

Helsinki, 20 September 2023

Addressee(s)

Registrant(s) of JS diisobutyl adipate as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

09 April 2018

Registered substance subject to this decision ("the Substance")

Substance name: Diisobutyl adipate

EC/List number: 205-450-3

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 **29 September 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.)
 - a) 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
 - b) only if the in vitro/in chemico test methods specified under point a) 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 on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201).

The reasons for the request(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.

Authorised¹ 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)

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Reasons common to several requests*0.1. Assessment of the read-across approach*

- 1 You have provided experimental data on dibutyl adipate (DBA), EC No. 203-350-4 for the following standard information requirements:
- 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 While you have not identified this information as a read-across approach, the test material used is different than the Substance. Therefore, the studies conducted with this substance (hereafter referred to as the "source substance") will be evaluated as a read-across adaptation under Annex XI, Section 1.5 of REACH.
- 3 You have also provided an adaptation under Annex VII, Section 9.1., Column 2 for the Short-term toxicity testing on aquatic invertebrates, using a read-across approach, which ECHA evaluated based on the same requirement.
- 4 We have identified the following issues with the prediction of ecotoxicological properties:

0.1.1. Absence of read-across documentation

- 5 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 information on the source substance(s).
- 6 You have provided robust study summaries for studies conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation to explain why this information is relevant for the Substance and why the properties of the Substance may be predicted from information on the source substance(s).
- 7 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance.

0.1.2. Unreliable source studies

- 8 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;
- 9 Specific reasons why the studies on the source substance do not meet this criterion are explained further below under Request 2 (Short-term toxicity testing on aquatic invertebrates) and 3 (Growth inhibition study on aquatic plants). Therefore, no reliable predictions can be made for these information requirements.

0.2. Conclusion on the read-across approach

- 10 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 and your read-across approach intended to fulfil Annex VII, Section 9.1, Column 2 is also rejected.

Reasons related to the information under Annex VII of REACH**1. Skin sensitisation**

- 11 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

- 12 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

- 13 You have provided:

(i) a Human Draize Test/Human Repeated Insult Patch Test (1967) with the Substance.

1.2. Assessment of the information provided

- 14 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

- 15 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

- 16 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

1.2.1. Only one source of information provided

- 17 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information based on which a conclusion on the information requirement can be drawn.

- 18 You have only provided one source of information.

- 19 Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

1.2.2. Assessment whether the Substance causes skin sensitisation

- 20 Information that can be used to support a weight of evidence adaptation for the information requirements of Section 8.3 at Annex VII includes similar information to that investigated by the internationally recognised in vitro, in chemico and/or in vivo test methods on skin sensitisation. The key investigations of such test methods address each of the 3 key events of skin sensitisation, either individually or in an integrated approach as follows:

(1) investigation of cell proliferation in the draining lymph nodes (local lymph

- node assay), or
- (2) investigation of local responses in animals or humans (guinea pig assays or human studies), or
- (3) investigation of molecular interaction with proteins, inflammatory response in keratinocytes and activation of dendritic cells (*in vitro* and *in chemico* assays).

- 21 The sources of information (study i) provides relevant information, as it investigates predicted properties on skin sensitisation i.e. investigation of local responses in animals or humans.
- 22 In addition, study (i) has the following deficiencies affecting the reliability of its contribution to the weight of evidence approach:
- 23 A study must be adequate for the corresponding information requirement. According to the Guidance on IRs and CSA, Section R.4. (page 1), "The evaluation of data quality includes assessment of adequacy of the information for hazard/risk assessment and C&L purposes". The Guidance on IRs and CSA, Section R.4. (page 1) defines adequacy as "the usefulness of data for hazard/risk assessment purposes". As a consequence, a study must be relevant for hazard assessment and for classification and labelling purposes.
- 24 You have provided a study according to the Human Draize Test/Human Repeated Insult Patch Test (study i), and you consider that the Substance is not a skin sensitiser.
- 25 Further, the reporting is limited to the total number of group (20) but no other exposure information is provided: number of exposures, concentration of the substance applied etc.
- 26 The study (i) appears to have been designed to establish safe levels for specific intended uses, as the Human Repeated Insult Patch Test method is intended to confirm the absence of irritation and sensitisation potential.
- 27 Moreover, due to lack of reporting, it is not known what the exposure conditions were and thus the relevance for hazard identification.
- 28 In conclusion, you have submitted single source of information, which has deficiencies affecting its reliability preventing drawing the conclusion on key investigation 2/local responses in humans.
- 29 Therefore, your adaptation is rejected.
- 30 On this basis, it cannot be concluded whether the Substance causes skin sensitisation.

1.2.3. No assessment of potency

- 31 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).
- 32 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.2 above), this condition cannot be assessed.
- 33 Therefore, the information requirement is not fulfilled.

1.3. Study design

- 34 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.

- 35 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

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

2.1. Information provided

- 37 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 substance:

(i) a short-term toxicity study on daphnia magna (1984) according to OECD TG 202 with the source substance: dibutyl adipate (DBA), EC No. 203-350-4;

- 38 You have also submitted an adaptation under Annex VII, Section 9.1., Column 2, based on experimental data from the same source substance:

(ii) a long-term toxicity study on daphnia magna (1996) 'according to OECD TG 202' with the source substance: dibutyl adipate (DBA), EC No. 203-350-4;

2.2. Assessment of the information provided

2.2.1. Read-across and Column 2 adaptations rejected

- 39 As explained in Section 0.1. and below, your adaptations based on grouping of substances and read-across approach under Annex XI, Section 1.5. and under Annex VII, Section 9.1., Column 2 are rejected. In addition, ECHA identified endpoint-specific issues addressed below.

2.2.1.1. Inadequate or unreliable short-term study on the source substance

- 40 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 202. Therefore, the following specifications must be met:

Validity criteria

- a) the percentage of immobilised daphnids is $\leq 10\%$ at the end of the test in the controls (including the solvent control, if applicable);
- b) the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;

Technical specifications impacting the sensitivity/reliability of the test

- c) the test duration is 48 hours or longer;

Characterisation of exposure

- d) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported

specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results

- e) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported.

41 In the provided study (i):

Validity criteria

42 The validity criteria a) - b) are not reported;

Technical specifications impacting the sensitivity/reliability of the test

- c) the test duration was 24 hours;

Characterisation of exposure

- d) no analytical monitoring of exposure was conducted

Reporting of the methodology and results

- e) the dissolved oxygen and pH measured at least at the beginning and end of the test is not reported.

43 Based on the above, the information on validity criteria of OECD TG 202 is missing. On that basis it is not possible to independently assess the reliability and confirm the validity of the study. There are also critical methodological deficiencies resulting in rejection of the study results. More specifically, the concentrations of the substance throughout the test duration were not analytically verified (monitored), which may result in an underestimation of aquatic toxicity.

44 On this basis, the specifications of OECD TG 202 are not met.

45 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG.

2.2.1.2. Inadequate or unreliable study (Long-term toxicity testing on aquatic invertebrates) on the source substance

46 As mentioned under section 2.2.1.1, the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211. Therefore, the following specifications must be met:

Validity criteria

- f) the percentage of mortality of the parent animals (female Daphnia) in the control is $\leq 20\%$ at the end of the test;
- g) the mean number of living offspring produced per surviving parent animal in the control is ≥ 60 at the end of the test;

Characterisation of exposure

- h) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

47 In the provided study (ii):

Validity criteria

48 The validity criteria f) – g) are not reported.

Characterisation of exposure

h) no analytical monitoring of exposure was conducted.

49 Based on the above, the information on validity criteria of OECD TG 211 is missing. Therefore, it is not possible to independently assess the reliability and confirm the validity of the study. There are also critical methodological deficiencies resulting in rejection of the study results. More specifically, the concentrations of the substance throughout the test duration were not analytically verified (monitored), which may result in an underestimation of aquatic toxicity.

50 On this basis, the specifications of OECD TG 211 are not met.

51 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG.

52 Therefore, the information requirement is not fulfilled.

2.1. Study design

53 The Substance is difficult to test due to the adsorptive properties ($\log K_{ow} > 4$, determined in an OECD 117 study with the Substance, provided in your dossier). 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 on aquatic plants

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

3.1. Information provided

55 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 substance:

(i) Growth inhibition study on algae (1984) according to OECD TG 201 with the source substance: dibutyl adipate (DBA), EC No. 203-350-4;

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

- 56 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.

3.2.1.1. Inadequate or unreliable study on the source substance

- 57 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 201. Therefore, the following specifications must be met:

Validity criteria

- a) exponential growth in the control cultures is observed over the entire duration of the test;
- b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- c) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is $\leq 35\%$;
- d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is $\leq 10\%$ in tests with *Raphidocelis subcapitata* (formerly known as *Selenastrum capricornutum*);

Technical specifications impacting the sensitivity/reliability of the test

- e) the pH of the control medium does not increase by > 1.5 units;

Characterisation of exposure

- f) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

Reporting of the methodology and results

- g) the test design is reported (e.g., number of replicates, number of test concentrations and geometric progression used);
- h) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

- 58 In the provided study (i):

Validity criteria

- 59 The validity criteria a) – d) are not reported.

Technical specifications impacting the sensitivity/reliability of the test

- e) the pH of the control medium is not reported;

Characterisation of exposure

- f) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

- g) on the test design, you have not specified the number of replicates and geometric progression used (you have only stated that five nominal test concentrations between 1-5 mg/L were tested);

h) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

60 Based on the above, the information on validity criteria of OECD TG 201 is missing. On that basis it is not possible to independently assess the reliability and confirm the validity of the study. There are also critical methodological deficiencies resulting in rejection of the study results. In particular, the concentrations of the substance throughout the test duration were not analytically verified (monitored), which may result in an underestimation of aquatic exposure.

61 On this basis, the specifications of OECD TG 201 are not met.

62 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG.

63 Therefore, the information requirement is not fulfilled.

3.3. Study design

64 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" under Request 2 (Short-term toxicity testing on aquatic invertebrates).

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 09 August 2022.

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

ECHA did not receive any comments within the commenting period.

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(s) 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
██████████	██████████	██████

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 (<https://echa.europa.eu/practical-guides>).

(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.

With that detailed information, ECHA can confirm 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 (<https://echa.europa.eu/manuals>).