



Committee for Risk Assessment
RAC

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

leucomalachite green

ECHA/RAC/CLH-O-0000001309-75-03/A2

Adopted
23 November 2010

ANNEX 2 – COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON LEUCOMALACHITE GREEN

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

[ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.]

Substance name: leucomalachite green

CAS number: 129-73-7

EC number: 204-961-9

General comments

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
23/06/2010	Sweden / Helena Kramer / MS	Sweden supports the agreement, on the proposed Classification and Labelling, taken by the Technical Committee on Classification and Labelling (Directive 67/548/EEC) ('TC C&L') between 2005 and 2007.	Noted	Noted
16/07/2010	France / MS	The recommendations agreed at the TC C&L regarding the classification of leucomalachite green for health effects are supported in absence of any new study since the TC C&L discussions and in agreement with the classification proposed in the CLH report. A classification N; R50-53 was also adopted for environment at the TC C&L in September 2005. Harmonisation of the environment classification should also be considered without any information on its application by self-classification.	Noted. During the accordance check of this dossier we received a comment that there needs to be a specific justification for community action for proposals for harmonised environmental hazard assessment; a reference to TC C&L was not considered to be sufficient. As there was no specific scientific justification other than the previous TC C&L decision, we decided not to include a proposal for N; R50-53.	With specific reference to corresponding discussions in RAC and to chapter 6.2 of the Guidance on the preparation of CLH dossiers the response of the dossier submitter is accepted by the Rapporteur. The Guidance requires a justification for action at Community level. Furthermore, the Guidance requires a comparison of available data with the DSD and CLP classification criteria.

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Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
23/07/2010	Denmark / Peter Hammer Sørensen / MS	<p>ECHA: copied from the attachment “Danish comments for Leucomalachite Green. Cas.nr.129-73-7”</p> <p>Danish comments to Annex XV report – Leucomalachite Green, Cas.no. 129-73-7</p> <p>Endpoints to be discussed: Muta. Cat. 3; R68 Carc. Cat. 3; R40.</p> <p>As the classifications were agreed September 2007 in the TC C&L group, Denmark supports the proposal for the classification. No further data or information is submitted.</p> <p>Overall classification will be:</p> <p>Xn, N R: 22-40-41-68-50/53</p>	<p>Noted. For clarification, the classification proposed in the dossier is:</p> <p>Xn R: 40-68</p> <p>(Muta. 2; H342, Carc. 2; H351).</p> <p>Classifications of Xn; R22 and N; R50-53 have not been proposed.</p>	Noted.
05/08/2010	Germany / Bernd Niederstrasser / MS	<p>Comment of the German CA: Leucomalachite green was previously agreed at TC C&L between 2005 and 2007. The TC C&L came to agreement on the following classification based on Directive 67/548/EEC criteria: Carc. Cat. 3; R40 Agreed 1006 Muta. Cat. 3; R68 Agreed 0907 Xn, R22 Agreed 1006 N; R50-53 Agreed 0905.</p> <p>Page 3 - Classification proposals based on Directive 67/548/EEC and CLP criteria should be completed for all TC C&L agreements. Therefore, classification of leucomalachite green as Xn, R22 / Acute Tox. 4; H302 and N; R50-53 / Aquatic Acute 1; H400, Aquatic Chronic 1; H410 should be added in the proposal.</p>	<p>Noted. During the accordance check of this dossier we received a comment that there needs to be a specific justification for community action for proposals for non-harmonised end-points; a reference to TC C&L was not considered to be sufficient. As there was no specific scientific justification other than the previous TC C&L decision, we decided not to include proposals for Xn;</p>	<p>With specific reference to corresponding discussions in RAC and to chapter 6.2 of the Guidance on the preparation of CLH dossiers the response of the dossier submitter is accepted by the Rapporteur. The Guidance requires a justification for action at Community level. Furthermore, the Guidance requires a comparison of available data with the DSD</p>

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		Furthermore, the annex VI report should be amended with data for classification of the above-named endpoints.	R22 and N; R50-53.	and CLP classification criteria.

Carcinogenicity

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
23/07/2010	Denmark / Peter Hammer Sørensen / MS	As the classifications were agreed September 2007 in the TC C&L group, Denmark supports the proposal for the classification. No further data or information is submitted.	Noted.	Noted.
05/08/2010	Germany / Bernd Niederstrasser / MS	<p>Comment of the German CA: Page 8, 12-14 - The proposal of classification is in line with a previous agreement at the TC C&L Meeting (October 2006) to classify leucomalachite green as Carc. Cat. 3; R40 / Carc. 2; H351.</p> <p>No data on human cancer were available. The described results from relevant cancer studies with leucomalachite green in rats and mice provide limited evidence of carcinogenicity. The data suggest a carcinogenic effect for leucomalachite green based on statistically significant dose-related increase in hepatocellular adenoma or carcinoma (combined) in female mice (the only sex investigated) and equivocal evidence of induction of liver tumours in female rats. The mutagenicity data indicates that genotoxicity is possibly involved in the induction of tumours. Altogether the given justification for the classification of leucomalachite green as Carc. 2; H351 / Carc. Cat.3; R40 is comprehensible.</p>	Noted.	Noted.

Mutagenicity

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
23/07/2010	Denmark / Peter	As the classifications were agreed September 2007 in the TC C&L	Noted.	Noted.

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	Hammer Sørensen / MS	group, Denmark supports the proposal for the classification. No further data or information is submitted.		
05/08/2010	Germany / Bernd Niederstrasser / MS	Comment of the German CA: Page 9-12 - The proposal of classification is in line with a previous agreement at the TC C&L Meeting (October 2006) to classify leucomalachite green as Muta. Cat. 3; R68. Agreement on the proposed classification Muta. 2; H341 / Muta. Cat. 3; R68.	Noted.	Noted.

Toxicity to reproduction

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
05/08/2010	Germany / Bernd Niederstrasser / MS	Comment of the German CA: no comment	Noted.	Noted.

Respiratory sensitisation

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
05/08/2010	Germany / Bernd Niederstrasser / MS	Comment of the German CA: no comment	Noted.	Noted.

Other hazards and endpoints

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
05/08/2010	Germany / Bernd Niederstrasser / MS	Comment of the German CA: no comment	Noted.	Noted.