



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

Annex 1  
**Background document**  
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/A1

**aluminium-magnesium-zinc-  
carbonate-hydroxide**

**EC number: 423-570-6**

**CAS number: 169314-88-9**

**Adopted**

**10 June 2011**

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## **PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING**

**Substance Name:** aluminium-magnesium-zinc-carbonate-hydroxide

**EC Number:** 423-570-6

**CAS number:** 169314-88-9

Registration numbers (under 67/548/EC): 96-03-0339 and 99-03-0439

Registration numbers (under REACH): 01-0000017006-79-0001 and 01-0000017006-79-0002

Remark:

The entry in Annex VI to the CLP is included based on information from the new substance notifications 96-03-0339 and 99-03-0439. These notifications indicate ambiguously “(hydrate)” in the substance name. As a result the EC number includes both anhydrous and hydrated forms of the substance as specified in last paragraph of point 1.1.1.5 of Annex VI to the CLP Regulation "Entries in Part 3 for salts (under any denomination) cover both anhydrous and hydrous forms, unless specified otherwise". The CAS number included is for anhydrous form only. Studies relevant for classification, namely studies related to water solubility and ecotoxicological effects, are all performed on the hydrated form.

### **Proposed classification based on Regulation EC 1272/2008 criteria:**

Environment:

Aquatic Chronic Category 4, H413: May cause long lasting harmful effects to aquatic life.

### **Proposed classification based on Directive 67/438/EEC criteria:**

Environment:

R53: May cause long-term adverse effects in the aquatic environment.

### **Proposed labelling:**

Regulation (EC) No 1272/2008:

H413

Directive 67/548/EEC

R: 53

S: 61

**Proposed specific concentration limits (if any):** not applicable

**Proposed notes (if any):** not applicable

## JUSTIFICATION

### 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

#### 1.1 Name and other identifiers of the substance

<b>EC number:</b>	423-570-6
<b>EC name (trade name):</b>	P-93; aluminium-magnesium-zinc-carbonate-hydroxide; Sorbacid ® 944
<b>CAS number (EC inventory):</b>	-
<b>CAS number:</b>	169314-88-9
<b>CAS name:</b>	Aluminium magnesium zinc carbonate hydroxide
<b>IUPAC name:</b>	Aluminium-magnesium-zinc-carbonate-hydroxide
<b>Annex VI index number</b>	030-012-00-1
<b>Molecular formula:</b>	$[Al_x Mg_y Zn_z (OH)_{2(x+y+z)} (CO_3)_{0.5x} \cdot (0.5x+y+z)]_n^*$
<b>Molecular weight range:</b>	745 – 1297 (with n=1)

\*Note: Additional information on the empirical formula:  $y + z = 1$ ;  $y < 1$ ;  $z < 1$ ;  $0 < x < 0.5$ ;  $m = 1 - 1.5x$ . The molecular weight is less than 99.68 and 99.68 is calculated with optimal values of the above indexes of x, y, z and n. Normally, the substance  $Mg_3ZnAl_2(OH)_{12}(CO_3)3H_2O$  (MW 594.417) will be used.

#### 1.2 Composition of the substance

Composition of the hydrate:

Constituent	Typical concentration	Concentration range	Remarks
Aluminium-magnesium-zinc-carbonate-hydroxide EC no.: 423-570-6	99.7% (w/w)	99.5 – 99.9% (w/w)	

Impurities	Typical concentration	Concentration range	Remarks
Water EC no.: 231-791-2	0.3% (w/w)	0.1 – 0.5% (w/w)	

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### 1.3 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	IUCLID section	Value	Remarks
Physical state at 20°C and 101.3 kPa		Solid white powder	
Melting/freezing point	4.2	No melting point. Decomposition at >150°C.	Data from Alcamizer 5 (EC 422-150-1).
Boiling point	4.3	No boiling point.	Study not performed.
Relative density	4.4	2.42 at 20°C	
Vapour pressure	4.6	0.7 Pa at 20°C	Data from Alcamizer 5 (EC 422-150-1).
Surface tension	4.10	74.4 mN/m (90% saturated solution)	Data from Alcamizer 5 (EC 422-150-1).
Water solubility	4.8  4.23	< 2.8 mg/l at 19.5 ± 1°C and pH 6  < 0.1 mg/l at 20°C and pH 7.5-7.7  >1 g/l at 37°C and pH 1-2	Based on measurements of Mg (2.8 mg/l), Zn (<0.08 mg/l) and Al (0.13 mg/l) by AAS <sup>(1)</sup> (EC 92/69 A.6 Column elution method) Based on measurements of Al (<0.1 mg/l) and Zn (<0.01 mg/l) by ICP-MS <sup>(2)</sup> (EC 92/69 A.6 Column elution method)  Based on measurements of Al (ca. 1.0 g/L at a nominal concentration of 1 g/L) and Zn (ca. 1.0 g/L at nominal concentrations of 1 and 50 g/L) by ICP-MS <sup>(2)</sup> (OECD 105 (1995) Flask method)
Partition coefficient n-octanol/water (log value)	4.7	Could not be determined	Not relevant for inorganic substances
Flash point	4.11	-	Not applicable for solids.
Flammability	4.13	Not flammable	Data from Alcamizer 5 (EC 422-150-1).
Explosive properties	4.14	Not explosive	Based on statement.
Self-ignition temperature	4.12	No self-ignition up to 400°C	Data from Alcamizer 5 (EC 422-150-1).
Oxidising properties	4.15	Not oxidising	Based on statement.
Granulometry	4.5	96% < 2µm; 4% 2-5 µm	Mass median diameter 0.8 µm

<sup>(1)</sup> NOTOX Project No. 173846 (Determination of the water solubility of P 93: 23 April 1997). After removing undissolved test substance by centrifugation, the supernatants were analysed for Al, Zn and Mg by atomic absorption spectrometry (AAS). Concentration determined as total metal content (Mg, Zn, Al).

<sup>(2)</sup> NOTOX Project No. 447277 (Determination of the water solubility of Alcamizer P93 at neutral pH (20°C) and at pH 1-2 (37°C): 12 December 2005). Molecular formula of Alcamizer P93 is Mg<sub>3</sub>ZnAl<sub>2</sub>(OH)<sub>12</sub>CO<sub>3</sub>·3H<sub>2</sub>O.

Analytical method: Inductively coupled plasma mass spectrometry (ICP-MS) , Analyte: – <sup>64</sup>Zn, <sup>66</sup>Zn, <sup>27</sup>Al.

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- a) The solubility of the test substance in double distilled water was determined to be <0.1 mg/l (Al, Zn) by (ICP-MS). The pH was measured to be 7.5-7.7.
- b) The solubility of the test substance in HCL/KCL buffer solution pH 1.3 at 39°C was determined to be 0.99g/l based on analysis of zinc and <0.04 g/l when based on the analysis of aluminium. The pH increased to 5.1 which probably caused precipitation of aluminium. When the test substance was dissolved/dissociated in HCL/KCL buffer solution pH 1.3 at 37°C at a concentration below the saturation concentration (i.e. 1.0g/l), the pH remained stable at 1.6 and zinc and aluminium remained in the solution. Based on these results, the exact solubility of Alcamizer P93 at PH1-2 could not be determined, but is >1g/l.

Based on the submitted data it is not clear whether the identical substances were tested in these two studies. In both cases, the tested substance was hydrate, but the molecular formula is only given in the second study. The water solubility of the substance is pH dependent and increases in acid medium. The differences in the measured water solubility values may be also influenced by the way of the test sample preparation, which is not specified in the second study.



## 2 MANUFACTURE AND USES

### 2.1 Manufacture

Brief description of the production process:

Chemical production:

- Stoichiometric reaction of  $MgCl_2 + Na_2Al_2O_4 + ZnCl_2 + NaOH + NaCO_3 + H_2O$

(- analysis)

- washing with water

(- analysis)

Production of the preparation (mixture):

- surface coating with stearic acid

- drying

(-analysis)

- packing

### 2.2 Identified uses

Table 1: Description of identified uses

Identified use	Sector of Use (SoU)	Preparation Category (PC)	Process category (PROC)	Article category (AC)
New chemical substance - Use category code: 011; Desired effects code: 049; Desired effects non-coded: STABILISERS	Detailed information on envisaged uses: ALUMINIUM-MAGNESIUM-ZINC-CARBONATE-HYDROXIDE-(HYDRATE) is used as a stabilizer in the polymer industry.		other (NACE code to be used only): POLYMERS INDUSTRY	
Use of Substance by Industry in closed systems: 95 % Use of Substance by Industry in open systems: 5 %				

Process(es) related to the use- Substance: The substance is single or after mixing (in closed reaction/mixing systems) with other additives/stabilizers charged into the closed reaction system for the preparation of plastics or plastic articles.

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Process(es) related to the use- Preparation: The preparation is single or after mixing (in closed reaction/mixing systems) with other additives/stabilizers charged into the closed reaction system for the preparation of plastics or plastic articles.

The substance is used in the polymer industry as a stabilizer for plastics. In compounding, the substance is mixed with other products to make a stabilizer package which contains 25% of the substance. The stabilizer package is added to a polymer (mainly PVC) which contains 1-6% of the substance in the end product. In end products (mostly moulded plastics) the substance will be bound, so exposure in that stage is not considered possible anymore.

### 2.3 Uses advised against

Not applicable.

## 3 CLASSIFICATION AND LABELLING

### 3.1 Classification in Annex VI of EC 1272/2008

Annex VI Index number: 030-012-00-1

Current classification: According to criteria EC 1272/2008

#### Classification

Phys/Chem hazards: -

Health hazards: -

Environment:

Aquatic Chronic 3    H412

#### Labelling

Signal Word: -

Symbol: -

Hazard statements codes: H412

M-factor: - not applicable.

Current classification: According to criteria 67/548/EEC

#### Classification

- for physical - chemical properties: not classified
- for health effects: not classified

- for the environment: R52-53 (Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment)

Labelling

Indication of danger: not applicable

R-phrases: R52/53

S-phrases: S61

Specific concentration limits: not applicable

**3.2 Self classification(s) and labelling**

The registrant proposes not to classify and label the substance.

## **4 ENVIRONMENTAL FATE PROPERTIES**

### **4.1 Degradation**

#### **4.1.1 Abiotic degradation**

##### **4.1.1.1 Hydrolysis**

Due to the low water solubility, the study could not be performed.

##### **4.1.1.2 Phototransformation/photolysis**

#### **4.1.2 Biodegradation**

##### **4.1.2.1 Biodegradation in water**

###### **4.1.2.1.1 Estimated data**

No data available

###### **4.1.2.1.2 Screening tests**

As the substance is an inorganic substance, a ready biodegradability study was not performed.

###### **4.1.2.1.3 Simulation tests**

No data available.

##### **4.1.2.2 Biodegradation in sediments**

No data available.

##### **4.1.2.3 Biodegradation in soil**

No data available.

##### **4.1.2.4 Summary and discussion on biodegradation**

The substance will not be biodegradable, as it is an inorganic substance.

#### **4.1.3 Summary and discussion on degradation**

There is no information on degradation. As an inorganic metal compound the substance is by default not degradable. There is no information on the rapid removal of the substance from the environment.

#### **4.1.4 Environmental distribution**

No data available.

#### **4.1.5 Adsorption/desorption**

The log K<sub>oc</sub> of the substance could not be determined or estimated.

#### **4.1.6 Volatilisation**

No data available.

#### **4.1.7 Distribution modelling**

No data available.

### **4.2 Bioaccumulation**

#### **4.2.1 Aquatic bioaccumulation**

No data available.

#### **4.2.2 Terrestrial bioaccumulation**

No data available.

#### **4.2.3 Summary and discussion of bioaccumulation**

**There is no information on bioaccumulation**

### **4.3 Secondary poisoning**

No data available.

## 5 HUMAN HEALTH HAZARD ASSESSMENT

## 6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

## 7 ENVIRONMENTAL HAZARD ASSESSMENT

### 7.1 Aquatic compartment (including sediment)

#### 7.1.1 Toxicity data

The substance used in all aquatic tests was aluminium-magnesium-zinc-carbonate-hydroxide-hydrate with ca. 99.7 % purity (0.3 % water) except in the algae study from 2007 where the purity was not known and thus the substance was treated as 100 % pure.

The results and key issues of the aquatic toxicity tests are presented in the Table below. More detailed information is available in the following paragraphs.

Species	Substance in water	Result	Analytical monitoring	Specific issues	Test guideline and test year
Cyprinus carpio, static test, fresh water	film on the water surface removed; ultra-sonication and magnetic stirring; test substance present as an undissolved, dispersed fraction but homogeneous	96h-LC50 > 100 mg (nominal), no adverse effects	Free aluminium analysed; none detected (no detection limit given), results based on nominal		OECD 203, GLP, Klimisch 1 1997
Cyprinodon variegatus, static test, salt water	magnetic stirring, test substance present as an undissolved, dispersed fraction but homogeneous	96h-LC50 > 100 mg (nominal), no adverse effects	No analytical confirmation		OECD 203, GLP, similar to OECD 203, Klimisch 1 1997

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Species	Substance in water	Result	Analytical monitoring	Specific issues	Test guideline and test year
Daphnia magna	test substance present as an undissolved, dispersed fraction but homogeneous	48h- EC50 > 100 mg/l (nominal), no adverse effects	Loading based on Cyprinus carpio test		OECD 202, GLP, Klimisch 1 1997
Acartia tonsa, marine copepod		48h -EC50 > 100 mg/l (nominal), no adverse effects	No		ISO/DIS 14669, GLP, Klimisch 1 1997
Pseudokirchneriella subcapitata	film on the water surface removed; magnetic stirring; test substance present as an undissolved, dispersed fraction	72h- ErC50 56 mg/l (nominal); NOECr 10.7 mg/l	Free aluminium analysed; none detected (no detection limit given), results based on nominal	Effects caused by reduced light conditions?	OECD 201, GLP, Klimisch 1 1997
Pseudokirchneriella subcapitata	Substance on petri-dishes, algal suspensions were exposed to light only via the petri-dishes with test solution	48h-ErL50 > 100 mg/l, NOELr = 100 mg/l (nominal)	No	Identity of the substance unknown	Essential parts based on EEC C-3, OECD 201, ISO 8692) Klimisch 1, GLP 1997
Pseudokirchneriella subcapitata	film on the water surface removed; ultra-sonication and magnetic stirring; filtration, filtrate used for testing, test solution clear and colourless; no aluminium caps used	48h-ErC50 > water solubility (100 mg/l nominal, 0.15 mg/l as aluminium and 0.12 mg/l as zinc); NOECr = water solubility; concentration are measured total metal content (ICP-MS)	Yes	Filtrate, key study for the proposal	OECD/EU/ISO, OECD Guidance on difficult to test substances, GLP 2007
Skeletonema costatum	Stirring, undissolved test substance particles, homogenous, milky dispersion	48h-ErC50 > 180 mg/l NOECr = 180 mg/l	No		ISO 10253, GLP, Klimisch 1 1997

### **7.1.1.1 Fish**

#### **7.1.1.1.1 Short-term toxicity to fish**

A static acute toxicity study in carp *Cyprinus carpio* (1997, GLP, OECD 203, Klimisch 1) was performed. The standard test procedures required generation of test solutions, which contained completely dissolved test substance concentrations or stable and homogenous mixtures or dispersions. The testing of concentrations that would disturb the test system was prevented as much as possible (e.g. film of the substance on the water surface). Ultra sonication and magnetic stirring were used to accelerate the suspension of the test substance at a concentration of 100 mg/l. In the range-finding test, subsequent dilutions were prepared to obtain the lower concentrations required. Test solutions were clear and colourless up to 1.0 mg/l. Test solutions of 10 and 100 mg/l were turbid but remained homogeneous throughout the test. No adverse effects were shown up to a nominal concentration of 100 mg/l and the study resulted in a 96h-LC50 which is above the water solubility limit (LC50 > 2.8 mg/l). Samples were taken during the range-finding test and analysed for free aluminium. No free aluminium was detected in any of these samples. Information on the limit of detection or limit of determination of the analytical method for free aluminium is not given. Hence, for the final limit test it was decided to make reference to the weighted amount of test substance used for the preparation of the test solution. In the final limit test, the test substance was mainly present as an undissolved, dispersed fraction at the maximum concentration of 100 mg/l.

A static acute toxicity study in the marine fish Sheepshead minnow *Cyprinodon variegatus* (1997, GLP, similar to OECD 203, Klimisch 1), showed no adverse effects up to a nominal concentration of 100 mg/l and resulted in a 96h-LC50 which is above the water solubility limit. Data on fresh water fish showed that the substance induced no visible effects in carp at a concentration of 100 mg/l during a 96-h test period. Therefore, a limit test was performed with 100 mg/l. The standard test procedure required generation of test solutions, which contain completely dissolved test substance concentrations or stable and homogenous mixtures or dispersions. The substance is a slightly water soluble substance. A stock solution was prepared at 1000 mg/l in 500 ml of Milli-Q water applying magnetic stirring for one hour to accelerate the dispersing of the test substance (507.1 mg in 500 ml). Then, the stock was quantitatively transferred to a 5 litres measuring flask and filled up with synthetic seawater to provide the final test concentration of 100 mg/l. The test solution was left stirring for another 5 minutes. The final test solution was a homogeneous white dispersion and the test substance was mainly present as an undissolved, dispersed fraction. No analytical confirmation of the test substance concentration was performed.

#### **7.1.1.1.2 Long-term toxicity to fish**

No data available.

### **7.1.1.2 Aquatic invertebrates**

#### **7.1.1.2.1 Short-term toxicity to aquatic invertebrates**

An acute study in *Daphnia magna* (1997, GLP, OECD 202, Klimisch 1) showed no adverse effects at a nominal concentration of 100 mg/l and resulted in a 48h-EC50 which is above the water solubility limit (EC50 > 2.8 mg/l). In the final limit test, the test substance was mainly present as an



undissolved, dispersed fraction at the maximum concentration of 100 mg/l. The test solution remained homogeneous during the test period. Based on the analysis performed on samples taken from the *Cyprinus carpio* toxicity test, it was shown that the actual test concentration could not be determined by analysis of free aluminium. The test solution used in the final test originated from solutions prepared for the acute fish toxicity test in Carp *Cyprinus carpio*.

An acute study in the marine copepod *Acartia tonsa* (1997, GLP, ISO/DIS 14669, Klimisch 1), showed no adverse effects at a nominal concentration of 100 mg/l and resulted in a 48h-EC50 which is above 100 mg/l.

#### 7.1.1.2.2 Long-term toxicity to aquatic invertebrates

No data available.

#### 7.1.1.3 Algae and aquatic plants

A freshwater algal growth inhibition test (1997, GLP, OECD 201, Klimisch 1) with *Pseudokirchnerella subcapitata*, showed cell growth inhibition and reduced growth rate at nominal concentrations of 18 mg/l and higher. The standard test procedure required generation of test solutions, which contain completely dissolved test substance concentrations or stable and homogenous mixtures or dispersions. The testing of concentrations that would disturb the test system was prevented (e.g. film of the substance on the water surface). The test solutions were prepared using a stock solution of 100 mg/l in ISO-medium. The stock solution was magnetically stirred for 3 hours before it was used to prepare of the lower test concentrations. The stock was a homogeneous, white and turbid suspension. Volumes of 50 ml of the various test solution were added to the respective replicates. Subsequently, a volume of  $\leq 1$  ml of an algal suspension was added to provide the required cell density in each replicate. At the start of the 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. The pH in the test medium ranged from 8.3 to 8.6. Samples were taken during the test and analysed for free aluminium. However, the solubility of the substance could not be detected as it is below the limit of determination. Information on the limit of detection or limit of determination of the analytical method for free aluminium is not given. For the final test it was decided to make reference to the weighted amount of test substance used for the preparation of test solution instead of analytical confirmation. The EC50 for growth rate reduction (72h-ErC50) was 56 mg/l, based on nominal concentrations. The NOEC was 10.7 mg/l. As test solutions were increasingly turbid it is possible that the solutions absorbed light increasingly, which may have contributed to the inhibitive effect on algal growth. Consequently, the issue was considered further.

A study was performed to assess the effect of the coloured solution of the test substance on the growth of the fresh water algae *Pseudokirchnerella subcapitata*. The study was performed as described with essential parts based on the following guidelines: EEC C-3 (1992), OECD 201 (1984), ISO 8692 (1989). The identity of the tested chemical is unclear. The test was performed with two replicates for each test concentration and two or three for the controls. Each replicate consisted of three petri-dishes. Two petri-dishes were filled with the respective test solution without algae present. The petri-dish with algal suspension was placed between the two petri-dishes containing the test solution. These three petri-dishes were placed in the incubator in such a way that the algal suspensions were exposed to the light only via the petri-dishes with test solution. Three replicates were exposed to light using untreated test medium (negative control), while two replicates

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were exposed via petri-dishes that were completely darkened (positive control). The 48h-EL50 was > 100 mg/l and NOELR 100 mg/l as nominal concentration. Thus, it was concluded in the study summary that the effects observed in the algal growth study prescribed in the chapter above were caused by toxic effects of the test substance rather than interception of the wavelengths required for normal cell growth. The study met the acceptability criteria prescribed by the protocol and was considered valid. However, due to the very low solubility of the test substance in water, concentration levels that might be toxic for algae could not be reached. Therefore an additional test was performed.

In an additional study with the same species of freshwater algae *Pseudokirchneriella subcapitata* (2007, GLP, OECD 201, EU C.3, ISO 8692, according to the OECD guidance document on aquatic toxicity testing of difficult to test substances, Klimisch 1) duration of the test was 48 hours and in addition to removing the film from the surface and magnetic stirring used in the 1997 test, ultrasonication and filtration was used. The standard test procedures required generation of test solutions, which contained completely dissolved test substance concentrations or stable and homogenous mixtures or dispersions. The testing of concentrations that would disturb the test system was prevented as much as possible (e.g. film of the substance on the water surface). The batch of the substance tested was a white powder and treated as 100 % pure. The substance was not completely soluble in test medium at a loading rate of 100 mg/l. Preparation of test solutions started with a loading rate of 100 mg/l applying a 15-minute treatment period with ultrasonic waves followed by 3 days of magnetic stirring to obtain maximum solubility of the test substance in test medium. The resulting mixture was filtered through a membrane filter (0.45 µm) and the filtrate was used for testing. In addition, three lower test concentrations were prepared by subsequent dilutions of the filtrate in test medium. The final test solutions were all clear and colourless. The control medium received the same treatment. After preparation, volumes of 50 ml were added to each replicate of the respective test concentration. Subsequently, 1 ml of an algal suspension was added to each replicate providing cell density of 10<sup>4</sup> cells/ml. Normally, test vessels are closed with perforated aluminium caps. For this specific study, test vessels were closed with a wad of cotton because the test substance contains aluminium and the analytical method was based on measured aluminium. For reference an extra control group was included in which the test vessels were closed in the standard way.

The temperature of the test medium was 21.8°C at the start of the test. During the exposure period the temperature measured in the incubator was generally maintained between 22,4 and 24°C, except for a relatively short period of two hours during which temperature increased to a maximum of 24,5°C. The pH in the test medium ranged from 7.7 to 8.0. The test samples were analysed with ICP-MS. The measured initial test substance concentrations in the undiluted filtrate were 0.24 mg/l based on the aluminium and 0.12 mg/l based on the zinc. Concentration based on the aluminium decreases during the 48-hour exposure period to 50% of initial, concentration based on the zinc appeared to remain stable, although the concentration measured after 24 hours of exposure was higher (0,19mg/l) than at the start and the end of the test. No explanation was given. The effect parameters were based on the loading rate, the average test substance exposure concentration based on the aluminium and the initial test substance concentration based on zinc. The concentrations are determined as total metal content. 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 48h-ErC50 for algal growth rate reduction is concluded to be above the water solubility limit.

A marine algal growth inhibition test (1997, GLP, ISO 10253, Klimisch 1) with *Skeletonema costatum*, showed no effects up to a nominal concentration of 180 mg/l and resulted in a 48h-EC50 > 180 mg/l. The substance did not significantly inhibit cell growth or reduce growth rate of

*Skeletonema costatum* at nominal concentrations and up to and including 180 mg/l. Effects on algal growth were not clearly test concentration related and were probably caused by the presence of undissolved test substance particles. Hence, the EC values all exceeded the solubility limits of the substance-components in water. Further, as effects were most prominent after 48-hours and non-affected algal suspensions had already reached an optimum growth within 48 hours, the EC50 values were based on the 0 - 48h interval. The EC50-48h for cell growth inhibition corresponded with a prepared concentration of 530 mg/l. The EC50 for growth reduction exceeded the range tested. The EC 0-48h for cell growth inhibition corresponded with the prepared concentration of 150 mg/l. The standard test procedure required generation of test solutions which contain completely dissolved test substance concentrations or stable and homogenous mixtures or dispersions. The substance is a slightly water soluble substance. However, homogeneous and milky dispersions could be reached in water at concentrations up to 10 000 mg/l. The protocol prescribed to test concentrations of 5.6 to 100 mg/l. However, due to an error in the procedure of preparation of the test concentrations, these were all a factor of 10 higher. The biological results were such that repetition of testing at the intended concentrations was not necessary. Preparation started with a 100 ml stock solution of 10 000 mg/l in Lilli-Q water. The stock solution was stirred until a homogenous, milky dispersion was reached. This stock solution was diluted by adding 900 ml of synthetic seawater providing a nominal concentration of 1000 mg/l. This solution was a turbid, still milky, dispersion, and it was used to prepare the other test concentrations in synthetic seawater. The final volume of Milli-Q water in the salt water did not exceed 10.5 (v/v). Then volumes of 50 ml of each solution were added to each replicate of the respective test concentration. Subsequently, a volume of 0.077 ml of an algal suspension was added to each replicate providing a cell density of  $2 \times 10^3$  cells/ml.

#### **7.1.1.4 Sediment organisms**

No data available.

#### **7.1.1.5 Other aquatic organisms**

A study with the marine bioluminescent bacterium *Vibrio fischeri* (1997, non GLP, NEN/ISO 11348, Klimisch 2) showed no significant inhibition on the light emission up to a nominal concentration of 5 mg/l.

#### **7.1.2 Calculation of Predicted No Effect Concentration (PNEC)**

For the purpose of this dossier, no PNEC values are derived.

#### **7.2 Terrestrial compartment**

No data available.

#### **7.3 Atmospheric compartment**

No data available.

## **7.4 Microbiological activity in sewage treatment systems**

### **7.4.1 Toxicity to aquatic micro-organisms**

In an activated sludge respiration-inhibition test (1996, GLP, OECD 209, Klimisch 1) a stock solution of 0.5 g/l was prepared in Milli-Q water. 100 mg of the test substance, corresponding to 100 ml of the prepared stock solution in 500 ml final volume, was tested in duplicate. No significant inhibition in respiration rate of the sludge was observed at a nominal concentration of 100 mg/l. Consequently the nominal 0.5h-IC50 of > 100 mg/l.

### **7.4.2 PNEC for sewage treatment plant**

For the purpose of this dossier, no PNEC values are derived.

## **7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)**

For the purpose of this dossier, not relevant.

## **7.6 Conclusion on the environmental classification and labelling**

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-ErC50 56 mg/l for the algae *Pseudokirchnerella 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 µm) 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 µm 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 EC50 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 EC50 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 aluminium 3+ ion is 96h-LC50 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 that shows 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)C50s, 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 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

## ANNEX 1 – BACKGROUND DOCUMENT TO RAC OPINION ON ALUMINIUM-MAGNESIUM-ZINC-CARBONATE-HYDROXIDE

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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 either.

Metal compounds whose water solubility estimated e.g. from the solubility product is greater or equal to the acute 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 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 PNEC<sub>add</sub>, 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<sub>3</sub>ZnAl<sub>2</sub>(OH)<sub>12</sub>(CO<sub>3</sub>)<sub>3</sub>H<sub>2</sub>O.

According to the revised draft guidance, where the chronic ERV<sub>compound</sub> 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<sub>compound</sub> 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 8 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.

## **JUSTIFICATION THAT ACTION IS REQUIRED ON A COMMUNITY-WIDE BASIS**

The substance P-93 is manufactured/imported at a level of >1000 tonnes per annum. Based on the information submitted under the notification system for new chemicals (67/548/EEC), the Dutch competent authorities proposed in September 2007 not to classify the substance.

The Technical Committee responsible for environmental classification and labeling did not meet after January 2007. As a consequence, the classification and labelling of P-93 has not been revised, and thus P-93 is included in the 31<sup>st</sup> ATP of Council Directive 67/548/EC with the classification R52/53.

As a consequence of the entering into force of the new CLP Regulation EC 1272/2008, this classification is included in Annex VI of this regulation by the 1<sup>st</sup> ATP to the CLP Regulation.

In line with the procedures as laid down in the CLP Regulation art 37(6), this proposal for de-classification has been prepared by Kisuma Chemical B.V., Veendam, The Netherlands, in accordance with the 2<sup>nd</sup> subparagraph of art 37(2).