

Decision number: TPE-D-0000002130-93-05/F

Helsinki, 20 December 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts, (EC No 931-534-0), 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 testing proposals set out in the registration dossier for sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts, (EC No 931-534-0), 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 proposals as part of the registration dossier to fulfil the information requirements set out in Annexes IX and X:

- Long-term toxicity to aquatic invertebrates: *Daphnia magna* reproduction test (OECD guideline 211), *Daphnia magna*, semi-static test
- Toxicity to soil-macro-organisms: earthworm reproduction test (*Eisenia fetida* / *Eisenia andrei*) (OECD guideline 222), *Eisenia fetida* / *Eisenia andrei*.

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

On 30 November 2011 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 02 January 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 January 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 of the receipt of the notification.

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

On 23 February 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 for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 5 March 2012, the draft decision was referred to the Member State Committee.

By 26 March 2012 the Registrant did not provide comments on the proposals for amendment.

After discussion in the Member State Committee meeting on 24-27 April 2012, a unanimous agreement of the Member State Committee on the draft decision was reached on 25 April 2012 and ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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 proposed tests using the indicated test methods and the registered substance:

- a) Long-term toxicity testing on invertebrates (*Daphnia* sp.) (Annex IX, 9.1.5., test method: EU C.20/OECD 211)
- b) Effects on terrestrial organisms: long-term toxicity testing on invertebrates (Annex X, 9.4.4., test method: OECD 222)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **20 September 2013** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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

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

- a) Long-term toxicity on invertebrates

The Registrant has submitted a testing proposal for long term toxicity to aquatic invertebrates (*Daphnia magna* reproduction test according to OECD guideline 211) in order to meet the information requirement of Section 9.1.5 of Annex IX of the REACH Regulation.

The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. The chemical safety assessment indicates risk characterisation ratios for the aquatic compartment that are close to 1 for some exposure scenarios. The information on long-term toxicity on invertebrates would allow the Registrant to refine his risk assessment for the aquatic compartment. Therefore, and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: *Daphnia magna* reproduction test (Annex IX, 9.1.5, test method: EU C.20/OECD 211).

b) Effects on terrestrial organisms: long-term toxicity testing on invertebrates

The Registrant has submitted a testing proposal for a long-term toxicity test on soil-macro-organisms (earthworm reproduction test (*Eisenia fetida* / *Eisenia andrei*) according to OECD guideline 222) in order to meet the information requirement of Section 9.4.4. of Annex X of the REACH Regulation.

The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

Direct or indirect exposure of the soil compartment by the registered substance cannot be excluded. Furthermore, the chemical safety assessment indicates risk characterisation ratios for agricultural soil that are close to 1 for some exposure scenarios and above 1 for overall exposure (combined for all relevant emission/release sources to agricultural soil). The Registrant shall refine his risk assessment for the soil compartment. Therefore, and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: earthworm reproduction test in *Eisenia fetida* or *Eisenia andrei* (Annex X, 9.4.4., test method: OECD 222)

When performing the tests and interpreting the results, the Registrant is advised to take into account the fact that the substance contains many components and is surface active. For that purpose, the Registrant can refer to Appendix 7.8-1 of ECHA guidance document R.7b. The Registrant may want to 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. This will ensure that the results obtained are meaningful and relevant to the substance properties.

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 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 tests, 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 tests 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 studies 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.



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