



Committee for Risk Assessment
RAC

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

**aluminium-magnesium-zinc-
carbonate-hydroxide**
ECHA/RAC/ No CLH-O-0000001743-75-01/A2

Adopted
10 June 2011

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON
ALUMINIUM-MAGNESIUM-ZINC-CARBONATE-HYDROXIDE

[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: Aluminium-magnesium-zinc-carbonate-hydroxide

CAS number: 169314-88-9

EC number: 423-570-6

General comments

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
12/11/2010	Spain / Member State	We are in agreement with the Dutch proposal to remove the environmental classification.	Thank you for your support.	It was decided in RAC15 to use metals strategy to classify this substance.
15/11/2010	Portugal / Portuguese Environment Agency / National Authority	Considering the present proposal, we agree with the removal of the environmental classification according to 67/548/EEC Directive and CLP Regulation.	Thank you for your support.	It was decided in RAC15 to use metals strategy to classify this substance.

Carcinogenicity

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur comments

Mutagenicity

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Toxicity to reproduction

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Respiratory sensitisation

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Other hazards and endpoints

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
08/11/2010	Belgium / Member State	Based on the new results of the aquatic acute toxicity tests (not toxic effects seen up to the water solubility : EC50 > 2.8 mg/l); the fact that, for an inorganic compound, the log Kow is irrelevant for determining the potential to bioaccumulate and the concept of degradability is not relevant, it is justified not to classify the substance.	Thank you for your support.	It was decided in RAC15 to use metals strategy to classify this substance.
10/11/2010	France / Elodie Pasquier / Member State	Environmental hazards: Before concluding on a classification proposal, we would like to point out that further information on test conditions is needed in order to confirm whether the first test performed on Pseudokirchneriella subcapitata (1997, OECD 201) should be taken into account for the classification. What did the	Test conditions were added in the Annex VI document. In the first test, the test solutions were clear and colourless up to 1.0 mg/l. The test solutions from 10 to 100 mg/l ranged from slightly turbid to turbid. The test substance was mainly present as an undissolved, dispersed fraction, which may lead to physical effects. In the second test, no EDTA was used.	Further information was submitted and evaluated during the process and is now included in the background document.

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		<p>rapporteur mean by “physical effects”? In this respect, further information that supports this conclusion might be relevant. It would also be necessary to know if EDTA was used in the 2nd test performed on <i>Pseudokirchneriella subcapitata</i> (2007), in such case it could explain the lack of toxicity. All this information should appear in section “7.1.1.3”. Therefore it is needed to clarify if “physical effects” are really justified in order to invalidate the classification proposal.</p> <ul style="list-style-type: none"> • If physical effects are not justified and effects observed in the 1st test (1997) are due to toxicity, as the 72h-ErC50 of 56 mg/L is based on nominal concentrations, this value seems to be higher than what may have been measured concentrations. This is due to sparingly soluble nature of the test substance. Indeed, this nominal concentration is widely above the highest water solubility observed with Mg (2.8 mg/L). As a consequence and according to the CLP Regulation, due to its potential effect on <i>Pseudokirchneriella subcapitata</i> at a concentration probably inferior of 2.8 mg/L and due to its low degradability, the substance should be classified as N; R51-53 (Aquatic Chronic 2) (instead of the previous proposal of R52-53 (Aquatic Chronic 3)). 	<p>But the solution was filtered (0.45 µm) and the filtrate was used for testing.</p> <p>This is not the case for this substance. Therefore, it is not necessary to classify the substance as suggested.</p>	<p>It was decided in RAC15 to use metals strategy to classify this substance.</p>

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		<p>• If physical effects are justified in the 1st test (1997) and if the 2nd test performed on Pseudokirchneriella subcapitata (2007) is validated after further documented information, then we uphold the proposal for de-classification of the substance.</p> <p>In addition, we have the following comments:</p> <p>Section 7.6 specifies that “the substance does not dissociate at environmental conditions”; however the scientific bases of this conclusion are unclear, as no transformation/dissolution study is available. Indeed, as such data are unavailable, there is no clear evidence that the transformation to metal ions will not occur.</p> <p>In addition, in section 1.1 the molecular formula and as a result the corresponding molecular weight range are not clear. It will be of interest to specify (cf. Table 2) the pH value of the water solubility value of “<2.8 mg/L” (based on measurement of Mg).</p>	<p>This is the case for this substance. Therefore, the removal of the classification is justified.</p> <p>We changed the sentence “The substance does not dissociate at environmental conditions” into “The substance may not dissociate at environmental conditions”.</p> <p>pH 7 has been added.</p>	<p>Noted.</p>
12/11/2010	Ireland / Health & Safety Authority	<p>Environment: We agree with the removal of the classification Aquatic Chronic 3 (H412), R52-53 (S61) based on the data submitted in the 2007 study on Algae</p>	<p>Thank you for your support.</p>	<p>It was decided in RAC15 to use metals strategy to classify this substance.</p>

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		Pseudokirchneriella subcapitata which showed no toxicity up to the solubility limit of 0.15 mg/l.		