

Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at Community level of
**aluminium-magnesium-zinc-
carbonate-hydroxide**

ECHA/RAC/DOC No CLH-O-0000001743-75-01/F

Adopted

10 June 2011

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**OPINION OF THE COMMITTEE FOR RISK ASSESSMENT
ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND
LABELLING AT COMMUNITY LEVEL**

In accordance with Article 37(4) of the Regulation (EC) No 1272/2008 (CLP Regulation), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name: *aluminium-magnesium-zinc-carbonate-hydroxide*
EC Number: *423-570-6*
CAS Number: *169314-88-9*

The proposal was submitted by *the Netherlands*
and received by RAC on *1 October 2010*

Harmonised classification originally proposed by the dossier submitter:

	Regulation (EC) No 1272/2008	Directive 67/548/EEC
Current entry in Annex VI of CLP Regulation (EC) No 1272/2008	Aquatic Chronic 3 - H412	R52/53
Proposal by dossier submitter for consideration by RAC	Not classified.	Not classified.
Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter	No entry.	No entry.

PROCESS FOR ADOPTION OF THE OPINION

The Netherlands has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at http://echa.europa.eu/consultations/harmonised_cl/harmon_cl_prev_cons_en.asp on **1 October 2010**. Parties concerned and MSCAs were invited to submit comments and contributions by **15 November 2010**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Riitta Leinonen***

Co-rapporteur, appointed by RAC: ***Helena Polakovicova***

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37(4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on **10 June 2011**, in accordance with Article 37(4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

The RAC Opinion was adopted by consensus.

OPINION OF RAC

The RAC adopted the opinion that aluminium-magnesium-zinc-carbonate-hydroxide should be classified and labelled as follows:

Classification & Labelling in accordance with the CLP Regulation:

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
030-012-00-1	aluminium-magnesium-zinc-carbonate-hydroxide	423-570-6	169314-88-9	Aquatic Chronic 4	H413		H413			

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
030-012-00-1	aluminium-magnesium-zinc-carbonate-hydroxide	423-570-6	169314-88-9	R53	R: 53 S: 61		

SCIENTIFIC GROUNDS FOR THE OPINION

The opinion relates only to those hazard classes that have been reviewed in the proposal for harmonised classification and labelling, as submitted by the Netherlands.

The substance is an inorganic substance containing metals. It is very similar to hydrotalcite, aluminum-magnesium-hydroxide-carbonate hydrate. There is no information on dissociation of metal ions in aquatic environment at environmentally relevant pH range.

In the dossier submitter's proposal the toxicity of the substance is determined by testing the substance in aquatic ecotoxicity tests. The lowest value to base the classification on is the 72h- ErC_{50} 56 mg/l for the algae *Pseudokirchneriella subcapitata*, based on nominal concentrations. As the observed effects could have been caused by reduced light conditions, a second study with the same species was performed. It was concluded in this study that the observed inhibition following direct exposure is due to toxicity or physical effects, but not due to interception of wavelengths required for normal cell growth. In the following additional study the test substance solution was prepared at a loading rate of 100 mg/l applying a 15 minute treatment period with ultrasonic waves followed by 3 days of magnetic stirring. The resulting mixture was filtered (0.45 μ m) and the filtrate was used for testing. In practice, the dissolved fraction of the substance in water is defined as the fraction that passes a 0.45 μ m filter. Ultra-sonication or filtration was not used in the first test. In addition, three lower test concentrations were prepared by subsequent dilutions of the filtrate in test medium. All final test solutions were clear and colourless. No toxicity was observed up to the solubility limit of 0.15 mg/l (based on aluminium) and 0.12 mg/l based on zinc (nominal 100 mg/l), as determined in this study. Therefore, the EC_{50} for algal growth rate reduction is concluded to be above the water solubility limit.

There is no evidence that the substance would be rapidly lost from the environment or would rapidly partition from the water column. There is no information on bioaccumulation.

The substance is an inorganic metal substance. Consequently the classification should be based on the metals strategy presented in the Guidance on the Application of the CLP criteria. Following the guidance consideration should be given to the level of the metal ion which may be present in solution following the addition of the metal compound. In case of this particular substance there are three metals to consider. The guidance does not give advice how to treat multi-metal compounds but it was decided to follow the guidance for each metal ion separately. The lowest acute toxicity value for zinc ion is EC_{50} for *Daphnia* of 0.07 mg/l as defined in the EU Risk Assessment Report on zinc metal (2010). The lowest acute toxicity value for aluminium³⁺ ion is 96h- LC_{50} of 0.095 mg/l for fish as referred in the EU Risk Assessment Report on AIF (2008)). Aluminium ion is not, however, classified for aquatic effects because of the evidence showing rapid removal from the water column. The acute toxicity values for magnesium ion are greater than 100 mg/l according to several databases. Based on this information the classification is based on zinc ion.

According to the metals strategy defined in the Guidance on the Application of the CLP criteria (2009) where the compound is sufficiently poorly soluble that the levels dissolved following normal attempts at solubilisation do not exceed the available $L(E)C_{50s}$, it is the rate and extent of transformation, which must be considered. In this case there are water solubility data in two studies showing that based on measurements of Zn the water solubility values are

< 0.08 mg/l and < 0.01 mg/l. Comparing to the EC₅₀ value for *Daphnia* of 0.07 mg/l the substance is_ noting that the values are very close to each other but based on the overall evidence_ treated as poorly soluble metal compound which means that more information on the rate and extent of transformation and dissolution is needed in order to conclude on the water solubility of the substance.

According to the metals strategy, where the L(E)C₅₀ for the metal ions of concern is less than or equal to 100 mg/l consideration must be given to the data available on the rate and extent to which these ions can be generated from the metal. Such data, to be valid and useable should have been generated using the Transformation/Dissolution Protocol. Where such data are unavailable, like in the case of this substance, the “safety net” classification should be applied if there is no evidence of both rapid partitioning from the water column and absence of bioaccumulation. In the case of this substance there is no evidence that the substance would be rapidly lost from the environment or would rapidly partition from the water column. In addition there is no information on bioaccumulation. The reason for the “safety net” is that the known classifiable toxicity of these soluble forms is considered to produce sufficient concern.

Conclusion of environmental classification according to Regulation (EC) No 1272/2008 (CLP Regulation)

The safety net classification is Aquatic Chronic Category 4, H413: May cause long lasting harmful effects to aquatic life.

Conclusion of environmental classification according to Directive 67/548/EEC

The “safety net” classification is R53: May cause long-term adverse effects in the aquatic environment.

Conclusion of environmental classification according to Regulation (EC) No 1272/2008 (CLP Regulation), 2nd ATP

The new criteria in the 2nd ATP takes into account the chronic ecotoxicity values when available. Consequently, the Guidance on the Application of the CLP Criteria is being updated. According to the guidance update that is available at the ECHA website (4.2b Further development of the RIP 3.6 guidance – Environmental hazards) at the stage of PEG consultation, the Al-Mg-Zn-carbonate-hydroxide should be classified following the metals strategy. There is no guidance for multi-metal substances in the new guidance.

Metal compounds whose water solubility estimated e.g. from the solubility product is greater or equal to the acute ecotoxicity reference value (ERV) of the dissolved metal ion concentration are considered readily soluble. As described before classification is based on the zinc ion and to the comparison of its water solubility data to the lowest acute ecotoxicity value (acute ecotoxicity reference value, ERV). There are two studies showing that based on measurements of Zn the water solubility values for the metal compound are < 0.08 mg/l and < 0.01 mg/l. Compared to the EC₅₀ value for *Daphnia* of 0.07 mg/l the substance is seen, based on the overall evidence, as poorly soluble metal compound which means that more information on the rate and extent of transformation and dissolution is needed in order to conclude on the water solubility of the substance.

Acute hazard:

According to the revised draft guidance, it is not possible to classify a poorly soluble metal compound for acute aquatic hazard without data generated using the Transformation/Dissolution test.

Long-term hazard:

When classifying a poorly soluble metal compound for long-term hazard a chronic ecotoxicity reference value (ERV) is used if available. For Al-Mg-Zn-carbonate-hydroxide it is calculated for zinc which is the most toxic of the three ions. It is stated in the EU Risk Assessment Report on Zinc metal that the "species mean" NOEC values for zinc ion, based on studies that were used for PNEC derivation (freshwater PNECadd, aquatic), range from 17 to 660 µg/l. Using the lowest value 0.017 mg/l for calculating a tentative ERV for the compound would be 0.15 mg/l (chronic ERV of the metal ion x (molecular weight of the metal compound/atomic weight of the metal = hydrate: (594.417/65.409) x 0.017 = 0.154; anhydrous: (456.384/65.409) x 0.017 = 0.119). The molecular formula used for calculation of the hydrate is $Mg_3ZnAl_2(OH)_{12}(CO_3)_3H_2O$.

According to the revised draft guidance, where the chronic ERV_{compound} is less than or equal to 1 mg/l consideration must be given to the data available on the rate and extent to which these ions can be generated from the metal compound. Such rate and extend data, to be valid and useable should have been generated using the Transformation/Dissolution Protocol for a 28d period. Where 28d T/Dp data are unavailable, the surrogate approach should be applied.

According to the surrogate system, where the acute ERV_{compound} is less than or equal to 100 mg/l consideration must be given to the data available on the rate and extent to which these ions can be generated from the metal. Such rate and extend data, to be valid and useable should have been generated using the Transformation/Dissolution Protocol for a 7d period. Where such 7d T/Dp data are unavailable, i.e. there is no clear data of sufficient validity to show that the transformation to metal ions will not occur; the "safety net" classification (Category Chronic 4) is applied.

Consequently, the chronic ERV being less than or equal to 1 mg/l and in the absence of Transformation/Dissolution data, Al-Mg-Zn-carbonate-hydroxide as well as the hydrate should be classified with the "safety net" classification: Aquatic Chronic Category 4, H413: May cause long lasting harmful effects to aquatic life.

Additional information

The Background Document, attached as Annex 1, gives the detailed scientific grounds for the Opinion.

ANNEXES:

- Annex 1 Background Document (BD)¹
- Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and rapporteurs' comments (excl. confidential information)

¹ The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter. The original CLH report may need to be changed as a result of the comments and contributions received during the public consultation(s) and the comments by and discussions in the Committees.