~~Confidential~~

Helsinki, 23 November 2022

Addressees
Registrant(s) of JS_EC688-147-2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
13/10/2017

Registered substance subject to this decision ("the Substance")
Substance name: 2-Propenoic acid, 2-methyl-, 7-oxabicyclo[4.1.0]hept-3-ylmethyl ester
EC/list number: 688-147-2

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 ***28 August 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. In vivo genetic toxicity study (triggered by Annex VII, Section 8.4., column 2): Transgenic rodent somatic and germ cell gene mutation assay (test method: OECD TG 488) in transgenic mice or rats, oral route on the following tissues: liver and glandular stomach; duodenum must be harvested and stored for up to 5 years. Duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive; OR In vivo mammalian alkaline comet assay (test method: OECD TG 489) in rats, or if justified, in other rodent species, oral route, on the following tissues: liver, glandular stomach and duodenum.

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

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

4. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

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

Information required depends on your tonnage band

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

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

How to comply with your information requirements

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

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

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

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

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

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

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. In vivo mammalian alkaline comet assay or Transgenic rodent somatic and germ cell gene mutation assays

1 Further mutagenicity studies must be considered under Annex VII, Section 8.4., Column 2, in case of a positive result in an in vitro gene mutation study in bacteria.

1.1. Triggering of the information requirement

2 Your dossier contains positive results for in vitro gene mutation study in bacteria (2014, 2004) and for in vitro gene mutation study in mammalian cells (2014) which raise the concern for gene mutations.

3 Therefore, the information requirement is triggered.

1.2. Assessment of the information provided

1.2.1. No in vivo study provided

4 The Guidance on IRs and CSA, section 7.7.6.3 states that following a positive result in an in vitro test, "adequately conducted somatic cell in vivo testing is required to ascertain if this potential can be expressed in vivo. In cases where it can be sufficiently deduced that a positive in vitro finding is not relevant for in vivo situations (e.g., due to the effect of the test substances on pH or cell viability, in vitro-specific metabolism: see also Section R.7.7.4.1), or where a clear threshold mechanism coming into play only at high concentrations that will not be reached in vivo has been identified (e.g., damage to non-DNA targets at high concentrations), in vivo testing will not be necessary.".

5 However, no data from an in vivo somatic cell genotoxicity study is available in the dossier. Moreover, you did not provide any considerations explaining that the genotoxic potential of the substance cannot be expressed in vivo, based e.g., on lack of relevance for in vivo situations or the existence of threshold mechanism.

6 ECHA considers that an appropriate in vivo follow up genetic toxicity study is necessary to address the concern identified in vitro.

In the comments to the draft decision, you agree to perform the requested study. You state that "[a] *testing proposal will be submitted to ECHA as soon as possible after ECHA will issue the final decision of the CCH*". Note that submitting such testing proposal is unnecessary and will be regarded as inadmissible (https://echa.europa.eu/regulations/reach/evaluation/examination-of-testing-proposals). By this decision you are already requested the information as specified in the following.

1.3. Test selection

7 According to the Guidance on IRs & CSA, Section R.7.7.6.3, either the in vivo mammalian alkaline comet assay ("comet assay", OECD TG 489) or the transgenic rodent somatic and germ cell gene mutation assay ("TGR assay", OECD TG 488) are suitable to follow up a positive in vitro result on gene mutation.

1.4. Specification of the study design

1.4.1. Comet assay

8 In case you decide to perform the comet assay, according to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified (OECD TG 489, paragraph 23).

9 Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

10 In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

1.4.1.1. Germ cells

11 You may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other aforementioned tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells in the comet assay, you should consider analysing the slides prepared with gonadal cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

1.4.2. TGR assay

12 In case you decide to perform the TGR assay, according to the test method OECD TG 488, the test must be performed in transgenic mice or rats.

13 Also, according to the test method OECD TG 488, the test substance is usually administered orally.

14 Based on OECD TG 488, you are requested to follow the 28+28d regimen, as it permits the testing of mutations in somatic tissues and as well as in tubule germ cells from the same animals.

15 According to the test method OECD TG 488, the test must be performed by analysing tissues from liver as slowly proliferating tissue and primary site of xenobiotic metabolism, from glandular stomach and duodenum as rapidly proliferating tissue and site of direct contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for mutagenicity at the site of contact in the gastro-intestinal tract. However, duodenum must be stored (at or below −70 ºC) until the analysis of liver and glandular stomach is completed; the duodenum must then be analysed only if the results obtained for the glandular stomach and for the liver are negative or inconclusive.

16 In your comments on the draft decision, you state that you intend to conduct and OECD TG 488. You specify that the test will be performed in transgenic rats the test substance will be administered orally, using the new 28+28d regimen. ECHA agrees that this in line with the above specifications.

1.4.2.1. Germ cells

17 You may consider collecting the male germ cells (from the seminiferous tubules) at the same time as the other tissues, to limit additional animal testing. According to the OECD 488, the tissues (or tissue homogenates) can be stored under specific conditions and used for DNA isolation for up to 5 years (at or below −70 ºC). This duration is sufficient to allow you or ECHA to decide on the need for assessment of mutation frequency in the collected germ cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

2. Short-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

19 You have provided a short-term toxicity study on aquatic invertebrates (2014) with the Substance

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the information requirement

20 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

21 Reporting of the methodology and results

a) the test design is reported (*e.g.* number of replicates);
b) the test procedure is reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel, age of Daphnia at the start of the test, test temperature);
c) the methods used to prepare stock and test solutions is reported;
d) the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;
e) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported;
f) 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.

22 Your registration dossier provides an OECD TG 202 study showing the following:

23 Reporting of the methodology and results

a) on the test design, you have not specified the number of replicates;
b) on the test procedure, you have not specified the composition of the test medium, the loading in number of Daphnia per test vessel, the age of Daphnia at the start of the test and the test temperature;
c) the methods used to prepare stock and test solutions is not reported;
d) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;
e) the dissolved oxygen and pH measured at least at the beginning and end of the

test is not reported;

f) on the analytical method adequate information, i.e. performance parameters of the method (i.e. specificity, recovery efficiency, precision, limits of determination and quantification), are not reported and the results of the analytically determined exposure concentrations are not provided.

24 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically,

- the test design and test procedure are not reported in sufficient detail and it is not possible to confirm the requirements of the test guideline and thereafter the validity of the study;
- the methods to prepare stock and test solutions are not reported and especially for substances difficult to test, the preparation methods are critical to report that the validity of the methods can be confirmed;
- the number of immobilised daphnids is not reported in detail and assessment of the effective concentrations cannot be done without detailed reporting of the immobility observations during the test;
- as dissolved oxygen concentration and pH are not reported at the beginning and and at the end of the test, the suitability of the abiotic conditions during the test cannot be confirmed to follow principles of the test guideline;
- the performance parameters of the analytical method are not reported in detail and it is not possible to conclude on the reliability of the measured test material concentrations when e.g. limit of quantification is not provided.
- the results of the analytical monitoring are not provided as measured values (raw data) and the current reporting detail does not allow e.g. statistical assessment of the measured values.

25 In your comments to the draft decision, you indicate that you will provide "*the missing information on methodology and results to fulfil the information requirements*". However, you have not provided this information in the dossier under evaluation and/or your comments and therefore ECHA cannot currently assess the validity of this study.

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

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

2.3. Study design and test specifications

28 The Substance is difficult to test due to the surface tension of 48.8 mN/m. OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

30 You have provided a study on toxicity to freshwater algae (2014) with the Substance;

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the information requirement

31 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 since the substance is difficult to test as the surface tension is 48.8 mN/m (Article 13(3) of REACH). Therefore, the following specifications must be met:

32 Reporting of the methodology and results

a) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);
b) the methods used to prepare stock and test solutions are reported;
c) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported. Algal biomass is normally determined based on dry weight per volume, or alternatively as cell counts or biovolume using microscopy or an electric particle counter. If an alternative method is used (*e.g.* flow cytometry, *in vitro* or *in vivo* fluorescence, or optical density), a satisfactory correlation with biomass must be demonstrated over the range of biomass occurring in the test;
d) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
e) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;
f) 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.

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

34 Reporting of the methodology and results

a) on the test conditions, you have not specified composition of the test medium;
b) on the test procedure, you have not specified the methods used to prepare stock and test solutions;
c) the method used to determine algal biomass is not reported;
d) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
e) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported;
f) on the analytical method adequate information, i.e. performance parameters of the method, is not reported and the results of the analytically determined exposure concentrations are not provided.

35 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically,
    - you have not provided adequate information on the test conditions and test procedure. Therefore, it is not possible to verify whether the test was

conducted under conditions that are consistent with the requirements of the OECD TG 201;
- the method used to determinate algal biomass is not described and the suitability of the method for algal biomass determination cannot be confirmed;
- in the absence of tabulated data on the algal biomass determined daily for each treatment group, it is not possible to conduct an independent assessment as whether the validity criteria of the test guideline were met;
- normal appearance and healthiness of the inoculum culture are not reported and therefore, it is not possible confirm that the algae were in sufficiently good condition for the test;
- the analytical method is not reported in detail and therefore, it is not possible to assess and confirm that the method had adequate performance capacity for analysis of the test material concentration in the test medium. Similarly, the results of the analytical measurements were not reported in detail and it is not possible confirm that the reported test concentration results are reliable.

36 In your comments to the draft decision, you indicate that you will provide "*the missing information on methodology and results and thus information requirements will be fulfilled*". However, you have not provided this information in the dossier under evaluation and/or your comments and therefore ECHA cannot currently assess the validity of this study.

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

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

3.3. Study design and test specifications

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

4. Ready biodegradability

40 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

4.1. Information provided

41 You have provided a ready biodegradability screening study (2014) with the Substance.

4.2. Assessment of information provided

4.2.1. The provided study does not meet the information requirement

42 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

43 Technical specifications impacting the sensitivity/reliability of the test

a) measurements of O_2 uptake in the test suspensions and inoculum blanks are done in parallel;

44 Reporting of the methodology and results

b) the test material is reported to be the sole source of added organic carbon;
c) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
d) the test conditions (e.g. mineral medium, temperature and pH) are reported;
e) the results of measurements at each sampling point in each replicate is reported in a tabular form;
f) the calculation of the ThOD is described and justified.

45 Your registration dossier provides an OECD TG 301F study showing the following:

46 Technical specifications impacting the sensitivity/reliability of the test

a) measurements of O_2 uptake in the test suspensions and inoculum blanks were not done in parallel;

47 Reporting of the methodology and results

b) the test material is not reported to be the sole source of added organic carbon;
c) the source of the inoculum, its concentration in the test (including suspended solids and bacterial cells / mL) and any pre-conditioning treatment are not reported;
d) the used mineral medium, the test temperature and pH are not reported;
e) the results of measurements (i.e. raw data) at each sampling point in each replicate is not reported in a tabular form;
f) the calculation of the ThOD is not described.

48 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the test procedure did not contain inoculum blanks and as the oxygen uptake by the inoculum is not known, the measured oxygen uptake values cannot be corrected for the true oxygen uptake by the test material degradation. As a result, the reported results cannot be confirmed to be reliable.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically,
  - the test material is not reported to be the sole source of added carbon and the measured oxygen consumption cannot be confirmed to be the result of test material degradation only;
  - the source of the inoculum, its concentration and any pre-conditioning treatment are not reported and it is not possible to confirm that the inoculum source, concentration and pre treatment followed the requirements of the test guideline;
  - the mineral medium, test temperature and pH were not reported and they cannot be confirmed to be in line with test guideline requirements.
  - the measurements at each sampling point and the calculation of the ThOD were not reported and it is not possible to assess the reliability of the reported test results.

49 Therefore, the requirements of OECD 301F are not met.

50 In your comments to the draft decision, you indicate that you will provide "*There is no need to repeat the test. The missing information on methodology and results will be provided for the existing study to fulfil the information requirements*". However, you have not provided this information in the dossier under evaluation and/or your comments and therefore ECHA cannot currently assess the validity of this study.

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

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 16 June 2021.

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

ECHA took into account your comments and did not amend 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
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

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

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

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

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

1.2. Test material

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

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

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

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

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

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

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

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