ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003558-66-04/F Helsinki, 31 March 2014

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

For inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle, EC No 923-511-9, 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle, EC No 923-511-9, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex IX, Sections 8.6.2. and 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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

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 3 January 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.

The compliance check was initiated on 6 May 2013.

On 31 May 2013 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 24 June 2013 ECHA received comments from the Registrant. The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 3 January 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 Annex IX, 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. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408); and
2. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

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 **31 March 2016**. The timeline has been set to allow for sequential testing as appropriate.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

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

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 requirement.

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant provided information with which he sought to fulfil this standard information requirement. The provided information stems from a "Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days. The technical dossier neither contained a testing proposal nor an adaptation in accordance with column 2 of Annex IX, Section 8.6.2. or with the general rules of Annex XI for this standard information requirement.

In his comments to the draft decision, the Registrant proposed to waive the sub-chronic toxicity study (90 day):

The Registrant sought to adapt the information requirement according the specific rules of Annex IX , 8.6.2 column 2 with the following arguments:

- lack of any toxicity in 56 day repeated dose toxicity study;
- in combination with limited human exposure;
- and there are sufficient data on the cleavage products.

In addition, the Registrant sought to adapt the information requirement according the general rules Annex XI, 1.2. and 1.5.:

- Oral OECD 422 screening study with NOAEL of 5000 mg/kg bw/d;
- low hazard profile;
- DNEL values were derived using a precautional approach;
- industrial and/or professional exposure but no consumer exposure;
- oral route for occupational exposure not likely;
- UVCB substance consisting primarily of inert calcium-, magnesium and sodium carbonates and hydroxide minerals;
- CSR and GLS advises to control for metal content and to waste batches containing metals.

ECHA evaluated the Registrant's arguments. ECHA notes that in order to meet Annex IX, 8.6.2., column 2 rules for adaptation, the Registrant failed to demonstrate that the substance is (i) unreactive, insoluble and not inhalable and (ii) there is no evidence of absorption.

With regard to the proposed weight of evidence approach in accordance with Annex XI, 1.2. ECHA notes that this adaptation does not meet the general rules for adaptation of Annex XI, 1.2. It cannot be assumed or concluded with sufficient certainty that the substance has no dangerous property when male and female rats are exposed for a prolonged period of 90 days because the substance is classified for skin irritation 2 and eye damage 1 which indicates some reactivity of the substance and at the highest dose non-adverse liver effects were observed (lymphohistiocytic and apoptotic foci). Therefore, adverse effects after a prolonged exposure period cannot be excluded.

In addition, ECHA notes that the Registrant made reference to Annex XI, 1.5., "Grouping of substances and read-across approach" for calcium-, magnesium and sodium carbonates and hydroxide minerals. ECHA understands that the Registrant indicates that the information requirement could be supported by read-across. However, the Registrant did not provide any information or studies on read-across substances that would cover the information requirement and that would enable the assessment of the proposed read-across.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In light of the properties of the substance (paste or dried solid, particle size LD10 9.1 µm, LD50 468 µm, LD90 1261 µm; irrtating to skin or eyes) and the information provided on the uses and human exposure (i.e. no obvious aerosol generation), ECHA considers that testing by the oral route is most appropriate. According to the test method the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on sub-chronic toxicity (90-day) in rats, oral route (test method EU B.26./OECD 408) derived with the registered substance subject to the present decision.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2)

A pre-natal developmental toxicity study is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has proposed to adapt the information requirement of prenatal developmental toxicity. The justification of the adaptation given by the Registrant in the chemical safety report is the following: "*To assess and evaluate the toxic characteristics of the GLS were done that comprises a reproduction and developmental toxicity screening test, according to OECD-Guideline 422, (ver. 22 March 1996). This study was performed by subacute oral administration via gavage to rats* [redacted] *once a day for 28 consecutive days in males and once a day until Day 4 post partum or for 54 Days in females. There was no test substance administration in the offspring. Results and details for this study can be found from section 5.9.11. Effect to fertility: oral. But conclusion of the developmental toxicity was that there was no indication for a test substance related effect on the offspring*". However, ECHA notes that neither Column 2 of Annex IX, 8.7. nor general rules for adaptation of Annex XI include such possibility to adapt this information requirement. Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

In his comments to the draft decision, the Registrant proposed to waive the pre-natal developmental toxicity study;

The Registrant sought to adapt the information requirement according the specific rules of Annex IX , 8.7. column 2 with the following arguments:

- UVCB substance of low toxicologcal activity (Ca/Mg/Na carbonates and hydroxides);
- limited human exposure.

In addition, the Registrant sought to adapt the information requirement according to the general rules Annex XI, 1.2. and 1.5:

- Oral OECD 422 screening study with NOAEL of 5000 mg/kg bw/d;
- no effects on reproduction;
- no pronounces sex difference;
- effects noted were minmal to mild;
- NOAEL at highest dose;
- DNEL values were derived based on known trace concentrations of hazardous/classified heavy metals;
- industrial and/or professional exposure but no consumer exposure;
- oral route for occupational exposure not likely.

ECHA evaluated the Registrant's arguments. ECHA notes that in order to meet Annex IX, 8.7., column 2 rules for adaptation, the Registrant failed to (i) prove from toxicokinetic data that no systermic absorption occurs via relevant routes of exposure and to demonstrate that (ii) there is no or no significant human exposure. Mentioning that industrial and/or professional exposure occurs may be indicative of significant human exposure.

ECHA further notes that the proposed weight of evidence approach is not in accordance with Annex XI, 1.2., since information on key parameters for pre-natal developmental toxicity like caesarean section of the dams with skeletal and visceral examination of the pups were not provided. The limited information derived with the screening study on peri- and postnatal pup toxicity is not sufficient to conclude on pre-natal developmental toxicity. Therefore the provided information is not sufficient to conclude on the dangerous property of the substance with regard to pre-natal developmental toxicity.

In addition, ECHA notes that the Registrant made reference to Annex XI, 1.5., "Grouping of substances and read-across approach". ECHA understands that the Registrant indicates that the informaton requirement could be supported by read-across. However, the Registrant did not provide any information or studies on read-across substances that would cover the information requirement and that would enable the assessment of the proposed read-across.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to submit information on Pre-natal developmental toxicity on rats or rabbits, oral route (test method EU B.31/OECD 414) on the registered substance.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to

Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

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. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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 grade(s) registered to enable the relevance of the studies to be assessed.

V. 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/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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