Annex VI report

PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Substance Name: ALUMINIUM-MAGNESIUM-ZINC-CARBONATE-HYDROXIDE

EC Number: 423-570-6

CAS Number: 169314-88-9

Submitted by: **Bureau REACH, RIVM, The Netherlands, bureau-reach@ rivm.nl**

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PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Substance Name: ALUMINIUM-MAGNESIUM-ZINC-CARBONATE-HYDROXIDE-(HYDRATE)

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

Purity: 99.5-99.9%

Impurities: 0.1-0.5% water

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. The CAS number included is for anhydrous form only,. Where tests are performed using the 'hydrate' the exposure levels/concentrations need to be corrected for the water content of the testsubstance. However in the underlying proposal evidence is provided for the fact that the effect observed in the algae study is a physical effect, and therefore no trigger for classification.

Proposed classification based on Directive 67/438/EEC criteria: not classified

Proposed classification based on Regulation EC 1272/2008 criteria: not classified

Proposed labelling: not labelled

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

EC number:	423-570-6
EC name (trade name):	P-93
CAS number (EC inventory):	-
CAS number:	169314-88-9
CAS name:	Aluminium magnesium zinc carbonate hydroxide
IUPAC name:	Aluminium-magnesium-zinc-carbonate-hydroxide
Annex VI index number	030-012-00-1
Molecular formula:	$[Al_x\ Mg_y\ Zn_z\ (OH)_{2(x+y+z)}\ (CO_3)_{0.5x}\ .\ (0.5x+y+z)]_n$*
Molecular weight range:	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 $Mg_3ZnAl_2(OH)_{12}(CO_3)3H_2O$ will be used.

1.2 Composition of the substance

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)	

1.3 Physicochemical properties

Table 2: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	Solid white powder	
Melting/freezing point	No melting point. Decomposition at >150°C.	Data from Alcamizer 5 (EC 422-150-1).
Boiling point	No boiling point.	Study not performed.
Relative density	2.42 at 20°C	
Vapour pressure	0.7 Pa at 20°C	Data from Alcamizer 5 (EC 422-150-1).
Surface tension	74.4 mN/m (90% saturated solution)	Data from Alcamizer 5 (EC 422-150-1).
Water solubility	< 2.8 mg/L at 20°C < 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) Based on measurements of Al (<0.1 mg/L) and Zn (<0.01 mg/L). 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)
Partition coefficient n-octanol/water (log value)	Could not be determined	Not relevant for inorganic substances
Flash point	-	Not applicable for solids.
Flammability	Not flammable	Data from Alcamizer 5 (EC 422-150-1).
Explosive properties	Not explosive	Based on statement.
Self-ignition temperature	No self-ignition up to 400°C	Data from Alcamizer 5 (EC 422-150-1).
Oxidising properties	Not oxidising	Based on statement.
Granulometry	96% < 2µm	

2 MANUFACTURE AND USES

2.1 Manufacture

Brief description of the production process:

Chemical production:

- Stochiometric reaction of MgCl2 + Na2Al2O4 + ZnCl2 + NaOH + NaCO3 + H2O

(- 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.

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: 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

As the substance is an inorganic substance, biodegradability is not a relevant endpoint. Furthermore, the substance has a low water solubility (<2.8 mg/L based on Mg).

4.1.4 Environmental distribution

No data available.

4.1.5 Adsorption/desorption

The log Koc 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

Not relevant for inorganic substances.

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

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

An acute toxicity study in carp (1997, GLP, 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 (LC50 > 2.8 mg/l).

An acute toxicity study in the marine fish sheepshead minnow (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 (LC50 > 2.8 mg/l).

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).

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 the water solubility limit (EC50 > 2.8 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 EC50 for growth rate reduction (72h-ErC50) was 56 mg/l, based on nominal concentrations. The NOEC was 10.7 mg/l. As the observed effects could have been caused by reduced light conditions, a second study was performed. It was concluded 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 an additional study with the same species of freshwater algae *Pseudokirchneriella subcapitata* (2007, GLP, according to the OECD guidance document on aquatic toxicity testing of low soluble compounds, Klimisch 1) no toxicity was observed up to the solubility limit of 0.15 mg/l (nominal 100 mg/l), as determined in this study. Therefore, the EC50 for algal growth rate reduction is 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 which is above the water solubility limit.

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) no significant inhibition in respiration rate of the sludge was observed at a nominal concentration of 100 mg/l and resulted in a 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 does not dissociate at environmental conditions and has a very low water solubility. No effects on freshwater and marine aquatic organisms were observed up to the water solubility limit, which ranges from <9 µg/l (water solubility study; lower limit) to 0.15 mg/l (algae test, based on Al). As the substance is an inorganic compound, it will not be biodegraded. As the substance is an inorganic compound the logPow cannot be used as an indicator of bioaccumulation. For this substance the bioaccumulation criterion for classification is not fulfilled.

The current classification (R52/53) of P-93 in Annex VI is based on results from an algae test with unfiltered solution and nominal concentrations. Additional information (two additional algae tests, second one with filtered solutions) has proven that the effect observed in the first algae test was only a physical effect.

Based on the absence of acute aquatoxic effects and as the bioaccumulation criterion is not met classification of P-93 for aquatic toxicity is not warranted.

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 31st 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 1st 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 2nd subparagraph of art 37(2).