EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114290469-35-01/F Helsinki, 19 December 2014

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

For Reaction mass of 2-methylbutyl salicylate and pentyl salicylate, EC No 911-280-7, 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 the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) there of for Reaction mass of 2-methylbutyl salicylate and pentyl salicylate, EC No 911-280-7, submitted by [redacted] (Registrant).

Earthworm, Acute Toxicity Test (OECD 207)

This decision is based on the registration dossier 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 4 September 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 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.

On 23 April 2013, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal set out by the Registrant in the registration dossier for the substance mentioned above.

On 30 June 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.

On 29 July 2014 ECHA received comments from the Registrant on the draft decision.

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

On 4 September 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.

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. Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: Toxicity for earthworms, EU C.8/OECD 207), or, if long-term testing is considered appropriate, Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., 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).

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. Short-term toxicity to plants (Annex IX, Section 9.4.3) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, Section 9.4.3., 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);

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

Once results of the requested toxicity test on terrestrial organisms are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

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 sound 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, 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 **28 September 2015** 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 proposal submitted by the Registrant for the registered substance.

Effects on terrestrial organisms

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

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.

a) Terrestrial invertebrates (Annex IX, 9.4.1.)

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207), with the following justification:

"*The exposure assessment using PNECsoil (screen) indicates a slight risk for the terrestrial compartment (see CSR, chapter 10). Although the risk is anticipated to be controlled due to lower expected exposure to soil compared to those predicted using EUSES, a proposal has been made to generate soil toxicity data to refine the hazard assessment. The substance belongs to soil hazard category 2 (REACH guidance, Table R.7.11 -2) and in line with the integrated testing strategy (ECHA Figure R.7.11-3 and Table R.7.11-2) it is proposed that a confirmatory short-term soil toxicity testing with invertebrates (e.g. earthworms) be conducted.*"

This test is suitable to address the information requirement of Annex IX, section 9.4.1.

However, the Guidance further advocates that if PECsoil/PNECsoil >1, based on the PNEC derived from the lowest value from short-term studies, additional or higher tier test on soil organisms should be conducted. ECHA considers that at this stage it is not possible to determine whether further testing for toxicity to terrestrial invertebrates will be required after the short-term test. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test requested by this decision.

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.

In his comments on the draft decision, the Registrant considers that performing the short term toxicity study (OECD 207) is appropriate for this substance due to it being readily biodegradabile and having log Kow and LogKoc < 5. However, as explained above, long term testing may still be reguired if PNEC based on the lowest value from the short term studies leads to PECsoil/PNECsoil >1.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out one of the following studies: Short-term toxicity to invertebrates (Annex IX, 9.4.1.); test method: Earthworm acute toxicity test (*Eisenia fetida/Eisenia andrei*), OECD 207), using the registered substance, or, if long-term is considered appropriate Long-term toxicity on terrestrial invertebrates (Annex X, Section 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), using the registered substance.

b) Terrestrial plants (Annex IX, 9.4.3.)

The proposed test that ECHA has accepted above can only address the information requirement of Annex IX, section 9.4.1. It is not sufficient by itself to address the standard information requirement of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant proposed to adapt this standard information requirement by the following justification:

"*According to column 2 in Annex IX of REACH (Regulation 1907/2006/EC), studies on soil organisms do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the ECHA "Guidance on information requirements and chemical safety assessment - Chapter R.7c: Endpoint specific guidance" this is further specified. In the case of readily biodegradable substances which are not directly applied to the soil it is generally assumed that the substance will not enter the terrestrial environment and as such no testing of soil organisms is required. Amyl salicylate is readily biodegradable and is not directly applied to soil. Therefore studies on the terrestrial plants are not required.* "

The Registrant proposes that testing may be adapted based on unlikely exposure. ECHA, however, notices that the PEC/PNECscreen >1 as indicated by the Registrant in his justification for the proposed short-term study with earthworms (see under a) above) contradicts this statement of no exposure and would rather indicate that exposure is significant. The adaptation is not justified. Therefore, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species) is in principle suitable to address the information requirement of Annex IX, section 9.4.3.

Furthermore, ECHA notes based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), ECHA agrees with the Registrant that the substance would fall into soil hazard category 2. 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 short-term soil toxicity test. ECHA notes that the strategy pursued by the Registrant under the endpoint terrestrial invertebrates (section 6.3.1 of the IUCLID dossier) is based on this approach.

However, the Guidance further explains that if PEC/PNECscreen > 1 (or there is indication of risk from confirmatory short-term soil toxicity test), then short-term toxicity tests should be conducted according to the standard information requirements of Annex IX (invertebrates, micro-organisms and plants) and the lowest value should be chosen for the derivation of PNECsoil. ECHA notices for this specific case that the Registrant has indicated that the PEC/PNECscreen is >1 and as the adaptation argument for this endpoint is not justified as explained above, short-term toxicity testing according to the standard information requirements of Annex IX is required.

As it is already explained above, ECHA considers that at this stage it is not possible to determine whether further testing will be required, and therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test requested by this decision.

In his comments on the draft decision, the Registrant considers that performing the short term toxicity study (OECD 208 with minumun of three species) is appropriate for this substance due to it being readily biodegradable and having log Kow and LogKoc < 5. However, as explained above, long term testing may still be reguired if PNEC based on the lowest value from the short term studies leads to PECsoil/PNECsoil >1.

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 short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Short-term toxicity testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, 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.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies: Short-term toxicity to plants (Annex IX, 9.4.3.); test method: Terrestrial Plant Test: Seedling emergence and seedling growth test, OECD 208); with at least three species tested, using the registered substance, or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex X, Section 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 Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030), using the registered substance.

c) Soil microorganisms (Annex IX, 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. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (a) above is not sufficient to address this standard information requirement.

The Registrant proposed to adapt this standard information requirement by the following justification:

"According to column 2 in Annex IX of REACH (Regulation 1907/2006/EC), studies on soil organisms do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the ECHA "Guidance on information requirements and chemical safety assessment - Chapter R.7c: Endpoint specific guidance" this is further specified. In the case of readily biodegradable substances which are not directly applied to the soil it is generally assumed that the substance will not enter the terrestrial environment and as such no testing of soil organisms is required. Amyl salicylate is readily biodegradable and is not directly applied to soil. Therefore studies on soil microorganisms are not required."

The Registrant proposes that testing may be adapted based on unlikely exposure. ECHA, however, notices that the PEC/PNECscreen >1 contradicts this statement of no exposure and would rather indicate that exposure is significant.

As already explained above, the adaptation argument is not justified. Therefore, the standard information requirement needs to be fulfilled.

ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

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, 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. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) 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 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.

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