

Committee for Risk Assessment
RAC

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

glyoxylic acid ...%

EC Number: 206-058-5

CAS Number: 298-12-4

CLH-O-0000001412-86-204/F

Adopted
8 June 2018

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: glyoxylic acid ...%

EC number: 206-058-5

CAS number: 298-12-4

Dossier submitter: Germany

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
11.08.2017	France		MemberState	1
Comment received				
FR is questioning about the skin irritation/corrosion potency of glyoxylic acid. Glyoxylic acid has a very acidic pH (0.3) and, according to the guidance, "prediction of skin corrosivity based on pH extremes shows a very high specificity (□ 90%) and therefore a low number of false positives (R.7.2.4.1, IR&CSA guidance)". Moreover, considering the results of the OECD 405 test for eye irritation and the result of the pre-screen test of the LLNA showing irritation for lower concentrations (undefined), could you please confirm that you have a good confidence in the Guillot et al. (1984a) study to base the classification for skin irritation?				
Dossier Submitter's Response				
The DS agrees that it can be expected that glyoxylic acid produces significant effects on the skin due to the low pH value of ≤ 0.3 of glyoxylic acid (50 %). However, there exists an in vivo acute dermal irritation/corrosion test with glyoxylic acid (50 %) which was performed according to OECD TG 404 and GLP (Guillot <i>et al.</i> 1984a). The test is considered reliable. No skin irritating effects were observed in the tested animals. Hence, based on these results it has been concluded that classification of glyoxylic acid (50 %) for skin corrosion/irritation is not justified.				
RAC's response				
RAC agrees that based on the low pH value of 0.3 for glyoxylic acid, corrosive effects on the skin would be expected. The results of the pre-screen test of the LLNA showing irritation may not be suitable to assess skin corrosion/irritation potential due to penetration enhancing vehicles. Using data on eye irritation may also not be appropriate for assessment of the skin corrosion/irritation potential. RAC noted some limitations in the Guillot study but agrees with the DS, that based on the very low scores observed in the <i>in vivo</i> study, no classification is warranted for glyoxylic acid ...50%.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
30.08.2017	Finland		MemberState	2
Comment received				
The eye irritation/corrosion study conducted with glyoxylic acid resulted in severe, irreversible eye effects. The results meet the criteria for classification as Eye Dam. 1; H318. FI CA supports the proposed classification of Eye Dam. 1; H318 for glyoxylic acid.				
Dossier Submitter's Response				
The DS appreciates the comment of the FI CA.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
30.08.2017	Finland		MemberState	3
Comment received				
The CLH report contains unclarity related to the proposed classification. In table 2.1 (p. 5), the dossier submitter proposes category 1 (H317) for skin sensitisation. Whereas under section 7.3.3 (p. 16) the following is stated "...justified to classify glyoxylic acid as Skin Sens. Category 1B H317". Skin sensitisation test (LLNA, OECD TG 429) conducted with glyoxylic acid showed positive results. FI CA considers that data for classification into sub-categories is not sufficient, because the actual test concentrations are not known. FI CA supports the proposed classification of Skin Sens. 1; H317 for glyoxylic acid.				
Dossier Submitter's Response				
The DS acknowledges the comment by the FI CA. In table 6 (section 2.1, p.5) in column 'Hazard Class and Category codes' in lines 2 and 3, Skin Sens.1 should be changed to Skin Sens. 1B. The classification proposal for Skin Sens. 1B was based on results of a LLNA study published by Anderson <i>et al.</i> , 2008. The test concentrations published in this study are considered as known and justified. The estimated EC3 value was 5.05 %. The study is considered to be sufficient to allow a sub-categorisation and to justify a Skin Sens. 1B classification for glyoxylic acid ...50%.				
RAC's response				
RAC agrees with the DS's response.				