EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002236-79-05/F Helsinki, 10 September 2012

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

For Tris(2-methoxyethoxy)vinylsilane, CAS No 1067-53-4 (EC No 213-934-0), 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 a testing proposal set out in the registration dossier for Tris(2-methoxyethoxy)vinylsilane, CAS No 1067-53-4 (EC No 213-934-0), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX and X:

- Pre-natal developmental toxicity study (OECD Guideline 414) with the registered substance

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

The examination of the testing proposal was initiated on 5 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 29 July until 12 September 2011. ECHA did not receive information from third parties.

On 24 January 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.

By 23 February 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 2 March 2012 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. Subsequently, the Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

ECHA reviewed the proposals for amendment received and decided to modify the draft decision.

On 4 April 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals within 30 days of the receipt of the notification.

On 16 April ECHA referred the draft decision to the Member State Committee.

On 4 May the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-8 June 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC and modified at the meeting was reached on 7 June 2012 and ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following proposed test using the indicated test method and the registered substance:

> Pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **10 September 2013** an update of the registration dossier containing the information required by this decision.

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 fulfill 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.

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. Pre-natal developmental toxicity

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

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 8.7.2. of the REACH Regulation.
The data for a pre-natal developmental toxicity study is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements of Annex IX, 8.7.2. and there is no valid adaptation to this standard information requirement. Consequently there is an information gap and the Registrant has proposed to generate the data to meet this information requirement.

In the CSR and in the IUCLID technical dossier the Registrant states that in contact with water the registered substance, Tris(2-methoxyethoxy)vinylsilane hydrolyses (0.9 min- ca. 1 hour depending on pH) into Vinylsilanetriol and 2-Methoxyethanol (CAS 109-86-4). However, the speed and extent of hydrolysis from the parent compound into 2-Methoxyethanol under physiological conditions is not fully known. This hydrolysis product has a harmonised classification in Annex VI of Regulation 1272/2008 of Repr 1B; H360FD (May damage fertility, may damage the unborn child) (Repr. Cat. 2 (R60-R61); DSD). Vinylsilanetriol has no harmonised classification. The Registrant has self classified the registered substance, Tris(2-methoxyethoxy)vinylsilane as a Repr 2; H361f (CLP) (Repr. Cat. 3 (R62); DSD), which is a less severe classification than that of the hydrolysis product, 2-Methoxyethanol.

Following the proposal for amendment from one of the MSCAs the Registrant indicated that he intends to self-classify the substance as Repr 1B and that he considers that the available data is adequate to support robust risk assessment.

Column 2 of Annex IX of the REACH Regulation allows a registrant to adapt the standard information requirement for developmental toxicity study if a substance is known to cause developmental toxicity meeting the criteria for toxic to reproduction category 1A or 1B: May damage the unborn child (H360D) and the available data are adequate to support a robust risk assessment.

If the conditions for the above adaptation are met and full justification is provided by the Registrant in the dossier, in accordance with column 2 of Annex IX, then the developmental toxicity study would not be needed.

However, the version of the registration dossier examined by ECHA to arrive at this decision does not contain such an adaptation. Therefore, there is currently a datagap which needs to be filled.

The Registrant specified neither the species nor the route to be used for testing.

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 by intubation. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rats, oral route (test method: EU B.31/OECD 414) using the registered substance Tris(2-methoxyethoxy)vinylsilane.

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

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is to be noted, however, that this information, or the information submitted by other registrants of the same 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 proposed test, 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 the joint registrants of the same substance to agree with the test proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studiy must be shared by the joint registrants concerned.

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/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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