EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005379-64-02/F Helsinki, 20 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 per year. This decision does not take into account any updates submitted after 24 July 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 4 October 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. That draft decision was based on submission number [redacted]

On 28 March 2014 ECHA received comments from the Registrant to ECHA's draft decision.

On 30 May 2014 the Registrant updated his registration dossier with the submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and update. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 24 July 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:

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 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 **27 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.

Initially the Registrant identified the registered substance as a well-defined mono-constituent substance. In the updated dossier, the registrant has changed the substance type to UVCB but maintained the same numerical identifiers referring to a well-defined 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" thereinafter, well-defined substances are these with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical speciation, including structural information. This impllies that constituents of well-defined substances must have a unique definitive molecular formulae. Contrary to well-defined substances, UVCB substances are those for which the constituents are either variable or partially unknown.

In Section 1.1 of the IUCLID dossier the Registrant refers to EC (**234-319-3**) and CAS (**11097-59-9**) entries which refer to a specific 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 (SMILES notation, InChi code) and the molecular weight indicated in the dossier refer to a specific substance where 6 magnesium ions are present in the molecule. Contrary to that, 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) can vary (values of y from 3 to 6). The structural formula reported has the same variability in y. In addition, the IUPAC name only generically refers to "MAGNESIUM-ALUMINIUM-HYDROXIDE-CARBONATE". The updated dossier also includes a description of the manufacturing process but without explaining how this process is related to the two specific stoichiometries reported in section 1.2 of the updated dossier. Due to these inconsistencies between the name and other identifiers it is thus unclear to which specific 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 formula and other identifiers so that the registration unambigiously identifies the substance registered. The Registrant shall ensure that the information reported is consistent throughout the dossier. 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 stiochiometry is required to be defined and cannot vary significantly.

ECHA took note of the registrant's comments on the draft decision where the rationale for the request to revise the name and other identifiers used was outlined. In the comments received, the registrant indicated that it is their belief that "[redacted]" refers to the same substance as that covered by the EINECS entry for 234-319-3 name: [carbonato(2-)]hexadecahydroxybis(aluminium)hexamagnesium and molecular formula CH16Al2Mg6O19. ECHA notes that the "[redacted]" has a different stoichiometry ([redacted]) from the substance referred to by the EC and CAS identifiers (Mg6Al2(OH)16CO3) and consequently cannot have the same IUPAC name or structural identifiers. It would therefore refer to a different substance.

ECHA reminds the Registrant that the EINECS entry and corresponding CAS entry cannot be used to identify two (or more) different substances. The Registrant stated that these EC and CAS entries refer to a substance with a broad stoichiometry. The ECHA secretariat notes that the entries refer to a substance of defined and precise stoichiometry, namely Mg6Al2(OH)16CO3.

In his comments, the Registrant also indicated that he wishes to change the numerical idenifiers for the substance registered if it is not possible to cover a broader stoichiometry under the currently used EC and CAS entries for [carbonato(2-)]hexadecahydroxybis(aluminium). He has indicated that he will in this case change the substance type to UVCB and cover a broad range of stoichiometries. ECHA confirms that it is not possible to cover stoichiometries other than those given in the EINECS entry under that entry. Regarding the request to change the substance type to UVCB to cover a broader range of stoichiometries as one substance, ECHA notes that the description of the substance(s) based on the information included in the updated dossier does not readily fit to that of UVCB as the stoichiometry is defined and specific. It is demonstrably neither variable or unknown.

ECHA observes that the Registrant has indicated that "*surface coating with organic coating agent*" is part of the manufacturing process for the substance. In this respect ECHA also notes that clay minerals 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]

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.

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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.

[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.

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.

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 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.

ECHA notes that the Registrant submitted comments in response to the above text and stated in the comments that the substance registered does not fulfil the criteria to be considered as a nanomaterial according to the EU recommendation. The Registrant additionally updated the registration dossier to include information on the particle size distribution. The data submitted indicated that the particles measured are greater than 100 nm. However, as no information was included on the method used to determine size, whether the particle size referred to is the "smallest constituent particle" referred to in the EU recommendation or whether the size distribution is mass or number based, it is not possible to verify the statement of the Registrant. However, it is the Registrant's responsibility to report grades he intends to cover by the registration and, without sufficient specification, grades that fulfil the EU recommendation cannot be covered.
The Registrant additionally stated in his comments that surface treatment is not considered by them as part of the manufacturing process but part of the formulation/preparation of a product. This statement may indicate that that the registrant does not carry out surface treatment. However, ECHA reminds the registrant that it is his responsibility to report in the registration dossier the grades he intends to cover. Failure to report sufficient information on surface treated grades may result in these grades not being covered by this registration.

[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

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 seperately in section 1.2. and sufficient analytical data for the grade shall be included in section 1.4. Information referring to other substances shall be removed from section 1 of the dossier.

- The revised molecular and structural formula and other identifiers shall be included in their respective fields in Section 1.1 of the IUCLID dossier
- The relevant appropriate CAS entry shall be included in the "CAS information" field, if available. 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".

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, initially the Registrant has reported one composition in Section 1.2 of the dossier and this composition identifies its main constituent with the same reference substance as included in section 1.1 "MAGNESIUM-ALUMINIUM-HYDROXIDE-CARBONATE" with water listed as an impurity. In the updated dossier the Registrant has revised the composition to report three composition blocks, one referring to the anhydrous substance identified in section 1.1 and two referring to hydrates of this substance. From the 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 identity of the substance referred to in the first composition block cannot be established. In addition, concerning the compositions of the hydrates reported, ECHA notes that each hydrate reported in the updated dossier does not necessarily refer to the same anhydrous substance due to the differences in their stoichiometric ratio of ions.

In accordance with section 4.2 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. Compositions referring to other substances shall be removed from section 1.2. 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".

As already mentioned in section III.A.1, 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 notes that the registrant updated his dossier in response to requests made in the draft decision to provide information that would enable the composition, stoichiometry and the phase, of the registered substance including all hydrates to be verified. The information included in the updated dossier is sufficient to verify the stoichiometry and composition of the anhydrous form and of each hydrate reported in the updated dossier. However due to the reasons outlined in section IIIA (1) and (2) above, the hydrates do not readily refer to the same anhydrous substance.
Consequently, the registrant shall remove from section 1.4 information that refers to hydrates of other substances than the one registered. The registrant shall revise the information included in section 1.4 such that it is consistent with the substance identifier in section 1.1 and the composition reported in section 1.2. in section 1.2.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 3 months from the date of adoption of the decision. In his comments on the draft decision of 28 March 2014, the Registrant has requested additional time if both stoichiometries cannot be covered by the current EINECS entry to assess the consequences and the impact of a revised EC entry may have on the supply chain of this substance and on other co-registrants for the registered substance. ECHA notes that the REACH registration number identifies the substance registered under REACH. It does not have an impact on how the substance has been identified under other legislations/jurisdictions provided the identifiers are given in the context of the legislation/jurisdictions. ECHA reminds the Registrant that the decision does not require him to revise the EC entry at this time but to indicate in the remarks field in section 1.1 that "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". He can initiate a change request once agreement with all joint submission members for the registration has been reached. Therefore, ECHA has not modified the deadline of the decision

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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