ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004717-67-03/F Helsinki, 5 November 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For [carbonato(2-)]hexadecahydroxybis(aluminium)hexamagnesium, CAS No 11097-59-9 (EC No 234-319-3), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for [carbonato(2-)]hexadecahydroxybis(aluminium)hexamagnesium, CAS No 11097-59-9 (EC No 234-319-3), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 19 November 2013.

On 28 February 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 31 March 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name, molecular and structural formula or other identifier of the substance (Annex VI, 2.1 and 2.2): Information which is suitable and necessary to allow ECHA to establish and verify the name and the identity of the registered substance, as specified under section III.A.1 below;
2. Composition of the substance (Annex VI, 2.3): Information which is suitable and necessary to allow ECHA to establish and verify the composition and the identity of the registered substance, as specified under section III.A.2 below;
3. The description of the analytical methods (Annex VI section 2.3.7.), as specified under section III.A.3 below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **12 February 2015**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein does not comply with the requirements of Article 10 of the REACH Regulation and Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name, molecular and structural formula or other identifiers of the substance (Annex VI, 2.1 and 2.2)

ECHA notes that the Registrant has not provided sufficient information to identify the substance, as required by Annex VI, Section 2.1 and 2.2 of the REACH Regulation. Based on the information included in Section 1.1 of the dossier, it is not possible to unambiguously establish the identity of the substance registered.

More specifically, the Registrant identified the registered substance as a well-defined mono-constituent substance. The Registrant shall note that in accordance with chapter 4.1 and 4.2 of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012)) - referred to as "the Guidance" hereinafter, well-defined substances are those with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical specification, including structural information. This implies that constituents of well-defined substances must have a unique

definitive molecular and structural formula. Well-defined monoconstituent substances shall be named after their fully defined main constituent.

In Section 1.1 of the dossier, the Registrant refers to the EC (234-319-3) and CAS (11097-59-9) entries which refer to a specifc stoichiometry (EC molecular formula: $CH_{16}Al_2Mg_6O_{19}$ and CAS molecular formula: CO_3 . 2 Al H_6 O_6 . 4 HO . 6 Mg). Also the specific structural information (structural formula, SMILES notation, InChi code) and the molecular formula and weight indicated in the section 1.1 of the dossier refer to a specific substance where 6 magnesium ions are present in the molecule. Contrary to that, the reported chemical name included in the IUPAC name field refers to the unspecific name "MAGNESIUM-ALUMINIUM-HYDROXIDE-CARBONATE", which does not relate to a specific stoichiometry and thus does not allow the main constituent of the substance to be unambiguously identified.

In addition, it is noted that the substance identity information included on page 2 of the Chemical Safety Report (CSR) attached to section 13 reports different molecular and structural formulae for the registered substance to those reported in section 1.1; in the CSR the reported molecular formula ("Alx Mgy (OH)2(x+y) 0.5x(CO3), with values for x and y specified as x=2; y = 4.5 ±1.5") is not specific as the ratio of magnesium (Mg) and hydroxide content (OH) is variable (values of y from 3 to 6). The reported structural formula reported has the same variability in y. It is thus unclear to which specific mono-constituent substance the registration refers to.

In addition, the substance where y = 6 is known to have different crystal phases. However, the Registrant has not indicated what phases (e.g. rhombohedral, hexagonal, etc. and their various polytypes) are to be covered by the current registration. This information is relevant for determing the scope of the registered substance.

In line with Annex VI, sections 2.1 and 2.2 the Registrant is requested to revise the chemical name, molecular and structural formulae and other identifiers so that the registration unambigiously refers to the substance registered. The Registrant shall ensure that the information reported is consistent throughout the dossier (section 1.1 and the chemical safety report shall refer to the same substance). The Registrant shall note that the EC (234-319-3) and CAS (11097-59-9) entries are specific for the stoichiometry of $CH_{16}Al_2Mg_6O_{19}$ and cannot be used to identify substances of other stoichiometries. The Registrant shall note that for well-defined substances, the stoichiometry is required to be defined and cannot vary significantly.

ECHA notes that clay minerals such as the registered substance are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.) that meet the EU recommendation for nanomaterials[1] in terms of primary particle size and/or specific surface area.

To ensure a high level of protection of human health and the environment, the REACH Regulation imposes the determination of hazards and risk irrespective of the form of the substances concerned. This includes more specifically nanoforms of substances, which may trigger specific hazardous properties and risks, as already highlighted by various institutions, including the European Parliament.[2]

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[1] Commission Recommendation on the Definition of Nanomaterials of 20 October 2011, 2011/696/EU, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

[2] "*Whereas nanomaterials [...] potentially present significant new risks due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species*". Recital D of European Parliament Resolution of 24 April 2009 on Regulatory aspects of nanomaterials.

In fact, the current scientific knowledge establishes that the risks of nanoforms of substances are likely and significant. Indeed, the specific risks of nanoforms are not founded on mere hypotheses that have not been scientifically confirmed. These risks have actually been fully demonstrated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).[3] The fact that there is still some degree of scientific uncertainty as to the existence or extent of such risks does not, by itself, discharge registrants from characterising nanoforms in order to carry out their duties under the REACH Regulation. Based on the above, the Registrant is compelled to scientifically assess the potentially adverse effects of nanoforms.

Furthermore, it is self evident that in order to determine the hazardous properties and the appropriate risk management measures for substances in different forms, it is necessary to characterise the substance in terms of its physical form, in particular regarding nanoforms, before determining the corresponding hazards and assessing the exposure of humans and the environment and the associated risk management measures. The characterisation of nanoforms of the substance is a pre-requisite to the determination of all the hazardous properties and appropriate risk management measures concerning the registered substance. Therefore, it is essential that suitable information on nanoforms is submitted, especially in order to identify precisely whether the registered substance includes nanoform(s).

Consequently, where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier, information on these grades in terms of their respective composition, phase(s) and form(s) (including information about particle sizes) will need to be included in section 1 of the dossier. In addition, the registrant shall make sure that the respective particle sizes covered by this registration are also reported in Section 4.5 of the joint IUCLID dossier information.

Similarly, the Registrant shall note that where it intends to cover chemically surface treated grades of high specific surface area in the dossier, information on these grades in terms of their respective composition, phase(s) and form(s) (including information about particle sizes) will also need to be provided. In this respect, the Registrant shall note that the FAQ available on the ECHA website concerning the exemption from registration obligations for chemically surface treated substances[4] is not applicable to high surface area particulates, as the question tackled by this FAQ only relates to "macroscopic particles" of low specific surface area.

Regarding how to report the requested information in IUCLID the following applies:

- The revised chemical name that is representative of the stoichiometry shall be included in the IUPAC name field and the details of the grades (compositions of defined phase and form as relevant) covered by the registration shall be included in the Description field in Section 1.1 of the IUCLID, respectively. The composition of each grade shall be reported separately in section 1.2. and sufficient analytical data for the grade shall be included in section 1.4.
- The relevant molecular and structural formula and other identifiers shall be included in their respective fields in Section 1.1 of the IUCLID dossier.

[3] "*There is sufficient evidence that there can be a change in some properties of the material at the nanoscale which is, for instance, due to the increase in surface-to-volume ratio. These nanospecific properties raise concerns over their potential to cause harm to humans and the environment. The chemical reactivity of nanoparticles often relates to the surface area. Consequently, the chemical reactivity per mass dose increases for smaller particles of the same type. This effect may or may not be associated with an increase in biological activity or toxicity*". SCENIHR, Opinion of 8 December 2010 on *Scientific Basis for the Definition of the Term «nanomaterial »*, page 31.

[4] Q&A pair [38] "Do I have to register chemically surface treated substances?" available ate http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/topic/reach

- The relevant appropriate CAS entry, if available, shall be included in the "CAS information" field.
- Where the current CAS entry (CAS number (11097-59-9) and CAS name Aluminate ($Al(OH)_6^{3-}$), (*OC*-6-11)-, magnesium carbonate hydroxide (2:6:1:4)) are not appropriate to identify the registered substance (i.e. with the stoichiometry of $CH_{16}Al_2Mg_6O_{19}$) they shall be reported under the "Related CAS information" header in IUCLID Section 1.1.
- Similarly where the current EC entry is not appropriate to identify the substance as decribed above, it will need to be revised. However, for technical reasons the Registrant is requested at this stage, not to remove or revise the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant is requested to include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons".
- The substance identity information included in the Chemical Safety Report attached to Section 13 shall be revised such that it refers unambiguously to the registered substance.
- If the registrant intends to cover nanoforms with this registration, the respective particle sizes covered by this registration are also to be reported in Section 4.5 of the joint IUCLID dossier (i.e. in the form of particle size distribution).

Further information on how to report the chemical name, the molecular and structural formula, other identifiers and the description of the manufacturing process is available in "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" published on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

ECHA highlights that failure to report sufficient information on each grade of a substance in the dossier, including nanoforms, whether surface treated or not, may result in these grades not being covered by this registration.

In the absence of suitable information, ECHA cannot be in a position to determine whether the registration covers any specific nanoforms of the substance. Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported. Only the Registrant is therefore able to determine the particle size distribution of primary particles and to report sufficient information on the respective grades manufactured. The information should be sufficient to ensure that ECHA is in a position to determine the particle size distribution of primary particles of the substance and to allow ECHA to identify each grade covered by the registration.

2. Composition of the substance (Annex VI, 2.3)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the Registrant has not included sufficient information on the composition of the substance to enable the identity of the registered substance to be verified, as required under Annex VI, Section 2.3. of the REACH Regulation

Specifically, the Registrant has reported one composition in Section 1.2 of the dossier and this composition identifies its main constituent with the same reference to "MAGNESIUM-ALUMINIUM-HYDROXIDE-CARBONATE" with water listed as an impurity. From this limited information and due to the inconsistencies in the identifiers of the reference substance, as reported in Section III.A.1 of this decision, the composition of the well-defined substance of specific stoichiometric ratio and any specific grades as relevant cannot be established.

In accordance with section 4.2 of the Guidance, the composition shall normally be described up to 100%, and each constituent requires a complete chemical specification, including structural information.

The Registrant shall revise the composition reported in section 1.2 such that the main constituent refers to the substance of specfic stoichiometry as identified in section 1.1 of the dossier. The name and other identifiers for each specific main constituent shall specify the phase and form the compostion refers to. Further technical details on how to report details on the constituents of a substance in IUCLID are available in the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH".

If the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different compositions of specifc phase and form as relevant, then these must be presented separately.Corresponding analytical data to enable the identity and composition of each grade listed in 1.2 to be verified shall be included in Section 1.4. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH".

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

3. Description of the analytical methods (Annex VI, 2.3.7.)

ECHA notes that the Registrant has not provided sufficient information on the methods used to determine the identity and composition of the substance registered by his legal entity.

Specifically, ECHA observes that the Registrant has not included quantitative analytical data that would enable the identity of the substance or its composition to be verified. The Registrant has included X-Ray Diffraction (XRD) data (attachment "[redacted]") in section 1.4 but has not indicated which stoichiometry the data refers to. The XRD pattern indicates that the test material is crystalline but the specific crystalline phase is not reported. Furthermore, the XRD pattern appears to correspond to the tri-hydrate or tetrahydrate form based on reference patterns available from the powder diffraction database. The Registrant has however not indicated that hydrates are within the scope of the substance registered by his legal entity based on the exemption for hydrates according to Annex V point 6 of the REACH Regulation. This information is required if the Registrant intends to cover hydrates with the registration of the anhydrous substance identified in section 1.1 of the dossier. The information submitted is therefore not sufficient for the determination of the chemical composition of the substance registered.

In line with Annex VI, 2.3.7, the Registrant is requested to submit quantitative analytical data on the registered substance and to include quantitative analytical data for the hydroxide and carbonate ion contents of the substance. The data shall be sufficient to enable the identity and composition of the substance to be verified. The Registrant may use any method or combination of methods to do this (e.g. elemental analysis, gravimetry, quantitative XRD, etc.). The Registrant shall include XRD data for each phase of the substance registered. For each method used, the Registrant shall include a description of the method in such detail that it may be reproduced. Where multiple grades (compositions of specific phases) of the substance are registered, sufficient data that will enable the identity and composition of each grade to be verfied shall be included.

Where the Registrant intends to cover hydrates, he is requested to report each hydrate to be covered by the registration in section 1.2 of the dossier and to include the corresponding quantitative chemical analysis for each hydrate in section 1.4. Information on how to make use of the specific provisions of Annex V point 6 for hydrates is specified in paragraph 2.3, Q&A 9 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

As for the reporting of the data in the registration dossier, the information should be attached in section 1.4 of the IUCLID dossier. The Registrant shall ensure that the composition reported in Section 1.2 of the dossier is consistent with the analytical results obtained.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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