ECHA
EUROPEAN CHEMICALS AGENCY

Final decision: TPE-D-0000001916-68-06/F Helsinki, 12 March 2012

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

For Reaction mass of divinylbenzene and ethylstyrene, List No 910-757-7, 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 Reaction mass of divinylbenzene and ethylstyrene, List No 910-757-7, submitted by [redacted] (the 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 requirement set out in Annex IX:

Annex IX, 9.2.1.2: Simulation testing on ultimate degradation in surface water

The examination of the testing proposal was initiated on 6 September 2010.

ECHA examined the testing proposal and drafted a decision in accordance with Article 40 of REACH.

On 9 September 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 7 October 2011 the Registrant provided to ECHA comments on the draft decision, requesting the proposed 15-month deadline to be prolonged.

ECHA reviewed the further information received and amended the draft decision accordingly, thus granting to the Registrant the requested extension in the time allowed to comply with the decision.

On 4 November 2011 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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 8 December 2011 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 for amendment within 30 days of the receipt of the notification.

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

On 16 December 2011 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

On 19 December 2011, the draft decision was referred to the Member State Committee.

After discussion in the Member State Committee meeting on 6-10 February 2012, the Member State Committee further modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 8 February 2012.

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.

II. Testing required

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

- Aerobic mineralisation in surface water – simulation biodegradation test (Annex IX, 9.2.1.2, EU Method C.25 or OECD 309)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **12 September 2013** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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

According to column 1, Section 9.2.1.2 of Annex IX of the REACH Regulation, simulation testing on ultimate degradation in surface water is required to fulfil the standard information requirements. Column 2 of Section 9.2 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed.

The Registrant has submitted a testing proposal for a simulation biodegradation study in surface water to cover this endpoint and has provided no adaptation to the standard information requirement according to column 2. The Registrant has based their proposal on the results for the screening test for biodegradability reported in the registration dossier, which indicated minimal biodegradation. The Registrant further indicated that the results of the proposed study will be used to refine environmental exposure assessment for the aquatic environment, and can be qualitatively used to assess potential persistence in other

environmental compartments.

Pursuant to Article 40(3)(a) of the REACH Regulation the Registrant is therefore requested to carry out the following test: Aerobic mineralisation in surface water – simulation biodegradation test (method C.25 of Regulation (EC) No 440/2008 or OECD test guideline 309).

The Registrant is responsible to ensure that the testing is carried out with due consideration of the provisions under point IV below. Additionally, the Registrant should ensure that the study is planned in a way that takes into consideration the worst-case scenario with regard to the composition of the tested substance, since it is clear that the registered substance is manufactured in different compositions. The choice of the test substance shall take into consideration the four main constituents of the test substance, 1,3- and 1,4-divinylbenzene and 3- and 4-ethylstyrene and shall be duly justified with evidence supporting the choice. This will ensure that the results obtained are meaningful and relevant to the substance properties. As such, the Registrant is reminded that the use of tools including Structure-Activity Relationship (SAR) models and screening tests for each of the four individual constituents may provide valuable information on the substance to be tested and may help ensure that an adequate representative for the substance is chosen.

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 by the Registrant in the technical dossier was sufficient to determine the composition of this substance for the purpose of assessing the testing proposal. The Registrant must note, 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. Furthermore, in the case of well-defined multi-constituent substances with different compositions, the tested substance or its constituents should reflect the worst possible case scenario for the substance or its constituents in relation to their effects. This will assist in the interpretation of the study results. 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 or additional information requirements) 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 study must be shared by the joint registrants concerned.

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

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> *"Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or*

other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

[redacted]

Jukka Malm
Director of Regulatory Affairs