~~Confidential~~

Helsinki, 14 March 2022

Addressees
Registrant(s) of CEM JS 28510-23-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
17/10/2016

Registered substance subject to this decision ("the Substance")
Substance name: 2,2-dimethylpropane-1,3-diyl 2-ethylhexanoate
EC number: 249-060-1
CAS number: 28510-23-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***20 December 2024***.

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

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

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

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

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats

2. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity

3. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to VIII of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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

[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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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

Grouping of substances and read-across approach

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 (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. Predictions for toxicological properties

You read-across between the structurally similar substances,
(i) 2-ethylhexanoic acid (EC No. 205-743-6)
(ii) (3-[(2-ethylhexanoyl)oxy]-2,2-bis{[(2-ethylhexanoyl)oxy]methyl}propyl 2-ethylhexanoate) (EC No. 230-743-8)
as source substances and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties:

(i) Source substance (i): *"Based on the chemical structure of the EHA-esters it can be assumed, that they may undergo enzymatic hydrolysis of the ester bond(s) after human intake. The potential resulting products would be the corresponding alcohol and 2-ethyl hexanoic acid (2-EHA), which is legally classified as Category 2 reproductive toxicant ("Suspected of damaging fertility or the unborn child"). As no data for the EHA-ester regarding reproductive/developmental toxicity were available, the risk assessment of these substances have to be attributed to 2-EHA (as a worst case scenario)".*

(ii) Source substance (ii): *"substances are considered to be similar on the basis of the structural similar properties and/or activities. The available endpoint information is used to predict the same endpoints for 2,2-dimethylpropane-1,3-diyl 2-ethylhexanoate (CAS No. 28510-23-8)".*

ECHA understands that you predict the properties of the Substance using a read-across

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

hypothesis which, for source substance (i) is based on the formation of common (bio)transformation products and for source substance (ii) assumes that different compounds have the same type of effects. The properties of your Substance are for source substance (i) predicted based on a worst-case approach and for source substance (ii) predicted to be quantitatively equal to those of the source substance.

In your dossier you refer to a read-across justification document in IUCLID Section 13. However, no separate documentation was found in that section.

ECHA notes the following shortcoming(s) with regards to prediction(s) of toxicological properties.

Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[4]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis for source substance (ii) is that the structural similarity between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar human health properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological property, based on recognition of the structural similarities and differences between the source substance (ii) and your Substance.

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[5]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include toxicokinetic information on the formation of the common compound, supporting information/bridging studies to compare properties of the

[4] *Guidance on information requirements and chemical safety assessment*, Chapter R.6: QSARs and grouping of chemicals.
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

Substance and source substances and information to confirm your claimed worst-case prediction.

a) Read-across from source substance (i)

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, information characterising the rate and extent of the (bio)transformation of the Substance and of the source substance(s) is necessary to confirm the formation of the proposed common (bio)transformation product and to assess the impact of the exposure to the parent compounds.

However, you have not provided any experimental information, about the (bio)transformation of the Substance nor the source substance to support your claims regarding formation of a common compound.

In the absence of this information, you have not provided supporting evidence establishing that the proposed common (bio)transformation product is formed as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Missing supporting information to substantiate worst-case consideration

As indicated above, your read-across hypothesis is based on the assumption that the source substance (i) constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

You have not provided any bridging studies (e.g. studies with repeated dosing) with the Substance or other adequate information on the Substance allowing to compare the properties of the Substance and of the source substance. Thus, the data set reported in the technical dossier does not include such relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

b) Read-across from source substance (ii)

Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances [the Substance and source substance (ii)] 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 substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

You have not provided any bridging studies (e.g. studies with repeated dosing) with the Substance or other adequate information on the Substance allowing to compare the properties of the Substance and of the source substance. Thus, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

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

B. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

2. Assessment of your exposure-based adaptation under Annex XI, Section 3.

You seek to adapt the following standard information requirements by applying an exposure-based adaptation in accordance with Annex XI, Section 3.2(a):

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

You have provided an adaptation in Sections 7.5.1, 7.8.1 and 7.8.2 of your dossier, and you conclude that "*As required under Regulation (EC) No. 1907/2006, Annex XI, 3.2 (a)(ii) and in a worst-case assumption, DNELs were derived […] and applied to derive Risk Characterisation Ratios (RCRs). As required under Regulation (EC) No. 1907/2006, Annex XI, 3.2 (a)(iii), the RCRs were << 1, showing that exposures are always well below the derived DNEL. The developed exposure scenarios demonstrating and documenting the fulfilment of the conditions mentioned above are provided in the Chemical Safety Report*"

ECHA has evaluated the above information under the rules set in Annex XI, Section 3. Substance-tailored exposure-driven testing.

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a), (b) or (c) shall be met. In particular:

- 3.2 (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled, where two conditions are that
  - i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
  - ii. a suitable DNEL can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and

We have assessed this information and identified the following issue(s):

i) Exposure assessment

REACH Annex XI 3.2 specifies that in all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I. According to ECHA Guidance Chapter R.5: Adaptation of information requirements (version 2.1 December 2011) in order to justify for a certain endpoint the omission of the standard information requirement, a high level of confidence is needed to demonstrate *no or no significant exposure* or *no release*.

You have identified numerous uses for the Substance, but you have created no exposure scenarios in the CSR. The CSR does not contain a chemical risk assessment covering all relevant exposures of the entire life-cycle of the substance subject to this decision.

Therefore, this condition is not fulfilled.

ii) DNEL derivation

For systemic effects, you have derived a DNEL based on a non-guideline one-generation study with the source substance EC 205-743-6. As explained in Section 1. of this Appendix, your read-across adaptation is rejected.

Therefore, this condition is not fulfilled.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3.

Therefore your adaptation is rejected, and the information requirement is not fulfilled.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Ready biodegradability

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

You have provided the following studies on the Substance:

i. A key study: an OECD TG 301B study; 2010
ii. A second key study: an OECD TG 301B study; 2012
iii. A supporting study: an OECD TG 301B study; 1995

We have assessed this information and identified the following issues:

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:

Common to all OECD 301

- The difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window is ≤ 20%;

OECD 301B

- For OECD 301B, the inorganic carbon content (IC) of the test material suspension in the mineral medium at the beginning of the test is < 5% of the total carbon (TC);

Common to all OECD 301

- The test duration is normally 28 days. This duration can be prolonged up to a maximum of 60 days. Prolongation of the test duration is not appropriate in case of late acceleration of biodegradation as it is likely to reflect an adaptation of the microorganisms (ECHA Guidance R.7b, Section R.7.9.4.1: Data on degradation/biodegradation).

OECD 301B

- The concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel.;
- The pH is adjusted to 7.4 ± 0.2;
- The source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
- The test temperature is reported;
- The methods of preparation of test solutions/suspensions is reported;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;

OECD 301B only

- For OECD 301B, the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported;

<u>On study i. above, you report</u>

OECD 301B

- The pH is adjusted to 7.6 - 8.1.

<u>Additionally, you have failed to report the following data necessary to assess the reliability and validity of the study</u>:

OECD 301B
- The concentration of the inoculum (bacterial cell density in the test vessel);

OECD 301B only
- The inorganic carbon content (IC) and total carbon content (TC) of the test substance suspension in the mineral medium at the beginning of the test.

Therefore, the applied pH adjustment is critical methodological deficiency affecting the reliability of the test results because it may result in over/underestimation of the results.

Further, in the absence of the required reporting information, we are not in a position to conduct an independent assessment of the validity and reliability of study i.

On study ii. above, you report:
Common to all OECD 301
- The difference of extremes of replicate values of the removal of the test material at day 27 was 24%;

Common to all OECD 301
- The reported test duration was 84 days.

Further to this, late acceleration of biodegradation was observed: at day 55, the average biodegradation of the test substance (mean value of Bottles A and B) is 57%.

Therefore, one of the validity criteria is not met.

Further, the test duration and the consequent late acceleration are critical methodological deficiencies affecting the reliability of the test results for study ii because they may result in overerestimation of the measured parameter.

On study iii. above, you report: "Original report not available and documentation insufficient for assessment."

You have failed to report the following data related to methodology and results:
The source of the inoculum, its concentration in the test and any pre-conditioning treatment;
- The test temperature;
- The methods of preparation of test solutions/suspensions;
- The results of measurements at each sampling point in each replicate in a tabular form;

OECD 301B only
- The inorganic carbon content (IC) and total carbon content (TC) of the test substance suspension in the mineral medium at the beginning of the test.

Therefore, we are not in a position to conduct an independent assessment of the reliability of study iii.

On this basis, the information requirement is not fulfilled.

Study design

In the technical dossier, you report that the water solubility of the Substance is estimated to be lower than 0.01 mg/L, its vapour pressure is estimated to be 0.000144 Pa, and the Log Koc value is above 4.

Appropriate test guidelines are selected based on the applicability domain of the test guidelines and properties of the substance. In this case, relevant properties reported in the

technical dossier are the Substance's low water solubility, low vapour pressure and high potential for adsorption (ECHA Guidance Chapter R.7b, Section 7.9. and OECD TG 301 and OECD TG 310). For adsorptive, poorly soluble, and non volatile substances test guidelines OECD TG 301 B, C, D and F, as well as OECD TG 310 apply.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided (i) an adaptation according to Annex XI, Section 1.5, and (ii) an adaptation according to Annex XI, Section 3 in your dossier. In support of your adaptation you provided one study:

- One generation study (1993) with the source substance EC 205-743-6.

We have assessed this information and identified the following issue(s):

As explained in the Appendix on Reasons common to several requests, your read-across and exposure-based adaptations are rejected.

Based on the above, the information you provided does not fulfil the information requirement.

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407) (as explained above under section 3.), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[6]

Information on study design

A study according to the test method EU B.64/OECD TG 422 must be performed in rats with oral[7] administration of the Substance.

For further information on the study design see request 2. below.

2. Short-term repeated dose toxicity (28 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement under Annex VIII to REACH. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier. In support of your adaptation you provided one study:

- Combined repeated dose/reproductive toxicity screening study (OECD TG 422, 2005) with the source substance EC 230-743-8.

We have assessed this information and identified the following issue(s):

[6] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)
[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

As explained in the Appendix on Reasons common to several requests, your read-across adaptation is rejected.

Based on the above, the information you provided does not fulfil the information requirement.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/ developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[8]

Information on the design of the study to be performed

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a liquid of very low vapour pressure.

Therefore the study must be performed according to the OECD TG 422, in rats and with oral administration of the Substance.

3. Long-term toxicity testing on fish

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

You have provided an OECD TG 203 study on fish but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

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 (ECHA Guidance R.7.8.5).

You have provided information which indicates that the Substance is poorly water soluble:
In the study conducted according to method EU A.6. that you provided in Section 4.8 of the technical dossier, the Substance has a water solubility lower than 0.01 mg/L.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

You have omitted this information and you provided the following justification:

- Considerations related to minimisation of vertebrate animal testing as well as

[8] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)

presumed differences in species sensitivity based on the findings of a long-term invertebrate test; a corresponding reference to Article 25(1) of REACH.

We have assessed this information and identified the following issue:

A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

On this basis, the information requirement is not fulfilled.

Study design

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

The Substance is difficult to test due to the low water solubility (<0.01 mg/L). OECD TG 210 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 210. 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.

Appendix C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[9].

B. Test material

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

1. Selection of the Test material(s)

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

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[10].

[9] https://echa.europa.eu/practical-guides
[10] https://echa.europa.eu/manuals

Appendix D: 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 7 December 2020.

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

In your comments on the draft decision, you requested an extension of the deadline to provide information from 24 to 30 months from the date of adoption of the decision. As a justification for your request you provided a document from a testing laboratory.

On this basis, ECHA has extended the deadline to 30 months.

ECHA took into account your comments and amended the deadline.

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.

Due to a cease of manufacture, the following four requests have been removed from the decision: Sub-chronic toxicity study (90-day); Pre-natal developmental toxicity study; Effects on soil micro-organisms; Long-term toxicity on terrestrial plants.

Appendix E: List of references - ECHA Guidance[11] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[12]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[14]

[11] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[12] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[13] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix F: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.