccumulation.

Date	Country	Organisation	Type of Organisation	Comment number
18.06.2015	France		MemberState	4

**Comment received**

MSCA-FR is not supporting the proposition of removal the classification of Aquatic Chronic 4 for Complex soap TH 28.

Complex soap TH 28 is a substance not readily biodegradable (48% of degradation within 28 days) and bioaccumulative (log Kow ≥ 4). This substance is not considered as toxic in acute test (LC50/EC 50 > water solubility) and no data are available for chronic test. Taking into account all these information, MSCA-FR considers complex soap TH 28 has to be still classified as Aquatic Chronic 4, H413.

**Dossier Submitter's Response**

Please see response to comment number 3.

RAC's response:

RAC agrees with classification as Aquatic chronic 4.