EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114295282-46-01/F Helsinki, 9 March 2015

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

For Oxidation products of seed oil obtained from Linum usitatissimum, Linaceae (linseed), CAS No 68649-95-6 (EC No 272-038-8), 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 Oxidation products of seed oil obtained from Linum usitatissimum, Linaceae (linseed), CAS No 68649-95-6 (EC No 272-038-8), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Sections 9.4 of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity, and the related environmental hazard assessment.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 30 October 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 compliance check was initiated on 16 August 2013.

On 22 October 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. That draft decision was based on submission number [redacted].

On 20 November 2013 ECHA received comments from the Registrant on the draft decision.

On 20 November 2013 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.
On 30 October 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 5 December 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and modified Section III of the draft decision whereas no amendments to the Information Required (Section II) were made.

On 15 December 2014 ECHA referred the draft decision to the Member State Committee.

By 5 January 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 19 January 2015 in a written procedure launched on 9 January 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

1. Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); 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;

2. Long-term toxicity testing on plants (Annex X, 9.4.6.); 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 test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);

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

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term 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 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.

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 **16 December 2015**.

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

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.

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 VII, VIII, IX, and X of the REACH Regulation.

Therefore, the Registrant must address the standard information requirements set out in Annexes IX and X, 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.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

1. Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

The Registrant did not provide information fulfilling the information requirements of Annex IX, 9.4.1. and Annex X, 9.4.4.

For clarification, in its updated dossier (submission number [redacted]), IUCLID section 6.3.1, the Registrant included a testing proposal for long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.). The testing proposal examination was however terminated (communication number TPE-C-0000005071-86-01/F) as ECHA considered the testing proposal to be inadmissible because the end-point in question was still subject to this compliance check process.

ECHA notes that the Registrant originally proposed to adapt the standard information requirements of Annex IX, 9.4.1. and Annex X, 9.4.4. claiming no exposure of the soil compartment. However, ECHA considered that, as neither an Exposure Assessment nor a Risk Characterisation has been submitted and the substance has wide dispersive outdoor and indoor uses, it has not been shown that there is no exposure of the soil compartment, regardless of the substance being readily biodegradable. Thus, ECHA considers that the Registrant has not proven that soil exposure is unlikely.

In his comments and dossier update submitted on 20 November 2013, the Registrant indicated a testing strategy for terrestrial toxicity. ECHA considered the testing strategy indicated by the Registrant in his comment and in the updated dossier for this compliance check draft decision.

In his comments, the Registrant claims that the substance would fall into soil hazard category 3 based on a high adsorption potential and no toxicity to aquatic organisms. ECHA agrees that the substance has a high adsorption potential. However, ECHA disagrees that "no toxicity to aquatic organisms" has been demonstrated since no toxicity was observed at levels up to the water solubility in the aquatic studies submitted as part of the technical dossier. Consequently, no predicted aquatic no effect concentration (PNECaqua) has been derived for this substance. ECHA therefore notes that the Integrated Testing Strategy (ITS) that the Registrant refers to in his updated dossier (submission number [redacted]) for effects on terrestrial organisms as specified in the ECHA Guidance on information requirements and chemical safety assessment Chapter R7C (version 1.1., November 2012) is not applicable for this substance.

Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.1. and Annex X 9.4.4. cannot be accepted.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 (Annex X, 9.4.4.) and at the same time to fulfil the information requirement of Annex IX, 9.4.1. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); 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.

2. Terrestrial Plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

The Registrant did not provide information fulfilling the information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6.

ECHA notes that the Registrant has originally proposed to adapt the standard information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. claiming no exposure of the soil compartment. However, as explained in section III.1. above, no Exposure Assessment or Risk Characterisation sections have been submitted as part of the CSR and the substance has wide dispersive outdoor and indoor uses. It is therefore not justified to state that soil exposure is unlikely. In his comments to the draft decision and in the updated dossier (submission number [redacted]) the Registrant argued that the plant study may be conducted conditional to the long-term earthworm study. As described above in Section III.1., ECHA considers that the ITS for effects on terrestrial organisms as specified in the ECHA Guidance on information requirements and chemical safety assessment Chapter R7C (version 1.1., November 2012) is not applicable for this substance. Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.3. and Annex X, 9.4.6. cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Terrestrial plants growth test (OECD 208), (subject to the conditions outlined below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants test (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing on plants (Annex X, 9.4.6.) and at the same time to fulfil the information requirement of Annex IX, 9.4.3.

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 to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: long-term toxicity to plants (Annex X, 9.4.6.): 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 test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

3. Soil microorganisms (Annex IX, section 9.4.2.)

The Registrant did not provide information fulfilling the information requirement of Annex IX, 9.4.2.

ECHA notes that the Registrant has originally proposed to adapt the standard information requirements of Annex IX, 9.4.2. claiming no exposure of the soil compartment. ECHA notes that, as fully explained in section III 1. above, since no Exposure Assessment or Risk Characterisation sections have been submitted as part of the CSR and the substance has wide dispersive outdoor and indoor uses, it is not justified to state that soil exposure is unlikely.

In his comments to the draft decision and in the updated dossier (submission number [redacted]) the Registrant indicated that the need for the soil microorganism study would be decided based on the effects of the long-term earthworm study to be conducted. As also explained in the "Note for the consideration of the Registrant" below, 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. does not apply for this endpoint. Furthermore, as described above, ECHA considers that the ITS for effects on terrestrial organisms as specified in the ECHA Guidance on information requirements and chemical safety assessment Chapter R7C (version 1.1., November 2012) is not applicable for this substance. Consequently data for all three terrestrial endpoints as defined under Section II will need to be provided.

Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.2 cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: 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 of the Registrant

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the Guidance (based on EPM and other data that is available for the substance) does not apply for the endpoint of soil microorganisms.

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. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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/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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