EUROPEAN CHEMICALS AGENCY

Helsinki, 30 June 2020

Addressees
Registrants of Monopentaerythritol UVCB listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
18/05/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Monopentaerythritol tetraesters and dipentaerythritol hexaesters of 3,5,5-trimethylhexanoic, n-heptanoic, n-octanoic and n-decanoic acids
EC number: 939-415-5
CAS number: NS

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 ***5 October 2022***.

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

1. Long-term toxicity testing on aquatic invertebrates also requested at C 3. below (triggered by Annex VII, Section 9.1.1., column 2) with the Substance;

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

1. Long-term toxicity testing on fish also requested at C 4. below (triggered by Annex VIII, Section 9.1.3., column 2) with the Substance.

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

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

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

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 and VIII of REACH, if you have registered a substance at 10-100 tpa;
- 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;

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

When a study is required under several Annexes of REACH, the reasons are provided in the corresponding appendices of this decision. The registrants concerned must perform only one study and make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants in accordance with Article 53 of REACH.

The 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.

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

In accordance with Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. Long-term toxicity testing on aquatic invertebrates also requested at C 3. below (triggered by Annex VII, Section 9.1.1., column 2) with the Substance

Short-term toxicity testing on aquatic invertebrates is a standard information requirement of Annex VII of REACH. However, under Annex VII, section 9.1.1, column 2, a long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered instead of an acute test for poorly water soluble substances. Hydrophobic and poorly water soluble substances require longer time to reach steady-state conditions and the short-term tests may not give a true measure of toxicity for this type of substances.

Based on the available information provided in your technical dossier, the Substance is hydrophobic and poorly water soluble (log Kow >9 and water solubility expected to be <1 mg/L).

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the information provided in the Lead dossier for this endpoint, your comments to the draft decision, as well as the selection of the requested test and the test design are addressed in Appendix C, section 3.

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Appendix B: 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. **Long-term toxicity testing on fish also requested at C 4. below (triggered by Annex VIII, Section 9.1.3., column 2) with the Substance.**

Short-term toxicity testing on fish is a standard information requirement of Annex VIII of REACH. However, under Annex VIII, section 9.1.3, column 2, a long-term toxicity study on fish (Annex IX, Section 9.1.6) must be considered instead of an acute test for poorly water soluble substances. Hydrophobic and poorly water soluble substances require longer time to reach steady-state conditions and the short-term tests may not give a true measure of toxicity for this type of substances.

Based on the available information provided in your technical dossier, the Substance is hydrophobic and poorly water soluble (log Kow >9 and water solubility expected to be <1 mg/L).

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the information provided in the Lead dossier for this endpoint, your comments to the draft decision, as well as the selection of the requested test and the test design are addressed in Appendix C, section 4.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided three studies on analogue substances based on a read-across approach together with an adaptation statement:

i. An OECD TG 407 study (2015) with the analogue substance hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC no 613-848-7)

ii. An OECD TG 407 study (1995) with the analogue substance fatty acids, C5-10, esters with pentaerythritol (EC no 270-291-9)

iii. A 7-day range-finder study (2014), no guideline, with the analogue substance hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC no 613-848-7)

iv. An adaptation statement according to Column 2 of Annex IX, Section 8.6.2.

We have assessed this information and identified the following issues:

Evaluation of the provided studies

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others:

1. At least 10 female and 10 male animals should be used at each dose level (including control group), and
2. Dosing of the Substance daily for a period of 90 days until the scheduled termination of the study.

The two repeated dose oral toxicity studies (OECD TG 407) you provided, as well as the range-finder study, do not have the required exposure duration of 90 days as required in OECD TG 408, because you indicated an exposure duration of 28 days, and they were conducted with less than 10 animals per sex per test dose group. The statistical power of the information provided is not sufficient because it does not fulfil the criterion of 20 animals (10 males + 10 females) for each test group set in OECD TG 408.

Similarly the 7-day range-finder study lacks the required exposure duration and statistical power.

In your comments to the draft decision you state that "*as a result of the low toxicity profile identified in the 28-d study which identified no significant, potentially human-relevant, toxicological findings at dose levels up to and including 1000 mg/kg/day,* [redacted] *does not*

believe that a 90-d study is warranted as it would not significantly change the hazard profile of the substance or the overall risk assessment".

As indicated above, a study has to meet the requirements of OECD TG 408 to enable concluding whether the Substance has dangerous properties related to subchronic toxicity. You have not submitted any study that fulfils this information requirement, and it is therefore not possible to conclude on the hazard profile for subchronic toxicity for your Substance.

Evaluation of your Column 2 adaptation

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement, provided you fulfil the following (cumulative) criterion, including among others that there is no evidence of absorption in a 28-day 'limit test', particularly if it is coupled with limited human exposure.

You have submitted a repeated-dose (28-day) toxicity study (2015) hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester which provided evidence of systemic effects. Such evidence included, for example, an increase in the amount of intraepithelial hyaline droplets, an increase in the incidence and severity of foci of basophilic tubules and granular cast formation at the corticomedullary junction in the kidneys of males from all the treated groups. These findings indicate that the Substance is systemically available as a result of absorption in the organism, even if the consequences on the target organ themselves, the negative effects, may not be relevant for humans.

Therefore you have not met the criterion above and your adaptation is rejected.

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

Information on the design of the study to be performed (route/ species/ strain)

Following 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. The substance is a liquid with a very low vapour pressure further supporting the oral route of administration.

Therefore, the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided one key study and one supporting study using a read-across approach, together with an adaptation statement:

i. An OECD TG 414 study (2004) with the analogue substance 2,2-bis[(octanoyloxy)methyl]butyl decanoate (EC no 234-392-1),

ii. An OECD TG 421 (2015) with the analogue substance hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC no 613-848-7), and

iii. An adaptation statement referring to the the lack of effects observed in the OECD 421 study.

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

A. In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414.

You provide a "reproduction/ developmental toxicity screening test" (OECD TG 421)/ "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 421) with an analogue substance with an adaptation indicating that the OECD TG 421 study *"gave no cause for concern and no adverse effects on rat pup development were reported"*. Based on that information you conclude that no further studies are needed.

However, in the OECD TG 421 study structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414). Hence, no conclusion on lack of effects on pre-natal developmental toxicity can be drawn from the information provided. Therefore, your adaptation is rejected.

B. As provided in Annex XI, Section 1.5, you may adapt the information requirement, provided you fulfil all of the identified criteria, and submit a scientifically-supported justification.

You have provided an OECD TG 414 with an analogue substance and a read-across justification document in IUCLID Section 13.

For the endpoint pre-natal developmental toxicity you predict the properties of the Substance from the structurally similar source substance: 2,2-bis[(octanoyloxy)methyl]butyl decanoate (EC no 234-392-1).

You have provided the following reasoning for the prediction of toxicological properties: *"The read-across justification is based primarily on structural and chemical similarities (i.e., polyol esters) that result in "close commonalities" in physicochemical and toxicological properties."*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcomings with regards to the predictions of (eco)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 the source substance(s).

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

"Supporting information" must include supporting information, such as "bridging" studies, to compare properties of the Substance and source substances.

Furthermore, according to Annex XI, Section 1.5 there needs to be structural similarity between substances resulting in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties.

In your read-across justification document you address the structural differences between the Substance and of the source substance(s) indicating that *"The substance and analogues contain a polyhydroxy alcohol and at least one ester function. They have a similar number of ester functions (3 or 4), but with a range in length of the carboxylic acid function (C5-C10), and the extent of unsaturation of the carboxylic acid group. These structural differences are expected to result in a similar range of physicochemical properties, especially partition coefficient and water solubility, and their associated environmental fate and toxicological properties".*

You further conclude that *"Mammalian toxicity data for acute, repeated-dose and genetic toxicity support grouping of these substances. The high molecular weight (>500) of the fully esterified substance should limit uptake from the gastrointestinal tract, and thus similar toxicity is expected".*

In your comments to the draft decision you conclude that you *"believe that the read-across of the OECD414 study on the source substance to the substance is valid and that a new PNT study on the substance is not justified, would not alter the current hazard assessment of the substance for reproductive toxicity or impact on the overall risk assessment and would be contrary to ECHA's aim to avoid unnecessary animal testing."*
You base this conclusion on:

- The expected low absorption via dermal and oral routes both your Substance and the source substance; and

- that there is no indication from the acute toxicity or genotoxicity studies conducted on the substance and source substance of any relevant differences in toxicity that would highlight any concerns relating to branched chain rather than linear chain metabolites.

With regard the structural differences between the Substance and the source substance 2,2-bis[(octanoyloxy)methyl]butyl decanoate (EC no 234-392-1), ECHA notes that the latter is a linear fatty acid. You have not submitted any "bridging" studies or other information that could be used to compare the hazard profiles of your Substance and the source. Therefore you have not demonstrated, neither in your dossier nor in your comments, that the potential branched metabolite of your Substance, 3,5,5-trimethylhexanoate, does not display higher toxicity than the linear fatty acid which has been used as source substance for this endpoint.

In addition, the study according to OECD TG 414 submitted in your registration dossiers applies administration by the dermal route. There is no information, neither in your dossier nor in your comments, to demonstrate the rate of dermal absorption in relation to oral absorption, neither for the Substance nor for the source substance used. Hence, the dermal study provided may underestimate the pre-natal developmental toxicity of the Substance.

Therefore you have not demonstrated and justified that the properties of the source substance(s) and of the Substance are likely to be similar despite the observed structural differences.

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

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[3] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Long-term toxicity testing on aquatic invertebrates is a standard information requirement of Annex IX of REACH.

In your technical dossier, you have provided two studies for this endpoint:

i. Key study, OECD 211 ([redacted] 2014) with analogue substance hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC: 613-848-7, CAS: 65870-94-2);

ii. A supporting 15-day reproduction test ([redacted] 1996) with analogue substance decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate (CAS-No. 11138-60-6). You have flagged this result as not reliable.

We have assessed this information and identified the following issues:

Under Article 13(3) of REACH, testing must be conducted in accordance with the corresponding OECD test guideline or another recognised international test method.

The OECD test guideline 211 is preferred to cover this information requirement.

Paragraphs 45 to 50 and paragraph 60 of OECD test guideline 211 require as key parameter analytical monitoring of exposure concentration to be performed and reported in the test report. Effect concentrations must then be based on the measured values rather than nominal values unless the test concentrations were maintained within 20% of the measured initial concentrations throughout testing.

For the key study ([redacted] 2014), a water accomodated fraction (WAF) method was used to prepare loading rates of 1.0, 3.2, 10, 32 and 100 mg/L. You derived a 21 day No Observed Effect Loading Rate (NOELR) of 10 mg/L.

However, your robust study summary for this study also mentions that the chemical analyses (GC/MS) of the fresh and old test media samples at the three highest nominal loading rates of 10, 32 and 100 mg/L resulted in measured concentrations ranging from 0.00023 to 0.33 mg/L.

Your provided data clearly indicate that the measured concentrations did not remain within 80-120% of the nominal loading rates.

Therefore, the 21 day NOELR of 10 mg/L, which is based on nominal loading rates, does not meet the requirements of OECD test guideline 211.

You have provided information on measured concentrations only as a range of all measured values. However, you have not reported the corresponding measured concentrations for each individual nominal loading rates.

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

Therefore, the information you provided for the key study ([redacted]2014) is insufficient to re-calculate a NOEC that could meet the recommendations of OECD test guideline 211.

With regard to the supportive study ([redacted]1996), ECHA agrees with you that it is not reliable and that it must not be taken into account for the chemical safety assessment.

In your comments to the draft decision you state that reporting concentrations as nominal loading rate concentrations (WAFs) is both relevant and appropriate. However, your comments do not address the issues raised above. The NOELR you have derived based on nominal loading rate concentrations does not reflect the much lower concentrations actually measured in the medium, and therefore underestimate the toxicity of the test item considerably.

Therefore, the information you provided does not fulfil the information requirement and you must perform a long-term toxicity study on aquatic invertebrates with the Substance.

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Long-term toxicity testing on fish is a standard information requirement of Annex IX of REACH.

In your technical dossier, you have provided an OECD test guideline (TG) 204 study (Fish, Prolonged Toxicity Test: 14-day study) with analogue substance hexanoic acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC: 613-848-7, CAS: 65870-94-2). As a deviation from OECD TG 204, you have indicated that a 21-day exposure period was used.

Long-term toxicity testing must address sensitive life stages (e.g. juveniles, eggs, larvae) and investigate chronic effects. Under Annex IX, Section 9.1.6. of REACH, there are several options to meet the standard information requirements for long-term toxicity testing on fish:

- fish early-life stage (FELS) toxicity test (Annex IX, section 9.1.6.1. of REACH),
- fish short-term toxicity test on embryo and sac-fry stages (Annex IX, section 9.1.6.2. of REACH) or
- fish juvenile growth test (Annex IX, section 9.1.6.3. of REACH).

OECD TG 204 is neither of the options provided under Annex IX, Section 9.1.6. of REACH. In the OECD TG 204 study the mortality of adult fish was examined. Sensitive life stages are not addressed. Besides, mortality is not regarded as an endpoint sensitive enough to investigate chronic effects. Therefore, ECHA does not regard the study you provided as a long-term toxicity study in the meaning of Annex IX, Section 9.1.6. of REACH, despite prolongation from 14 to 21 days.

ECHA considers that the fish early-life stage (FELS) toxicity test (OECD test guideline (TG) 210) is the most appropriate to meet the information requirement. This test guideline covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth. Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of hydrophobic/poorly soluble substances, which are expected to cause effects under a longer-term exposure, or which require a longer period of time to reach steady state.

Therefore, you must apply OECD TG 210 when performing the test.

In your comments to the draft decision, you propose to adapt the information requirement by using a long-term fish study according to OECD TG 210 on analogue substance hexanoic

acid, 3,5,5-trimethyl-, 1,1'-[2-ethyl-2-[[(3,5,5-trimethyl-1-oxohexyl)oxy]methyl]-1,3-propanediyl] ester (EC: 613-848-7, CAS: 65870-94-2) (Chaowu, 2015). An abstract summary of this study is attached to your comments.

We have assessed this information and identified the following issues.

Paragraph 7 of OECD TG 210 requires that the test concentrations should be analytically measured for the test to be valid. Paragraph 24 of that test guideline further specifies that effect concentrations must be based on the measured values rather than nominal values if the test concentrations do not remain within 20% of the measured initial concentrations throughout testing.

In the study of [redacted] (2015) referred to in your comments, a water accomodated fraction (WAF) method was used to prepare loading rates of 10, 18, 32, 56 and 100 mg/L. From the abstract provided, it appears that these loading rates were not measured. It is indicated that they were all below the limit of quantification of the analytical method used for this test, i.e. 0.033 mg/L.

Based on the findings for the long-term toxicity study on aquatic invertebrates (see Appendix C, section 3), actual concentrations remaining in the test medium can be expected to be much lower than the nominal concentrations for the fish test from [redacted] (2015) as well. For the *Daphnia* test, it was possible to measure test concentrations by using an analytical method with a much better limit of quantification (0.11 µg/L). Therefore, the analytical method used for the fish test from [redacted] (2015) can be regarded as not sensitive enough. Similarly to the *Daphnia* test addressed in Appendix C, section 3, NOELR were based on nominal loading rate concentrations for the fish test of [redacted], 2015 and underestimate the toxicity of the test item.

Therefore, the information you provided in your dossier or in your comments does not fulfil the information requirement. You must perform a long-term toxicity study on fish with the Substance and according to OECD TG 210.

Appendix D: 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 17 January 2019.

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

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 E: 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'[4].

4. Test material

   Selection of the test material(s) for UVCB substances

   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*".

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

In order to meet this requirement, all the constituents/group of constituents of the test material used for each test must be identified as far as possible. For each constituent/group of constituents 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/group of 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" on the ECHA website[5].

5. List of references of the ECHA Guidance and other guidance/ reference documents[6]

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)[7]

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.

[5] https://echa.europa.eu/manuals
[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] 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[8]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

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

Appendix F: 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.