EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003147-77-05/F Helsinki, 10 March 2014

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For calcium carbonate, CAS No 471-34-1 (EC No 207-439-9), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for calcium carbonate, CAS No 471-34-1 (EC No 207-439-9), by [redacted] (Registrant).

- 90-day inhalation toxicity study (OECD 413).

This decision is based on the registration dossier 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 after 20 June 2013, 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.

The present decision does not imply that the substance identification of calcium carbonate, or other endpoints of the dossier, is in compliance with the REACH requirements, and is without prejudice to any future decisions on the substance identification of calcium carbonate. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

On 1 October 2010 pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposal from 15 July 2011 until 29 August 2011. ECHA did not receive information from third parties.

On 23 November 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 2 January 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received.

On 20 June 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 26 July 2013 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on this proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and amended the draft decision accordingly.

On 5 August 2013 ECHA referred the draft decision to the Member States Committee.

On 21 August 2013 the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 9 September 2013 in a written procedure launched on 29 August 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2.; test method: OECD 413).

The REACH Regulation requires the Registrant to identify the sub-chronic toxicity potential of the substance irrespective of its phase or form, as they may, in principle, entail different hazards. In theory, in order to fulfil that requirement, experimental information is needed on each specific form and phase covered by the dossier of the registered substance. However, the Registrant may take the responsibility to select one or more representative phase(s) or form(s) of the substance in order to address the hazards of the different forms or phases.

If the Registrant decides not to perform the study with each form and phase concerned by the dossier, he shall demonstrate, in accordance with the specific requirements outlined in Section IV below, that the material used for testing is representative for every form and phase covered by the dossier, in order to establish the relevant hazards of each of these forms and phases. The information ultimately submitted by the Registrant shall thus demonstrate that the testing of such material does not result in an underestimation of the hazards of any phases or forms covered by the dossier of the registered substance. The registrant should provide adequate information on the characteristics of the tested substance.

In case where more than one form or phase of the substance is tested, the Registrant shall submit a new testing proposal for each additional experimental study planned.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **10 September 2015** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

1. Sub-chronic toxicity study (90-day)

a) Selection of the test material(s)

ECHA notes that the registration dossier is submitted for the substance calcium carbonate, CAS No 471-34-1 (EC No 207-439-9). However, the IUCLID dossier also contains (under the section-related CAS information), entries for calcite (CAS No. 13397-26-7), and aragonite (14791-73-2). Furthermore, ECHA notes that the dossier has included as synonoms the crystalline phases aragonite, calcite, vaterite, as well as "lime mud", "sugar factory lime", "precipitated calcium carbonate", and "ground calcium carbonate". Finally, under section 1.2 of the IUCLID dossier, the Registrant has indicated that the dossier covers different forms of the substance, named "bulk calcium carbonate", and "nano calcium carbonate". However, the testing proposal has not specified which of these different forms, or crystalline phases is proposed to be tested. The different forms and crystalline phases may have different toxicological properties, and the Registrant has not justified if a certain form or crystalline phase is anticipated to be representative of the hazard properties of all forms and phases.

The purpose of the REACH Regulation is to ensure a high level of protection of human health and the environment. In order to achieve this objective, the REACH Regulation imposes the determination of hazards and risks of substances manufactured or imported into the European Union. The determination of hazards and risks is irrespective of the phases or forms of the substances concerned.

It is therefore of utmost importance that the data generated with the test proposed allows the determination of the actual hazards posed by the registered substance, irrespective of its phases or forms. Specifically, and in view of the considerable difference in the phases or forms of the registered substance, the proposed test shall aim at identifying all the actual human health hazards of the registered substance, and shall preclude underestimation of hazards. Indeed, it should be noted that the difference in phases and forms of the registered substance does not relieve the Registrant from complying with the obligation to identify accurately hazards posed by the substance, irrespective of these phases or forms.

Accordingly, when a registration dossier concerns a substance subject to different phases or forms, which may result in different hazards and risks, the Registrant is compelled to determine the specific hazards and risks relevant for each specific phase or form. This concerns both crystalline phases, where differences in the crystalline phase of a substance may result in different toxicity, as is known for amorphous and crystalline silicon dioxide, and nanoforms of substances, which may trigger specific hazardous properties and risks, as already highlighted by various institutions.

In that context, the REACH Regulation also promotes alternative methods for the assessment of hazards of substances, including the specific phases or forms of these substances. As a result, the REACH Regulation allows the Registrant to identify the hazards of these specific phases or forms by alternative means offering equivalence to test methods.

In the present case, ECHA notes that the Registrant has not identified which phase or form he intended to test in this testing proposal. More specifically, the Registrant has not demonstrated in the dossier that a test performed with one of the phases or forms of the substance would allow identifying the hazards of all the phases or forms of the substance in such a way that an underestimation of hazard, that may be associated with the different phases or forms, is excluded.

The responsibility to decide which phases or forms of the substance to test falls to the Registrant. Based on the above and on his knowledge of the substance identity, the Registrant may consider necessary to test all the phases or forms of calcium carbonate in order to determine their specific hazards. Alternatively, the Registrant may decide to test only one or some of these phases or forms. This approach may fulfil the information requirement only if the Registrant can scientifically justify why he considers a particular phase or form to be representative of the toxicological hazards of other forms or phases of calcium carbonate and documents that this choice would not lead to an underestimation of the hazards.

If, upon further consideration of the documentation provided, ECHA considers the justification inadequate to exclude an underestimation of the hazards, it reserves the right to request additional tests necessary to fulfil the fundamental objectives of the REACH Regulation.

Finally, should the Registrant decide to test more than one phase or form of the substance in order to identify its specific hazard, he shall submit a new testing proposal for each additional experimental study planned.

b) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant proposed testing by the inhalation route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the inhalation route is appropriate.

The Registrant did not specify the species to be tested. According to the test method OECD 413 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

c) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, inhalation route (OECD 413) using each specific phase and form concerned by the dossier of calcium carbonate or one or several representative forms, as described in section III.1.a.

IV. Adequate identification of the tested material

In relation to the proposed test, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the test proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance and does not lead to an underestimation of the hazards, taking into account the fact that different phases and forms of the substance may result in different hazards.

There must therefore be adequate information on substance identity for the sample tested, in particular concerning the phase and/or form concerned by the sample, to enable the assessment of the relevance of the study. In particular, if a representative phase or form is tested, given the variability of the registered substance in relation to its phases or forms (as indicated in Section III.1 above), information as specified below has to be provided:

a) detailed information on the composition of the sample tested: this must include information on the particle size and phase of the tested material;
b) an explanation why the sample tested represents the phases and forms of the registered substance. In particular it should be explained how all the phases and forms with possible different hazards are represented in the composition of the sample tested;
c) information, based on available knowledge on the known hazards of possible combinations of phase and form of the registered substance, to demonstrate that testing that sample does not result in an underestimation of the hazards.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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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