~~Confidential~~

Helsinki, 12 January 2023

Addressees
Registrant(s) of JS_911_280_7 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18/09/2020

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of 2-methylbutyl salicylate and pentyl salicylate
EC number: 911-280-7

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***17 January 2025***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to

http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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.

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

1.1. Information provided

2 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

(i) A study on long-term toxicity to aquatic invertebrates (OECD 211, 2017) with the souce substance hexyl salicylate (EC 228-408-6);

3 You provide the following reasoning for the prediction of this information requirement: 'This read-across is based on the hypothesis that the source and target substance have similar ecotoxicological properties as a result of structural similarity (both the target- and source-substances are Carboxylic Acid-Esters), the same expected mode of action for aquatic toxicity and similar physicochemical properties relevant for the read-across ecotoxicological endpoint.'

4 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

1.2. Assessment of the information provided

5 We have assessed this information and identified the following issue(s):

1.2.1. Read-across adaptation rejected

6 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, 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.

7 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

8 We have identified the following issue(s):

1.2.1.1. Inadequate or unreliable study on the source substance

9 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211, and meet the requirements of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

10 Reporting of the methodology and results

a) the full record of the daily production of living offspring during the test in each replicate is provided;
b) the number of deaths among the parent animals (if any) and the day on which they occurred is reported;
c) the coefficient of variation for control reproductive output is reported;

11 Your registration dossier provides an OECD TG 211 study showing the following:

12 Reporting of the methodology and results

a) the full record of the daily production of living offspring during the test in each replicate is not provided;
b) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;
c) the coefficient of variation for control reproductive output is not reported;

13 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. As indicated by you, the final report is missing. Therefore, relevant information on key parameters is missing and it is not possible to verify the validity criteria.

14 Therefore, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) as specified in the corresponding OECD TG.

15 In your comments, you submitted the full study report. ECHA has assessed the information against the requirements as outlined above. The information you have provided in your comments addresses the deficiencies identified in this section (1.2.1.1) of the draft decision. However, the information is currently not available in your registration dossier. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision

1.2.1.2. The interpretation of the results is not reliable

16 Guidance on IRs and CSA, Section R.7.8.5 specifies that it is not reliable to correct the measured parameters by applying an acute to chronic ratio (ACR) for the toxicity on aquatic invertebrates: '*Especially the extrapolation from acute to chronic toxicity is hardly possible. Analysis of a large number of validated data on new and existing chemicals revealed that acute data have only limited predictive value for long-term effects in aquatic ecosystems.'*

17 You extrapolated the results of the OECD 211 study (performed on the analogue substance) to the Substance by applying an acute to chronic ratio (ACR) for the toxicity on Daphnia. As you explain in the IUCLID dossier: 'In order to derive the 21-day EC_{10} for the Substance from the analogue substance and to compensate for the higher hydrophobicity of the analogue substance, the ratio of the Acute-to-Chronic ratio (ACR) for the *Daphnia* toxicity for the source substance (ACR = 7.2) is derived, which is then applied to the 48 hour EC_{50} value of the target substance in order to derive the Substance 21-day EC_{10}.

18 However, as explained above, it is not reliable to adjust/correct the measured parameters by applying an acute to chronic ratio.

19 In your comments, you have not addressed the issue explained in this section (1.2.1.2). As already explained above, it is not reliable to apply an acute to chronic ratio as *acute data have only limited predictive value for long-term effects in aquatic ecosystems*. To be able to predict the relevant property of the Substance from data on the source substance you have to use the measured results obtained from the applicable study on the source substance.

20 Therefore, unless this issue is also addressed (i.e. by removing the correction of the measured parameters) the update of the dossier with the information requested in section 1.2.1.1, will not remove the identified deficiencies of you read-across adaptation. To address a data gap a requested study on the Substance will need to be provided.

21 As explained above, based on the information in the dossier and in your comments you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

22 On this basis, the information requirement is not fulfilled.

1.3. Study design and test specifications

23 The Substance is difficult to test due to the adsorptive properties (log Kow 4.47 and log Koc 3.7). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 05 Juy 2021.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 32 months from the date of adoption of the decision. To support your request, you provided documentation from testing facilities, indicating that final reports could be received in 14-20 months. The deadline of the draft decision was set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals