Helsinki, 09 November 2023

**Addressees**
Registrant(s) of JS_Lanthanum trihydroxide as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
11/06/2020

**Registered substance subject to this decision ("the Substance")**
Substance name: Lanthanum trihydroxide
EC/List number: 238-510-2

**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 ***14 August 2026***.

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

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

1. Water solubility (Annex VII, Section 7.7.; test method: OECD GD 29)

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

3. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211) only if the results of Request 1 show the Substance is poorly water soluble (i.e. water solubility < 1 mg/L)

**Information required from all the Registrants subject to Annex VIII of REACH**

4. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2) only if the results of Request 1 show the Substance is poorly water soluble (i.e. water solubility < 1 mg/L)

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

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

6. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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 VII of REACH**

## 1. Water solubility

1 Water solubility is an information requirement under Annex VII to REACH (Section 7.7). However, information on transformation/dissolution in aqueous media shall be provided (Section 7.7., Column 2) when the substance is a metal or sparingly soluble metal compound.

### *1.1. Triggering of the information required*

2 Based on a secondary source submitted in your dossier, the Substance is concluded to be a sparingly soluble metal compound as its solubility in water was reported to be 0.2 mg/L at 20°C.

3 Therefore, water solubility is required in accordance with Section 7.7., Column 2.

### *1.2. Information provided*

4 Guidance on IRs and CSA, Section R.7.1.7.3. specifies that, for metal or sparingly soluble metal compound, water solubility must be determined according to the OECD GD 29 (Transformation/Dissolution of metals and metal compounds in aqueous media).

5 You have provided a water solubility estimate from a handbook (2009) but no information on the transformation/dissolution in aqueous media of the Substance.

6 In the absence of information on transformation/dissolution in aqueous media, the information requirement set out in Section 7.7., Column 2 is not fulfilled.

7 In your comments to the draft decision, you agree to perform the requested study.

### *1.3. Study design and test specifications*

8 Under Section 4.5. of your technical dossier a key non TG study on granulometry (Laser scattering / diffract) shows that the registered substance has particle size ranging between 20.74 µm and 256.4 µm with a mass median diameter ($D_{50}$) of 100.6 µm. For powders (particle size < 1mm), the test must be conducted using a test material having the smallest representative particle size on the market. OECD TG GD 29 on Transformation/Dissolution of metals and metal compounds in aqueous media specifies that the specific surface area of the test material must be determined.

## 2. Long-term toxicity testing on aquatic invertebrates

9 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

### *2.1. Triggering of the information requirement*

10 Poorly water-soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

11 For the reasons explained under Request 1, the information requirement on water solubility is not fulfilled.

12 If the results of the information requested under Request 1 show that the Substance is poorly water soluble (i.e. water solubility under relevant conditions < 1 mg/L), information on long-term toxicity on aquatic invertebrates will need to be provided.

*2.2. Information provided*

13 You have provided information on short-term toxicity to aquatic invertebrate for an analogue substance but no information on long-term toxicity on aquatic invertebrates for the Substance.

*2.3. Assessment of the information provided*

14 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 5.

## 3. Growth inhibition study aquatic plants

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

*3.1. Information provided in your dossier*

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

(i) an OECD 201 study (2014) with Lanthanum fluoride, EC 237-252-8

*3.2. Assessment of the information provided in your dossier*

17 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.

18 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).

19 While you do not provide a justification document for addressing your Grouping of substances and read-across approach you provide the following reasoning for the prediction of this information requirement in CSR (section 7.1.3): "Read-across to structurally similar substance, lanthanum tricarbonate, is justified on the basis that toxicological effects will be driven by the metal cation species (La3+) which is analogous to the registered substance and the read-across substance".

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

Lanthanum fluoride, EC 237-252-8

21 ECHA assumes that your read-across hypothesis is based on the production of common ionic metal species. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

We have identified the following issues with the prediction of growth inhibition on algae:

*3.2.1. Absence of read-across documentation*

22 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 a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

23 You have provided robust study summary for study conducted with other substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance.

24 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance.

*3.2.2. Missing supporting information*

25 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.).

26 Supporting information must include transformation/dissolution information on the formation of the common ionic metal species and bridging studies to compare properties of the Substance and source substances.

27 As indicated above, your read-across hypothesis is based on the production of common ionic metal species from the Substance and the source substances. In this context, information characterising the rate and extent of the transformation/dissolution of the Substance and of the source substances is necessary to confirm the production of the proposed ionic metal species and to assess the impact of the exposure to the parent compounds.

28 Furthermore, also indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substances is necessary to confirm that both 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 substances.

29 However, you have not provided any experimental information, about the transformation/dissolution of the Substance nor the source substances to support your claims regarding formation of a common compound.

30 Furthermore, for the source substances, you provide the study used in the prediction in the registration dossier. 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.

31 In the absence of this information, you have not provided supporting evidence establishing the extent that the proposed common ionic metal species is formed as assumed in your read-across hypothesis. Furthermore, also you have not established that the Substance and the source substances are likely to have similar properties. Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis.

32 As explained above, 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.

*3.2.3. The provided study does not meet the information requirement*

33 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

34 Characterisation of exposure

a) if the concentration of the test material has not been maintained within ±20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material over the exposure period;

35 Reporting of the methodology and results

b) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
c) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

36 Your registration dossier provides an OECD TG 201 study showing the following:

37 Characterisation of exposure

a) the concentrations of the test material were 0.0015 mg/L and thus not within ± 20 % of nominal or measured initial concentration throughout the test. You have expressed the effect values based on the initial measured concentration only. Therefore, it does not correspond to either the geometric mean of measured concentrations during exposure or a model describing the decline of the concentration of the test material over the exposure period;

38 Reporting of the methodology and results

b) tabulated data on the algal biomass determined daily for each treatment group and control are not reported; You report biomass data for the beginning (0h) and the end of the test (72h) only.
c) on the analytical method adequate information, i.e. test conditions and the performance parameters of the method are not reported.

39 Based on the above,

- there is a critical methodological deficiency resulting in the rejection of the study results. More specifically, the results are not based on the geometric mean of

measured concentrations during exposure or on a model describing the decline of the concentration of the test material over the exposure period;

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, you have not provided measured biomass data and information on the analytical method. Therefore, it is not possible to verify whether the validity criteria of the OECD TG 201 were met and to verify the interpretation of the results of this study.

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

### *3.3. Information provided in your comments on the draft decision*

41 In the comments to the draft decision, you do not agree to perform the requested study. However, you state that "*a document, summarising and discussing all available data on the growth inhibition of rare earths to aquatic plants*" will be added to the dossier. On this basis ECHA undesrands that, you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

42 ECHA takes note of your intention to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make any assessment, no conclusion on the compliance can currently be made.

43 On this basis, the information requirement is not fulfilled and you remain responsible for complying with this decision by the set deadline.

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

### *3.4. Study design and test specifications*

45 The Substance is difficult to test due to its low water solubility. OECD TG 201 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 201. 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.

**Reasons related to the information under Annex VIII of REACH**

## 4. Long-term toxicity testing on fish

46 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

### *4.1. Triggering of the information requirement*

47 Poorly water-soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

48 For the reasons explained under Request 1, the information requirement on water solubility is not fulfilled.

49 If the results of the information requested under Request 1 show that the Substance is poorly water soluble (i.e. water solubility under relevant conditions < 1 mg/L), information on long-term toxicity on fish will need to be provided.

### *4.2. Information provided*

50 You have provided information on short-term toxicity on fish for an analogue substance but no information on long-term toxicity on fish for the Substance.

### *4.3. Assessment of the information provided*

51 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section 6.

**Reasons related to the information under Annex IX of REACH**

## 5. Long-term toxicity testing on aquatic invertebrates

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

*5.1. Information provided in your dossier*

53 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification: "*chemical safety assessment concludes that the substance is of no immediate concern to the environment*".

*5.2. Assessment of the information provided in your dossier*

*5.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study*

54 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

55 Your adaptation is therefore rejected.

*5.3. Information provided in your comments on the draft decision*

56 In the comments to the draft decision, you do not agree to perform the requested study. However, you state that "*reliable data*" are available for the "*water soluble compound ($LaCl_3$)*". On this basis, ECHA undesrands that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

57 ECHA takes note of your intention to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make any assessment, no conclusion on the compliance can currently be made.

58 On this basis, the information requirement is not fulfilled and you remain responsible for complying with this decision by the set deadline.

*5.4. Study design and test specifications*

59 OECD TG 211 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 3.

## 6. Long-term toxicity testing on fish

60 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

*6.1. Information provided in your dossier*

61 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification "*chemical safety assessment concludes that the substance is of no immediate concern to the environment*".

*6.2. Assessment of the information provided in your dossier*

*6.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study*

62 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

63 Your adaptation is therefore rejected.

*6.3. Information provided in your comments on the draft decision*

64 In the comments to the draft decision, you do not agree to perform the requested study. However, you state that "*reliable data will be available for a water soluble compound on this endpoint*". On this basis, ECHA undesrands that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

65 ECHA takes note of your intentions to submit a read-across approach for this information requirement. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

66 On this basis, the information requirement is not fulfilled and you remain responsible for complying with this decision by the set deadline.

*6.4. Study design and test specifications*

67 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

68 OECD TG 210 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 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).

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 07 December 2021.

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

ECHA took into account your comments and amended the requests.

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 |
|---|---|---|
| ALBEMARLE CATALYSTS COMPANY B.V. | 01-2119985857-12-0002 | Annex IX |
| NPM Silmet OÜ | 01-2119985857-12-0000 | Annex IX |
| Oerlikon Metco WOKA GmbH | 01-2119985857-12-0003 | Annex VIII |
| Treibacher Industrie AG | 01-2119985857-12-0001 | Annex VIII |

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.

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

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].

[3] https://echa.europa.eu/manuals