Decision number: CCH-D-0000002671-77-08/F Helsinki, 17 September 2014

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

For 3-trimethoxysilylpropyl methacrylate, CAS No 2530-85-0 (EC No 219-785-8), 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 for 3-trimethoxysilylpropyl methacrylate, CAS No 2530-85-0 (EC No 219-785-8, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI Section 2.3.5, Annex VIII Section 9.2.2.1, and Annex IX section 9.4.2. of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000tonnes or more 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 substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2015.

The compliance check was initiated on 16 July 2013.

On 30 September 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 30 October 2013 ECHA received comments from the Registrant on the draft decision.

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 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)(a), 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. Spectral data (Annex VI, 2.3.5.);

B. Information in the technical dossier derived from the application of Annexes VII to XI

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

2. Hydrolysis as a function of pH (Annex VIII, 9.2.2.1.; test method: Hydrolysis as a function of pH, EU C.7./OECD 111);
3. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

Deadline for submitting the required information
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 **24 June 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.

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

1. Spectral data

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.

"Spectral data" is a standard information requirement as laid down in Annex VI, Section 2.3.5. 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.

ECHA notes that the technical dossier does not contain nuclear magnetic resonance (NMR) and ultra-violet (UV) spectra. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infrared data. NMR spectroscopic analyses such as a 1H-NMR or a 13C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. As the reported main constituent contains characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance. As an alternative to an NMR spectrum, mass spectra (MS) generated as part of mass spectroscopic analysis for the elucidation of the structure of the main constituent in the substance can be provided. Furthermore the substance absorbs in the UV range due to the presence of chromophores in the composition. A UV spectrum representing the absorption of these constituents in the UV range can be recorded and should therefore be included in the technical dossier.

In the comments to the draft decision, the Registrant agreed to add NMR and UV spectral data if technically feasible. However, as no dossier update was not received, ECHA did not amend the draft decision.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit the spectral data (NMR and UV spectra) for the registered substance in order to confirm the identity of the substance subject to the present decision.

As for the reporting of the spectral data in the registration dossier, the information should be attached in IUCLID section 1.4.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes X of the REACH Regulation.

2. Hydrolysis as a function of pH

Hydrolysis as a function of pH is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1. 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.

For this endpoint the Registrant has provided QSAR predictions showing that the half-life of the substance at pH=7 is 4.7 h. The QSAR method used is unknown. The registrant refers to QMRF and QPRF documents attached to the technical dossier. However, ECHA is not able to find these documents within the technical dossier. The Registrant also provides supporting information that an experimental hydrolysis study was commissioned, but it could not be performed due to the lack of a suitable analytical method.

Due to the absence of QMRF and QPRF, ECHA cannot verify that the QSAR prediction for hydrolysis on the registerd substance falls within the applicability domain of the QSAR model, as required by Annex XI, 1.3 and specifically the conditions to provide ECHA with a QSAR model whose scientific validy has been established and to provide adequate and reliable documentation. Consequently, the adaptation of the testing requirement is not acceptable, and the information requirement for this endpoint is not fulfilled.

In the comments to the draft decision, the Registrant agreed to update the dossier with a method description of the QSAR predictions and also the QMRF and QPRF documents whithin a given time. However, as no dossier update was received, ECHA did not amend the draft decision.

Therefore, pursuant to Article 41(1)(a)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the information for this endpoint using the test method Hydrolysis as a function of pH, EU C.7./OECD 111on the registered substance.

3. Effects on terrestrial organisms – Effects on soil micro-organisms

Effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, Section 9.4 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 waived testing on effects on soil microorganisms using the following justification: "In accordance with Section 1.2 of REACH Annex XI, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to soil microorganisms". ECHA considers that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined in column 2 of Annex IX, Section 9.4 for that information requirement does not apply for the present endpoint.

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.

Useful guidance can be found in ECHA Guidance on information requirements and chemical safety assessment (November 2012, version 1.1, Chapter R.7C, R.7.11.3.1. p115, where it is explained how the nitrogen transformation test is considered sufficient for most non-agrochemicals.

In the comments to the draft decision, the Registrant has stated that as the substance falls in the hazard soil category 1, no further testing for soil was proposed. The Registrant also indicated that neither in the ECHA Guidance nor in any scientific publication he was able to find indications that the equilibrium partitining method (EPM) is an unsuitable basis to approach the integrated testing startegy for soil microorganisms.

In response to the Registrant's comment ECHA notes that according to the guidance R.7.11 (ECHA, 2008) the PNECscreen for soil compartment is calculated through EPM on the basis of aquatic toxicity data only, which do not include the results of toxicity test on aquatic microorganisms. Therefore the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Thus, ECHA considers that the hazard to soil microbial communities need to be evaluated as a standard information requirement under Annex IX. 9.4.2. and is irrespective of the soil hazard category. Furthermore ECHA has assessed that the PNEC for the soil compartment calculated based on the EPM is not always conservative enough to cover microroganisms. This position was agreed at the Member State Committee (MSC) at its 29th meeting and it has been made public avaialble on ECHA's website[1].

While the Registrant agrees with ECHA that the microbial inhibition test is not part of the PNEC aquatic derivation, he states that EC50 and NOEC values are demonstrated to be less sensitive than the effects levels in other throphic levels. However, no quantitative information is submitted to support this claim. ECHA also notes that in the comments to the draft decision the Registrant has provided justifications for waiving soil micro-organisms testing, using a weight of evidence approach based on the following information:
- no toxicity observed in an activated sludge respiration inhibition test (ASRIT) (NOEC>=1000 mg/L
- IC50=5548 mg/L and IC10=2164 mg/L (7h) in test with Pseudomonas putida
- data including nitrification controls for fourteen organosilicon substances and showing no heterotrophic inhibition or nitrification inhibition to sewage sludge microorganisms
- the experimental observation that substances which do indicate some inhibition of nitrification, heterotrophic inhibition is also observed.

However, no reliable and adequate documentation has been provided in the registration dossier, therefore the conditions for the weight of evidence adaptation in Annex XI, 1.2 of the REACH Regulation are not fulfilled.

With regards to the Activated Sludge Respiration Inhibition (ASRI) data on fourteen organosilicon substances, and the suggestion to test another compound instead of the registered substance, ECHA points out that there is no sufficient information in the registration dossier to allow an evaluation of the read across and decide if the proposed test substance would be suitable. The identity of the read across substances, as well as their structures, physico-chemical characteristics and relevant hazard data are not reported. In addition, adequate and reliable documentation in the registration dossier is missing. Therefore, ECHA takes the view that the conditions in Annex XI, 1.5 of REACH are also not fulfilled.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

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1 http://echa.europa.eu/documents/10162/13628/compliance_pt4_webinar_06_terrestrial_en.pdf; http://echa.europa.eu/documents/10162/13628/07_terrestrial_webinar_en.pdf

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by 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 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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