~~Confidential~~

Helsinki, 18 April 2023

Addressees
Registrant(s) of JS_271-434-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
27/09/2018

Registered substance subject to this decision ("the Substance")
Substance name: 3-methyl-2-butenyl salicylate
EC/List number: 271-434-8

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 ***24 July 2025***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.)

   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and

   ii. only if the *in vitro/in chemico* test methods specified under point i.) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429).

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201 or EU C.26./OECD TG 221)

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 request(s)
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 request(s)

Contents

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Skin sensitisation (Annex VII, Section 8.3.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 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.

4 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).

0.1.1. Predictions for toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

- Isobutyl salicylate, EC No. 201-729-9.

7 You provide the following reasoning for the prediction of toxicological properties: "This read-across is based on the hypothesis that Isobutyl salicylate (source substance) and Prenyl salicylate (target substance) have the same type of toxicological effects based on common underlying mechanisms. This prediction is supported by physicochemical, ecotoxicological and toxicological data on the substances themselves".

8 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

9 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.1.1.1. Missing supporting information to compare the properties of the substances

10 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

11 Supporting information must include (bridging) studies to compare properties of the source and target substances.

12 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

13 For the source substance, you provide in the registration dossier the studies used in the prediction of skin sensitisation properties. Apart from that study, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

14 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.2. Bias of the prediction from the selection of source substance(s)

15 In order to make an accurate prediction of toxicological properties, all relevant information must be considered in the prediction. If not all information is considered in the read-across approach, bias can be introduced in the predictions which may result in an over/underestimation in the prediction (RAAF, 2017; Chapter 4.5.1.5.). Bias may be caused by incorrect/incomplete selection of source substance(s); or due to a particular selection of study(ies) performed on the source substance(s).

16 To justify the selection of source substances, you must provide documentation how the source substance(s) have been chosen, for example, what methods/tools have been used to map the field of potential source substance(s), which other substances have been considered and why they have been discarded (RAAF, 2017, Chapter 4.4.1.5/4.5.1.5). If there are structural analogue(s) not used as source substances and data show significantly different results for the properties to be predicted without any justification for setting aside these different results, then the proposed prediction are considered biased.

17 You report information from the source substance isobutyl salicylate (EC No. 201-729-9), which you describe as follows: "The source substance Isobutyl salicylate has a shorter carbon chain and lacks the additional double bond before the additional methyl group in comparison with the target substance". You have not provided any justification on the selection of this substance used to predict the properties of the Substance but highlight their structural similarity as follows: "The structure of both substances is quite similar. Both substances contain the following organic functional groups: the basis for both substances is an alcohol (isobutyl alcohol and prenol) conjugated with salicylic acid.".

18 Another substance, isopentyl salicylate (EC No. 201-730-4), has the following structure: it is also composed of an alcohol (isopentanol) conjugated with salicylic acid. The following studies are available on that substance from ECHA's dissemination website:

- OECD TG 442B study (2018), showing significant skin sensitising effects in mice (EC 1.6 <0.5%);
- OECD TG 442E study (2018), showing positive results i.e. activation of dendritic cells.

19 Another substance, (4Z)-hept-4-en-2-yl salicylate (EC No. 700-488-1), has the following structure: it is also composed of an alcohol ((4Z)-hept-4-en-2-ol) conjugated with salicylic

acid and the alcohol moiety contains a double-bond. The following study is available on that substance from ECHA's dissemination website:

- OECD TG TG 429 study (2010), showing sensitising effects (EC3= 13.8%)

20 Isopentyl salicylate (EC No. 201-730-4) is a closer structural analogue of the Substance than the source substance that you have identified because its carbon chain has the same number of carbons and the same structure as the Substance, although, like the source substance, it does not contain a double bond.

21 On the basis of your justification, (4Z)-hept-4-en-2-yl salicylate (EC No. 700-488-1) could be considered as a closer structural analogue of the Substance than the source substance that you have identified because its branched carbon chain contains a double bond like the Substance, and is slightly longer.

22 The available data on the above substances differ from the studies on the source substance you use to draw a conclusion and show a higher concern for skin sensitisation.

23 You have not justified why these other substances have not been considered as sources.

24 Therefore, your predictions are biased and may underestimate the hazards of the Substance.

0.1.2. Predictions for ecotoxicological properties

0.1.2.1. Aquatic toxicity

25 You provide a read-across justification document in IUCLID Section 13.

26 You predict the properties of the Substance from information obtained from the following source substance(s):

- Isobutyl salicylate, EC No. 201-729-9.

27 You provide the following reasoning for the prediction of aquatic toxicity: " This read-across is based on the hypothesis that Isobutyl salicylate (source substance) and Prenyl salicylate (target substance) have the same type of toxicological effects based on common underlying mechanisms. This prediction is supported by physicochemical, ecotoxicological and toxicological data on the substances themselves".

28 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

29 We have identified the following issue(s) with the prediction(s) of aquatic toxicity:

0.1.2.1.1. Missing supporting information to compare the properties of the substances

30 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

31 Supporting information must include bridging studies to compare properties of the source and target substances.

32 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

33 For the source substance, you provide study summaries on acute toxicity to aquatic invertebrates and on algae. Apart from these studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

34 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2.1.2. Bias of the prediction from the selection of source substance(s)

35 In order to make an accurate prediction of ecotoxicological properties all relevant information must be considered in the prediction. If not all information is considered in the read-across approach, bias can be introduced in the predictions which may result in an over/underestimation in the prediction (RAAF, 2017; Chapter 4.5.1.5.). Bias may be caused by incorrect/incomplete selection of source substance(s); or due to a particular selection of study(ies) performed on the source substance(s).

36 To justify the selection of source substances, you must provide documentation how the source substance(s) have been chosen, for example, what methods/tools have been used to map the field of potential source substance(s), which other substances have been considered and why they have been discarded (RAAF, 2017, Chapter 4.4.1.5/4.5.1.5). If there are structural analogue(s) not used as source substances and data show significantly different results for the properties to be predicted without any justification for setting aside these different results, then the proposed prediction are considered biased.

37 You report information from the following source substances: isobutyl salicylate (EC No. 201-729-9), which you describe as follows: "The source substance Isobutyl salicylate has a shorter carbon chain and lacks the additional double bond before the additional methyl group in comparison with the target substance". You have not provided any justification on the selection of this substance used to predict the properties of the Substance but highlight their structural similarity as follows: "The structure of both substances is quite similar. Both substances contain the following organic functional groups: the basis for both substances is an alcohol (isobutyl alcohol and prenol) conjugated with salicylic acid.".

38 Another substance, isopentyl salicylate (EC No. 201-730-4), has the following structure: it is also composed of an alcohol (isopentanol) conjugated with salicylic acid. The following studies are available on that substance:

39 The following studies are provided for that substance on the ECHA dissemination website showing the following effects:

- OECD TG 201 study (2016), showing an E_rC_{50}=1.12 mg/L and an E_rC_{10}=0.442 mg/L.
- OECD TG 202 study (2017), showing an EC_{50}=1.92 mg/L

40 Another substance, (4Z)-hept-4-en-2-yl salicylate (EC No. 700-488-1), has the following structure: it is also composed of an alcohol ((4Z)-hept-4-en-2-ol) conjugated with salicylic acid. The following studies are available on the ECHA dissemination website for that substance:

- OECD TG 201 study (2016), showing an E_rC_{50}>0.409 mg/L.
- OECD TG 202 study (2010), showing an EC_{50}=0.382 mg/L.

41 On the basis of your justification, Isopentyl salicylate (EC No. 201-730-4) could be a closer structural analogue of the Substance than the source substance that you have identified because its carbon chain has the same number of carbons and the same structure as the Substance, although, like the source substance, it does not contain a double bond.

42 On the same basis, (4Z)-hept-4-en-2-yl salicylate (EC No. 700-488-1) could also be considered as a closer structural analogue of the Substance than the source substance that you have identified because its branched carbon chain contains a double bond like the Substance, and is slightly longer.

43 The available data on the above substances differ from the studies on the source substance you use to draw a conclusion and show a higher concern for aquatic toxicity.

44 You have not justified why these other substances have not been considered as sources.

45 Therefore, your predictions are biased and may underestimate the hazards of the Substance.

0.1.3. Conclusion on the read-across approach

46 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

47 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

48 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a key OECD TG 442C study (2018) with the source substance isobutyl salicylate (EC No. 201-729-9) that resulted negative;

(ii) a key OECD TG 442D study (2018) with the source substance isobutyl salicylate (EC No. 201-729-9) that resulted negative;

(iii) a key OECD TG 442E study (2018) with the source substance isobutyl salicylate (EC No. 201-729-9) that resulted positive.

1.2. Assessment of the information provided

1.2.1. Assessment whether the Substance causes skin sensitisation

1.2.1.1. Read-across adaptation rejected

49 As explained in Section 0.1.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

50 Therefore, it cannot be concluded whether the Substance causes skin sensitisation.

1.2.2. No assessment of potency

51 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

52 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1. above), this condition cannot be assessed.

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

1.3. Specification of the study design

54 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

55 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. Short-term toxicity testing on aquatic invertebrates

56 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

2.1. Information provided

57 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) OECD TG 202 study (2017) with the source substance isobutyl salicylate (EC No. 201-729-9;

2.2. Assessment of the information provided

58 As explained in Section 0.1.2, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

59 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

60 The Substance is difficult to test due to the high partition coefficient (log Kow >4). OECD TG 202 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 202. 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.

3. Growth inhibition study aquatic plants

61 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

3.1. Information provided

62 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(ii) OECD TG 201 study (2017) with the source substance isobutyl salicylate (EC No. 201-729-9;

3.2. Assessment of the information provided

63 As explained in Section 0.1.2, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

64 Therefore, the information requirement is not fulfilled.

3.3. Study design and test specifications

65 OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 2.

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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are 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 14 September 2021.

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

ECHA did not receive any comments within the commenting period.

The deadline of the decision is 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]

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