~~Confidential~~

Helsinki, 14 April 2023

Addressee
Registrant of JS_855-027-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23/06/2020

Registered substance subject to this decision ("the Substance")
Substance name: Pyridinium, 1-[2-[[4-[[3-[2-[6-amino-1-hydroxy-3-sulfo-5-[2-[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazenyl]-2-naphthalenyl]diazenyl]-4-sulfophenyl]amino]-4-oxobutyl]sulfonyl]ethyl]-3-carboxy-, inner salt, sodium salt (1:4)
EC/list number: 855-027-8

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 ***21 April 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) with Prival modification.

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

4. 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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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.)
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- 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 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).

5 You predict the properties of the Substance from information obtained from the following source substance:

- 2-Naphthalenesulfonic acid, 7-amino4-hydroxy-, coupled with diazotized 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid and diazotized dehydrochlorinated 2-amino-4-[[4-[(2-chloroethyl)sulfonyl]-1-oxobutyl]amino]benzenesulfonic acid, sodium salts, EC/list number: 833-951-2, CAS: 2246977-27-3.

6 Whilst you do not provide a specific read-across justification document in IUCLID Section 13/CSR, you do provide in IUCLID Sections 6.1.3, 6.1.5, 7.4.1, 7.6.1 the following reasoning for the prediction of (eco)toxicological properties: ”The read-across target has structure similarity to CR SB3A. Therefore, the data is applied.”

7 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.

8 We have identified the following issues with the prediction of (eco)toxicological properties:

0.1.1. Inadequate read-across hypothesis

9 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 include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based

on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the (eco)toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

10 Your read-across hypothesis is only based on the structural similarity between the source substance, which you consider a sufficient basis for predicting the properties of the Substance. However, your hypothesis does not explain why the structural differences between the substances do not influence the (eco)toxicological properties or do so in a regular pattern.

11 While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar (eco)toxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a (eco)toxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substance.

0.1.2. Unreliable source studies

12 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

- have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;

13 Specific reasons why the studies on the source substance do not meet this criterion are explained further below under the applicable information requirement sections 1, 2, 3 and 4. Therefore, no reliable predictions can be made for these information requirements.

0.1.3. Conclusion on the read-across approach

14 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. 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

15 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

16 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) an in vivo skin sensitisation study (2019) with the source substance EC/list number: 833-951-2, CAS No. 2246977-27-3.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

17 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issues addressed below.

1.2.2. Assessment whether the Substance causes skin sensitisation

1.2.2.1. The provided study does not meet the specifications of the test guideline(s)

18 To fulfil the information requirement, and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the OECD TG 442B (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the highest concentration is the highest technically possible concentration that maximises exposure while avoiding systemic toxicity and/or excessive local skin irritation.

19 In study (i) described as a Local Lymph Node Assay: BrdU-ELISA:

a) no dose level selection rationale was provided for selecting the highest dose of 20%.

20 Therefore the study does not cover the specification(s) required by the EU method OECD TG 442B and does not allow to make a conclusion whether the Substance causes skin sensitisation.

1.2.2.2. No assessment of potency

21 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).

22 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.2.1. above), this condition cannot be assessed.

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

1.3. Specification of the study design

24 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.

25 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.

1.4. On your comments to the draft decision

26 In the comments to the draft decision, you indicate that an OECD 442B (Local lymph node assay- BrdU-ELISA) study has been conducted with the Substance to fulfil the regulations in [redacted].

27 However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

2. In vitro gene mutation study in bacteria

28 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2.1. Information provided

29 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) an in vitro bacterial reverse mutation study (2019) with the source substance EC/list number: 833-951-2, CAS No. 2246977-27-3.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

30 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issues addressed below.

2.2.2. The provided study does not meet the specifications of the test guideline(s)

31 To fulfil the information requirement, a study must comply with the OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) if the Substance is an azo-dye or a diazo-compound, the test in presence of metabolic activation is performed following the Prival modification;

32 In study (i) described as an in vitro gene mutation study on bacteria:

a) although the tested substance is an azo-dye, the test in presence of metabolic activation was not performed following the Prival modification.

33 The information provided does not cover the specification(s) required by the OECD TG 471.

34 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

35 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

36 Your Substance is an azo dye for which the standard procedure may not detect all mutations. Therefore, you are required to use the Prival modification (see Paragraph 10 of OECD TG 471).

2.4. On your comments to the draft decision

37 In the comments to the draft decision, you indicate that an OECD 471 study has been conducted with the Substance.

38 However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

3. Short-term toxicity testing on aquatic invertebrates

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

3.1. Information provided

40 In your registration dossier, 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 source substance:

- 2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-, coupled with diazotized 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid and diazotized dehydrochlorinated 2-amino-4-[[4-[(2-chloroethyl)sulfonyl]-1-oxobutyl] amino]benzenesulfonic acid, sodium salts, EC/list number: 833-951-2, CAS No. 2246977-27-3.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

41 Regarding the information on the Source substance, as explained in Section 0.1. and below, your adaptation based on grouping of substances and read-across approach under

Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issues, as follows.

3.2.1.1. Source study not adequate for the information requirement

42 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 202. Therefore, the following specifications must be met:

43 Characterisation of exposure

a) the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test (see also Guidance on IRs and CSA, Section R.7.8.4.1).

44 The study (Daphnia sp., Acute Immobilisation Test, [redacted], 2019) is described as OECD Guideline 202. However, the following specifications are not according to the requirements of OECD TG 202:

45 Characterisation of exposure

a) the reported effect value is based on nominal concentration. However, measured concentrations of the test material at 48 hours were: 166.883, 162.585, 166.216, 166.883 mg/L which is not within ± 20 % of the nominal concentration (100 mg/L).

46 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the concentration of the test substance has not been maintained within ± 20 % of the nominal concentration throughout the test.

47 Therefore, the requirements of OECD TG 202 are not met.

48 Based on the above, the study does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 202 and this study is not an adequate basis for your read-across predictions.

3.2.2. The information submitted with your comments to the draft decision

49 In the comments to the draft decision, you have provided a copy of a Robust Study Summary (RSS) conducted with the Substance. This new OECD 202 RSS was found to be compliant with the information requirement. However, as this information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

3.1. Study design and test specifications

50 The Substance is difficult to test due to its colouring properties (the technical function of the substance reported in section 3.5.3 of the IUCLID dossier is dye). 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.

4. Growth inhibition study aquatic plants

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

4.1. Information provided

52 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 source substance:

- 2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-, coupled with diazotized 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid and diazotized dehydrochlorinated 2-amino-4-[[4-[(2-chloroethyl)sulfonyl]-1-oxobutyl]amino] benzenesulfonic acid, sodium salts, EC/list number: 833-951-2, CAS No. 2246977-27-3.

4.2. Assessment of the information provided

4.2.1. Read-across adaptation rejected

53 Regarding the information on the Source substance, as explained in Section 0.1. and below, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issues addressed below.

4.2.1.1. Source study not adequate for the information requirement

54 As explained in Section 0.1.2, the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 201. Therefore, the following specifications must be met:

55 Characterisation of exposure

a) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

56 Reporting of the methodology and results

b) adequate information on the analytical method (including performance parameters of the method).

57 The study: Alga Growth Inhibition Test (Study of shading effect), [redacted], 2019 is described as OECD TG 201. However, the following specifications are not according to the requirements of OECD TG 201:

58 Characterisation of exposure

a) you have expressed the effect values based on nominal concentrations. However,

measured concentrations of the test material at 72 hours were: 168.521, 164.672, 170.797, 169.337, 172.811 mg/L and thus not within ± 20 % of nominal concentration (100 mg/L) throughout the test.

59 Reporting of the methodology and results

b) on the analytical method adequate information, i.e. the name of the analytical method including its performance parameters: specificity, the recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range of the method are not reported.

60 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the concentration of the test substance has not been maintained within ± 20 % of the nominal concentration throughout the test. In addition, the reporting of the study is not sufficient to conduct an independent assessment of its reliability (no information on the analytical method and its performance parameters).

61 Therefore, the requirements of OECD TG 201 are not met.

62 Based on the above, the study does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 201 and this study is not an adequate basis for your read-across predictions.

4.2.2. The information submitted with your comments to the draft decision

63 In the comments to the draft decision, you have provided a copy of a Robust Study Summary (RSS) conducted with the Substance. This new OECD 201 RSS was found to be compliant with the information requirement. However, as this information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

4.3. Study design and test specifications

64 The Substance has colouring properties. While OECD TG 201 is the preferred method to fulfil the information requirement, OECD TG 221 can be an acceptable alternative for coloured substances (see Guidance on IRs and CSA, Chapter R.7b, Table R.7.8-3: Summary of difficult substance testing issues).

65 OECD TG 201 and OECD TG 221 specify 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 3.

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 06 April 2022.

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

ECHA took into account your comments and did not amend the request(s).

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: Addressee 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;

Registrant Name	Registration number	Highest REACH Annex applicable to you
[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

(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 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.

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