ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308121-70-01/F Helsinki, 27 August 2015

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

For 2-Propenoic acid, butyl ester, reaction products with butadiene, sulfur and tri-Ph phosphite, CAS No 93925-37-2 (EC No 300-339-7), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 2-Propenoic acid, butyl ester, reaction products with butadiene, sulfur and tri-Ph phosphite, CAS No 93925-37-2 (EC No 300-339-7), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Sections 9.4 of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after the deadline for updating (12 March 2015) communicated to the Registrant by ECHA on 3 February 2015. Any later updates under Article 22(1) of the REACH Regulation will be considered by ECHA in the follow up dossier evaluation after the deadline set in the present decision has passed.

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 7 August 2014.

On 14 November 2014 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 16 December 2014 ECHA received comments from the Registrant on the draft decision. On 11 December 2014 the Registrant updated his registration dossier with the submission number [redacted].

On 2 March 2015 the Registrant updated his registration dossier again with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and updates.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 23 July 2015 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. Information required

A. Information required in the technical dossier regarding effects on terrestrial organisms

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 testing on 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);

   or

   Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, 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); and

2. 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), 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 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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, by the deadline set below will result in a notification to the Enforcement Authorities of the Member States.

The Registrant is reminded that application of the Integrated Testing Strategy (ITS) for terrestrial toxicity information requirements may provide the opportunity for adaptation of standard information. Nevertheless, should risk to the terrestrial compartment remain after performing the tests outlined above, further testing may be needed and the Registrant should submit a testing proposal accordingly.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **3 June 2016**. The timeline has been set to allow for sequential testing as appropriate.

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.

A. Information required in the technical dossier regarding effects on terrestrial organisms

Pursuant to Articles 10(a)(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.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on 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.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

In their comment on the draft decision and subsequent dossier updates, the Registrant has provided information relevant to the present evaluation. The Registrant has provided a newly calculated PNECaquatic, which is based on a newly available daphnia toxicity study. Additionally, the Registrant has indicated he has addressed ECHA's arguments concerning Hazard, Exposure and Risk characterisation. The Registrant has included four detailed documents in its comments, one for each of the terrestrial trophic levels for which information was requested and a general one summarising the Registrant's position on the need to perform the tests requested by ECHA.

Based on the aquatic toxicity results available and on the chemical properties of the substance, the registered substance can be categorised as terrestrial HC3, whereby the Registrant may be able to apply ITS and may need to perform as a minimum one of the two long-term terrestrial toxicity studies initially requested (invertebrates or plants). The Registrant would still need to perform a test on toxicity to microorganisms.

0. Read-across approach

ECHA notes that in the updated dossier submitted on 02/03/2015 (Submission number: [redacted]), QSAR Toolbox predictions are provided in IUCLID section 6.3.2, 6.3.3 and 6.3.4 (respectively for toxicity to terrestrial arthropods, toxicity to terrestrial plants and

toxicity to soil microorganisms). The registrant flagged these predictions as (Q)SAR predictions, but these are not results derived from a (Q)SAR model whose scientific validity has been established, as required by Annex XI, 1.3. Further, ECHA considers that these results are not obtained from a valid quantitative or qualitative structure-activity relationship model, but that these are read-across/category predictions based on nearest neighbours, an adaptation according to Annex XI, 1.5.

As described in REACH Annex XI - 1.5, grouping of substances and read-across approach can be used for substances that are structurally similar.

ECHA further notes that the registered substance is a UVCB and that for this type of substance, a read-across/category approach must take account of all the chemical constituents of the substance. The Registrant used a single representative structure to predict all terrestrial toxicity endpoints. However no justification was provided as to why this single structure represents all of the constituents contained in the registered substance. In fact, other constituents contain chemical structures that have marked differences from this single structure. This is the case for components called B, H and J in section 1.1 of IUCLID. In addition, the source chemicals used contain very different chemical features than the target, and there is no reasoning set out to explain why these source substances can be used to predict the properties of the registered substance.

On the basis of the justification supplied, ECHA considers that it is not possible to reliably predict the properties of the registered substance from the single chemical whose structure is provided, and it is not possible to predict the properties of the registered substance from the source substances used, and so the requirement of Annex XI, 1.5, that the human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach), is not met. Accordingly, it is concluded that the requirements of REACH Annex XI, 1.5 are not fulfilled.

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

Or

Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates and on terrestrial plants using the following justification:

"*This substance is not directly applied to soil and based on its intended use will not enter the terrestrial environment and therefore no testing of terrestrial organisms is required. The indirect exposure of soil to this substance via sewage sludge is also of no concern based on the treatment of the sludge. In accordance with section 9.4 of REACH Annex IX and X, further tests do not need to be conducted if direct and indirect exposure of the terrestrial compartment is unlikely. The substance is not directly applied to soil and based on its intended use and handling will not enter the terrestrial environment. ECHA Chapter R.7B and R.7C guidance states that if the PEC/PNEC ratio is below 1, then no risk for the compartment is indicated, that the information available may be sufficient to conclude the assessment, and there is no need to perform further tests. In addition, ECHA Chapter R.7B guidance states that if the substance is not considered a PBT or vPvB candidate, then it is*

considered not necessary to conduct further testing on the compartment. Therefore, on the basis of a lack of potential exposure, and hence risk, and low risk demonstrated by the RCRs less than 1 based on EUSES modeling, it is considered that the information available is sufficient and further testing is not required. If necessary, data available from aquatic toxicity testing can be used as a worst case scenario if further characterization of the terrestrial compartment is desired."

In his proposed adapation the Registrant claims that exposure to soil is unlikely. However, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded e.g. ERC 8d, and also that the exposure estimations provided by the Registrant in the chemical safety report indicates that there is exposure to soil in a number of developed exposure scenarios. ECHA therefore considers that the Registrant has not demonstrated that soil exposure is unlikely.
In his proposed adapation the Registrant further claims that he has derived RCRs below 1. ECHA notes that he has used the equilibrium partitioning method (EPM) to derive the PNECsoil.

According to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the EPM approach.

ECHA notes that PNECaquatic was revised on the basis of the results from the toxicity tests on fish and aquatic invertebrates requested in Decision CCH-D-0000003878-58-03/F from 16 December 2013. Therefore, ECHA considers that the substance can be categorised as HC3 for the purposed of applying the ITS for terrestrial toxicity testing, according to table R7.11-2, of the abovementioned guidance, is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

As explained above, the adaptation proposed by the Registrant is not justified. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates or plants. The Registrant may then propose further testing if the Risk Assessment indicates that the risk to the terrestrial compartment is not fully managed.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), substances that have a log K_{ow} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil, and the Guidance further specifies that this would be the default setting in the absence of a DT_{50} <180 days unless substance is classified as readily biodegradable. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 3.7-7.81) and ECHA notices that the Registrant concludes in the Chemical Safety Report (CSR) that the substance has high adsorption potential. According to the evidence presented within the Registration dossier, the substance is also not readily biodegradable. As no appropriate half-life in soil is provided, the substance should be considered as highly persistent. ECHA also notices that the Registrant concludes for his PBT-assessment that the substance is being potentially persistent.

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. Each of these tests is suitable to also address the

information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. 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 Plant Test: Seedling Emergence and Seedling Growth) 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(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

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

OR

Terrestrial Plant Test: Seedling Emergence and Seedling Growth (test method: 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 (test method: ISO 22030).

2. Soil micro-organisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation.

The Registrant has provided information based on QSAR predictions, which cannot be accepted based on the arguments contained in section III.0.

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

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

Notes for consideration by the Registrant:

If the results of the requested toxicity tests on fish and aquatic invertebrates (Decision CCH-D-0000003878-58-03/F) allow the subsequent derivation of a PNECwater, the Registrant may consider the ITS as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. This means that based on the data generated in accordance with Decision CCH-D-0000003878-58-03/F and the results of one of the requested long-term soil toxicity tests ((1) or (2) above) as well as the results from the toxicity test on soil microorganisms ((3) above) the Registrant may be able to justify an adaptation of the other requested long-term soil toxicity test ((1) or (2) above). Specifically he could examine whether or not screening assessment based on Predicted No Effect Concentration (PNEC) for soil organisms (derived by using Equilibrium Partitioning Method (EPM)) with additional safety factor of 10 applied indicates the risk to soil compartment when compared to relevant environmental concentrations in soil and whether or not performed toxicity tests with terrestrial organisms indicate a risk to the tested organisms. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirement for the long-term soil toxicity test which he has – on the basis of the new information – found to be no longer necessary.

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 present endpoint.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 18 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested both a long term toxicity study on terrestrial invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.) and a long term toxicity study on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.). As the need to perform one of these two studies may be waived by the Registrant based on the fact that the registered substance can be categorised as HC3 and the ITS for terrestrial testing may be applied, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 9 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted 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 to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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.

Furthermore, 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://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

[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.