EUROPEAN CHEMICALS AGENCY

Helsinki, 19 May 2020

Addressees
Registrants of CEM JS 68130-53-0 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
5 November 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Decanoic acid, mixed esters with heptanoic acid, octanoic acid and trimethylolpropane
EC number: 268-596-7
CAS number: 68130-53-0

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***24 February 2023***.

A. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490) with the Substance;

B. Requirements applicable to all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rabbit), oral route with the Substance.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route with the Substance, specified as follows:

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity); and
   - Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning.

   You must report the study performed according to the above specifications. Any expansions of the study design must be scientifically justified.

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

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 Christel Schilliger-Musset, 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 general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)
- Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach 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.

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

In your registration dossier you have formed a group (category) of '*polyol esters (with pentaerythritol or trimethylolpropane)*'. You have provided a read-across justification document in IUCLID Section 13.

You provide the following reasoning for the grouping the substances:
"*1) a common functional group and*
2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals.".

You define the applicability domain of the category as follows: "*The fatty acid components contain chains from C5 to C18, including C16 to C18 (including unsaturated). Although the range of carbon atom chain lengths is broad, the physico-chemical properties of the substances are similar.*".

A. Predictions for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties: "*These substances are esters of polyols and have a common metabolic fate that involves stepwise hydrolysis to fatty acids and polyols (pentaerythritol, or trimethylolpropane).*" and "*The results of repeated dose toxicity studies and a developmental toxicity study with CAS 11138-60-6 do not indicate any significant adverse effects. Based on the negative results of the available in vitro genetic toxicity studies, it can be concluded that target substance is not genotoxic.*".

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

hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance (target substance) are predicted to be quantitatively equal to those of the source substance.

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

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*"[2]. 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 other category members. Supporting information must include toxicokinetic information on the formation of the common compounds.

Missing information on the formation of common compound

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

You have not provided any experimental data or other adequate and reliable information, neither about the hydrolysis of your Substance nor about the hydrolysis of the source substance.

In the absence of this information, you have not provided supporting evidence establishing that the proposed common hydrolysis 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 information on the impact of non-common compounds

As indicated above, your read-across hypothesis is based on the (bio)transformation of the category members to a common compound(s). In this context, exposure to the category members may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

You have not provided information characterising the exposure to the non-common compounds resulting from exposure to the target and source substance. No experimental data or other adequate and reliable information addressing the impact of exposure to these non-common compounds is included in the documentation of your read-across approach.

In the absence of such information, you have not established that a reliable prediction of the property under consideration of the target substance can be derived on the basis of your

[2] ECHA Guidance R.6, Section R.6.2.2.1.f

read-across hypothesis. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Relevance of the supporting information

According to the ECHA Guidance[3], "*it is important to provide supporting information to strengthen the rationale for the read-across approach*. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals".

In order to support your claim that the substances included in the category have similar properties for the endpoint under consideration in the read-across approach, you have referred to repeated dose toxicity studies on the target substance, pre-natal developmental toxicity studies in rat (oral, target substance; dermal, analogue substance) as well as *in vitro* gene mutation study in bacteria and *in vitro* cytogenicity study.

The studies provided do not inform of the relevant properties of the target substance. These studies are irrelevant for the following reasons:

- For *in vitro* gene mutation study in bacteria and *in vitro* cytogenicity study, these studies do not inform on the mutagenic properties of the category members in mammalian cells.
- For pre-natal developmental studies in rat, these studies do not provide information on pre-natal developmental effects in rabbit.
- For Extended one-generation reproductive toxicity study, there is no data for the relevant key parameters that would meet the requirements of OECD TG 443 as specified in REACH.

B. Conclusions on the grouping of substances and 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.

[3] ECHA Guidance R.6, Section R.6.2.2.1.f

Appendix A: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Your dossier contains negative results for both an *in vitro* gene mutation test in bacteria and an *in vitro* cytogenicity study. Therefore, the information requirement is triggered.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained above in Appendix on general considerations, your grouping and read-across approach is rejected.

Therefore, the information requirement is not fulfilled. To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

In your comments which are provided on behalf of the co-registrants, you agree to conduct the requested OECD TG 490 study with the Substance.

Appendix B: Reasons for the requests to comply with Annex X of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier at a tonnage abve 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to REACH.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have provided an adaptation according to Column 2, referring to low toxicity.

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

According to Annex X, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, including:

1. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
2. that there is no or no significant human exposure.

In your adaptation justification, you consider that "*The substance is a polyol ester, and is considered to be part of a group of polyol esters that are all of low toxicological activity*". ECHA understands that you intend to fulfil the above-mentioned criteria with information provided for this group of substances.

Furthermore, you refer to studies conducted with the Substance, i.e. a pre-natal developmental toxicity study and a repeated dose toxicity study (90-day) which do not show adverse effects on development or toxic effects to reproductive organs.

Your grouping and read-across approach is rejected as explained above in Appendix on general considerations.

Your adaptation and the read-across justification state that "*The polyols do not accumulate in the body but are readily excreted via urine.*" However, you have not provided any toxicokinetic data to prove that there is no systemic absorption. On the contrary, in the dossier and CSR you refer to information on the Substance and a read-across substance (pentaerythritol ester, tetrasubstituted), concluding that "*The results of an oral repeated dose toxicity study indicate that decanoic acid, mixed esters with heptanoic acid, octanoic acid and trimethylolpropane may be absorbed orally in the rat.*" Therefore you have not proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure.

The uses of the Substance indicate that there is significant human exposure, as the Substance is intended to be used by professionals and consumers. Therefore, you did not prove that that there is no or no significant human exposure. Therefore, your adaptation is rejected.

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

Information on study design

Species

The test in the first species was carried out by using a rodent species (rat). A PNDT study according to the test method OECD TG 414 must be performed in rabbit as preferred non-rodent species.

Administration route

The study shall be performed with oral[4] administration of the Substance.

In your comments which are provided on behalf of the co-registrants, you agree to conduct the requested OECD TG 414 study in a second species (rabbits) with the Substance.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement under Annex X to REACH. Furthermore Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

You have provided an adaptation in IUCLID section 7.8.1 referring to low toxicity: *"REACH Annex IX, 8.7 column 2, which states that a reproductive toxicity study does not need to be conducted if the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure and there is no or no significant human exposure. The results of the available read across studies indicate that the substances are of low toxicity. Review of the repeat dose and developmental data on the analogues indicates that there are negligible effects associated with subchronic dosing of the substances. Furthermore, there is not considered to be significant exposure to this non-hazardous substance during its intended uses as a component of a lubricant that would result in exposures, which could cause a significant toxic effect. Therefore, the conduction of a reproductive toxicity study is scientifically not justified."*

In your comments to the draft decision which are provided on behalf of the co-registrants, you acknowledge that this endpoint is currently not present within the dataset. You refer to the possibility to adapt this information requirement under Annex X, 8.7., Column 2, third indent, based on low toxicity of the Substance and you provide considerations on each of the criteria set out in Annex X, Section 8.7., Column 2, third indent.

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

According to Annex X, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity.
This needs to be demonstrated with three concomitant criteria, including:

1. that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
2. that there is no or no significant human exposure.

On the criterion of '*it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure*', you state in your comments to the draft decision that '*No specific data exists for this endpoint*' and '*It is not anticipated that the substance will be absorbed*' with a reference to Chapter R.7C –Endpoint specific guidance, Table R.7.12-1. ECHA notes that you have not provided specific data to support the claim of no systemic absorption of the Substance and you state that "*Given that there are no effects noted, it is not possible*

[4] ECHA Guidance R.7a, Section R.7.6.2.3.2.

to determine if systemic absorption has occurred or not of the substance". However, you have reported test substance related alterations in the OECD TG 408 study, which are indicative of systemic absorption.

Regarding the second criterion '*there is no or no significant human exposure*', you are referring in your comments to Annex XI section 3.2(a) as a proxy for demonstrating no significant exposure as part of Annex X, Section 8.7., Column 2, third indent. ECHA notes however that in your registration dossier you have not provided a justification based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I. Consequently, ECHA cannot assess whether the results of the exposure assessment demonstrate no significant human exposure.

Additionally, regarding your reference to Annex XI 3.2(a), ECHA points out that the adaptation requires that a DNEL can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that the DNEL is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes. According to the footnote (1) of Annex XI 3.2(a)(ii), a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit an extended one generation reproductive toxicity study. The DNELs that you provide in your comments are based on existing data from developmental toxicity / teratogenicity studies and therefore, they cannot be used to omit an extended one generation reproductive toxicity study.

Furthermore, you refer in your comments to the third concomitant criterion of '*the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available*'). In this context, ECHA notes that there were minor test substance-related effects in the OECD TG 408 study, to which you also refer in your comments: '*On SD 92 (terminal necropsy), test substance-related alterations in clinical pathology parameters were minor*').

For these reasons and as further explained above under request B.1, the information in your dossier does not fulfil the criteria according to Annex X, Section 8.7, Column 2, third indent. Therefore, your adaptation is rejected.

In your comments, you also propose first to conduct a study according to OECD TG 421 to assess findings for fertility, and to serve as a dose range finding study for the subsequent OECD TG 443 study in case adverse effects are observed. You further propose to submit a dossier update to discuss the findings of the OECD TG 421 study with ECHA, and assess the requirement for an OECD TG 443 study via a further draft decision. You justify your proposal by stating that the existing information (OECD TG 408 and 414 in the rat with the Substance as well as OECD TG 414 with '*a close analogue*') as well as the future OECD TG 414 with the Substance in the rabbit did not and will not show effects at the highest dose levels, and that the OECD TG 421 study will allow for subsequent assessment of fertility. You also intend to update your justification for read-across.

ECHA notes that performing a study according to OECD TG 421 does not require a formal testing proposal to be accepted by ECHA. ECHA further notes that it cannot take future studies which '*will show no effects*', or any other future intentions, into account in decision-making.

Finally, you refer to animal welfare reasons to justify the omitting the OECD TG 443 study. ECHA notes that an OECD TG 421 study generates only limited information concerning reproductive performance. Moreover, a study according to OECD TG 443 is a standard information requirement under Annex X.

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

The specifications for the study design

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance[4]. In this specific case ten weeks exposure duration is supported by the lipophilicity of the Substance (logK_{ow} 9.66 at 20°C) to ensure that the steady state in parental animals has been reached before mating.

Therefore, the requested premating exposure duration is ten weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

Species and route selection

The study must be performed in rats with oral[5] administration.

Cohorts 1A and 1B

Cohorts 1A and 1B belong to the basic study design and must be included.

Extension of Cohort 1B

If the Column 2 conditions of 8.7.3., Annex X are met, Cohort 1B must be extended.

The extension is inter alia required, if the use of the registered substance is leading to significant exposure of consumers and professionals (column 2, first paragraph, lit. (a) of Section 8.7.3., Annex X) and

- if there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure (column 2, first paragraph, lit. (b), second indent of Section 8.7.3., Annex X).

The use of the Substance is leading to significant exposure of consumers and professionals because the Substance is used by professionals as lubricants and greases (PROCs 1, 8a, 8b, 10, 11, 13, 20) and consumers as lubricants and greases, including filling and draining of

[5] ECHA Guidance R.7a, Section R.7.6.2.3.2.

containers and enclosed machinery.

Furthermore, there are indications that the internal dose for the Substance will reach a steady state in the test animals only after an extended exposure. Specifically, the $logK_{ow}$ for the substance is above 4.5 indicating potential accumulation.

Therefore, Cohort 1B must be extended.

The F2 generation shall be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151[6]. It is recommended to aim to 20 litter per dose group in order to have similar statistical power for investigations than in P0 generation.

Further expansion of the study design

No triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and/or Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[7].

6 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2013)10&doclanguage=en

7 ECHA Guidance R.7a, Section R.7.6.

Appendix C: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 18 June 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

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

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 D: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

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

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

   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: 'How to report robust study summaries'[8].

4. Test material

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account 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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

   The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents".

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

In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

Technical reporting of the test material for UVCB substances

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[9].

5. List of references of the ECHA Guidance and other guidance/ reference documents[10]

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[11]

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.

[9] https://echa.europa.eu/manuals
[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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.

OECD Guidance documents[12]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[12] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.