Decision number: CCH-D-0000004065-80-03/F Helsinki, 30 September 2014

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

For reaction mass of calcium carbonate and calcium dihydroxide and silicon dioxide, List No 932-084-8, 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 dossier for reaction mass of calcium carbonate and calcium dihydroxide and silicon dioxide, List No 932-084-8, submitted by [redacted] (Registrant).

The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 8.4. and Annex VIII, Section 8.4. of the REACH Regulation.

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 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 dossier at a later stage.

The compliance check was initiated on 21 September 2012.

On 17 December 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. That draft decision was based on submission number [redacted]

On 14 January 2013 ECHA received comments from the Registrant on the draft decision. On 31 May 2013 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 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

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes VII and VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1) *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: EU B.13/14/OECD 471);
2) *In vitro* cytogenicity study in mammalian cells (Annex VIII, 8.4.2., test method: EU B.10/OECD 473) or *in vitro* micronucleus study (Annex VIII, 8.4.2.; test method: OECD 487);
3) *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17/OECD 476), provided that there is a negative result in the studies requested under 1) and 2)

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **7 October 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements. The scope of the present decision are the *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1. of the REACH Regulation), the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, 8.4.2 of the REACH Regulation) and the *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3. of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported by a registrant at the tonnage level of 1000 tonnes or more per year shall contain this information.

1. Mutagenicity, *in vitro* gene mutation study in bacteria

At the time of the sending of the draft decision pursuant to Article 50(1) of the REACH Regulation, the technical dossier contained an unjustified adaptation, as was reasoned in the draft decision and acknowledged by the Registrant. The Registrant, in his comments, requested time to improve his adaptation argument. ECHA granted this request. The thus updated technical dossier contained the following adaptation argument:

"Instead of conducting new tests, data on the constituents of the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide were used to evaluate the genotoxic potential of the substance. Guideline studies or information are available demonstrating the absence of genotoxic activity in vitro for each of the constituents. Therefore the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide is considered non-genotoxic."

In the technical dossier the Registrant provides (robust) study summaries of *in vitro* gene mutation studies in bacteria according to OECD TG 471 for the three main constituents calcium carbonate, calcium dihydroxide and silicon dioxide.

However, the registered substance has a degree of purity of [redacted]%w/w and contains [redacted] impurities. No (robust) study summaries or any other information are provided for the impurities, which together can constitute up to [redacted]% of the registered substance.

ECHA concludes that there is not sufficient weight of evidence to conclude whether or not the registered substance is genotoxic, as the weight of evidence justification does not address all components.

ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation. No valid adaptation was provided, and no test information for the registered substance itself is included for this endpoint in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using the abovementioned test method on the registered substance.

2. Mutagenicity, *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study

At the time of the sending of the draft decision pursuant to Article 50(1) of the REACH Regulation, the technical dossier contained an unjustified adaptation, as was reasoned in the draft decision and acknowledged by the Registrant. The Registrant, in his comments, requested time to improve his adaptation argument. ECHA granted this request. The thus updated technical dossier contained the following adaptation argument:

"Instead of conducting new tests, data on the constituents of the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide were used to evaluate the genotoxic potential of the substance. Guideline studies or information are available demonstrating the absence of genotoxic activity in vitro for each of the constituents. Therefore the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide is considered non-genotoxic."

In the technical dossier the Registrant provides (robust) study summaries of *in vitro* cytogenicity studies in mammalian cells according to OECD TG 473 for calcium carbonate and silicon dioxide and an non-guideline study (reliability code 2 'reliable with restrictions') with calcium dihydroxide.

For the same reasons as explained under subsection 1 of Section III above, ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation.

No valid adaptation was provided, and no test information for the registered substance itself is included for this endpoint in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using one of the abovementioned test methods on the registered substance.

3. Mutagenicity, in vitro gene mutation study in mammalian cells.

According to Annex VIII, section 8.4.3. of the REACH Regulation, the *in vitro* gene mutation study in mammalian cells is required if there is a negative result in the *in vitro* studies specified under Annex VII, section 8.4.1. and Annex VIII, section 8.4.2.

At the time of the sending of the draft decision pursuant to Article 50(1) of the REACH Regulation, the technical dossier contained an unjustified adaptation, as was reasoned in

the draft decision and acknowledged by the Registrant. The Registrant, in his comments, requested time to improve his adaptation argument. ECHA granted this request. The thus updated technical dossier contained the following adaptation argument:

"Instead of conducting new tests, data on the constituents of the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide were used to evaluate the genotoxic potential of the substance. Guideline studies or information are available demonstrating the absence of genotoxic activity in vitro for each of the constituents. Therefore the reaction mass of calcium carbonate, calcium dihydroxide and silicon dioxide is considered non-genotoxic."

In the technical dossier the Registrant provides (robust) study summaries of *in vitro* gene mutation studies in mammalian cells according to OECD TG 476 for two of the main constituents: calcium carbonate and silicon dioxide.

For the main constituent calcium-dihydroxide the technical dossier contained an adaptation to the standard information requirement concerning *in vitro* gene mutation study in mammalian cells with reference to three (negative) comet assays in section 7.12, toxicokinetic arguments and ubiquitous occurrence. In his adaptation argument for this main constituent, the Registrant argues that testing does not appear scientifically necessary (Annex XI, 1.1.2. and 1.1.3.) and that there is sufficient weight of evidence for the constituent from "standard textbook knowledge" and toxicokinetic information.

However, ECHA notes that there is no section 7.12 in the IUCLID technical dossier and no study summaries of comet assays to be found in the Chemicals Safety Report (CSR). The "wealth of information" referred to by the Registrant is not documented in the dossier. Specifically the toxicokinetic section in the IUCLID dossier and the CSR does not contain a basic toxicokinetic assessment based on all available information but a waiving statement:

"The substance is a reaction mass of calcium carbonate, calciumdihydroxide and calcium oxide. The main bioavailable constituents are inorganic substances which are naturally present in the environment and their systemic toxicity is low. Furthermore the toxicokinetics of these constituents are known. Because the toxicokinetics of the constituents are known a specific study with this reaction mass is not needed or useful."

Weblinks to information sources were provided in the endpoint summary. However, ECHA notes that weblinks to information sources (which may or may not contain elements on which adaptation could be justified) are not sufficient to demonstrate that the conditions of an adaptation are fulfilled. The information leading to fulfilment or adaptation of information requirements needs to be included in the registration dossier.

Furthermore, even if sufficient data to conclude on the main constituent calcium-dihydroxide had been included in the registration dossier, the adaptation argument would still have failed for the same reasons as for information requirements 1 and 2 above. The registered substance has a degree of purity of [redacted]%w/w and contains [redacted] impurities. No (robust) study summaries or any other information are provided for the impurities, which together can constitute up to [redacted]% of the registered substance.

ECHA concludes that there is not sufficient weight of evidence to conclude whether or not the registered substance is genotoxic, as the weight of evidence justification does not address all components.

ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation.

No valid adaptation was provided, and no test information for the registered substance itself is included for this endpoint in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using the abovementioned test method on the registered substance provided there is a negative result in both studies requested under II.1. and II.2.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies 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 who manufacture or import the same substance to agree on the appropriate composition of the test material 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 studies 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 studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

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 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.

Leena Ylä-Mononen
Director of Evaluation