EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114321110-76-01/F Helsinki, 14 March 2016

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

For Reaction product of naphthalene, butanol, sulfonated and neutralized by caustic soda, EC No 939-707-2, 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 the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for Reaction product of naphthalene, butanol, sulfonated and neutralized by caustic soda, EC No 939-707-2, submitted by [redacted] (Registrant).

- Earthworm Acute toxicity test (OECD 207)
- Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test (OECD 208)
- Soil Microorganisms: Nitrogen Transformation Test (OECD 216)

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after 13 October 2015, i.e. 30 calendar days after the end of the commenting period.

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

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 29 May 2013.
On 4 August 2015 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 8 September 2015 ECHA received comments from the Registrant on the draft decision. The ECHA Secretariat considered the Registrant's comments. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 21 January 2016 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. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);

The Registrant shall carry out the following additional tests pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232;

Or,

Long-term toxicity testing on plants (Annex IX, 9.4., column 2); test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030.

while the originally proposed tests for a Earthworm Acute toxicity test (OECD 207) and Seedling Emergence and Seedling Growth Test (OECD 208) are rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

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.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **21 December 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

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

A. Tests required pursuant to Article 40(3)

Terrestrial toxicity testing (Annex IX, Section 9.4.2. and 9.4., Column 2)

The Registrant must address the standard information requirements set out in Annex IX, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

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

1) Effects on soil microorganisms (Annex IX, Section 9.4.2.)

a) Examination of the testing proposal

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

The Registrant submitted a testing proposal for a Soil microorganisms: Nitrogen transformation test (OECD 216). According to section R.7.11.3.1., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), ECHA considers the proposed test appropriate to fulfil the information requirement of Annex IX, Section 9.4.2.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

2-3) Terrestrial Invertebrates and plants (Annex IX, Section 9.4.1. and 9.4.3.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".
According to Annex XI, Section 1.5., there needs to be structural similarity among the substances within a group or category and furthermore, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). Furthermore, Annex XI, Section 1.5 lists several additional requirements, including that adequate and reliable documentation of the applied method is to be provided.

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207) and a short-term toxicity test on terrestrial plants (OECD 208). The Registrant intended to cover the information on toxicity to aquatic organisms, adsorption/desorption and ready biodegradability by applying a read-across approach in accordance with the principles set out in Annex XI, Section 1.5. More specifically, in the registration dossier, the PNEC soil has been derived by means of the Equilibrium Partitioning Method (EPM) on the basis of the PNEC aquatic and the log K_{oc} determination, in accordance with ECHA Guidance R.10 on *Characterisation of dose [concentration]-response for environment*. The information on toxicity to aquatic organisms, as well as the log K_{oc} determination and the ready biodegradability test refer to an alleged analogue substance, 'Reaction product of naphthalene, propan-2-ol, sulfonated and neutralized by caustic soda' (EC No 939-368-0).

ECHA has evaluated the proposed read-across and considers it plausible for the purpose of applying the Integrated Testing Strategy (ITS) for terrestrial toxicity and identifying the correct soil hazard category, as further specified below.

Consequently, the proposed aquatic PNEC can be considered as valid and the ITS and the EPM can be used to fulfil the current information requirements on terrestrial toxicity.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, and substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is considered very persistent, which is the default setting for not readily biodegradable substances when the value of the half-life in soil is not available and therefore the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6. of the above mentioned Guidance, ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on invertebrates or plants (and not the short-term) will provide the adequate information.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution.

For long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, the study Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) is also considered as a suitable test guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

b) Outcome

Therefore, the short-term toxicity tests on terrestrial invertebrates (OECD 207) and on terrestrial plants (OED 208) are rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional studies using the registered substance subject to the present decision:

Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232);

Or,

Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) as a long-term test, or to carry out the study Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030)

Note for consideration by the Registrant:

In his comments to the draft decision, The Registrant indicated that he intends to carry out the required studies only on one of the two structure analogues, i.e. [redacted], for which a testing proposal decision has been adopted by ECHA on 15 January 2016 requesting to carry-out the same tests outlined in Section II above of this decision. In this regard, while the Registrant is reminded of the possibility for adaptation indicated in the 'Notes for consideration by the Registrant' in Section II of this decision, ECHA notes that the present registration dossier does not contain any adequate and reliable documentation in support of a possible read-across adaptation for the terrestrial toxicity endpoints, according to Annex XI, Section 1.5 of the REACH Regulation.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to

the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

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 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.