EUROPEAN CHEMICALS AGENCY

Helsinki, 15 May 2020

Addressee
Registrant of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
06/04/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Benzene, mono-C11-C13-branched alkyl derivatives
EC number: 810-801-4
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 ***23 May 2022***.

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

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

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

2. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: OECD TG 443) in Sprague Dawley rats, oral gavage 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);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation; and
   - Cohort 3 (Developmental immunotoxicity)

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

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.; test method OECD TG 210) with the Substance;

5. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method EU C.23./OECD TG 307) at a temperature of 12 °C with the Substance including degradation of each relevant constituent present in concentration at or above 0.1% (w/w);

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance including degradation of each relevant constituent present in concentration at or above 0.1% (w/w);

7. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method among those requested above (requests B.5 and B.6) with the Substance;

8. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method OECD TG 305) with the Substance.

ECHA has provided justification for these requests in several appendices:
- Appendix entitled "Reasons common to several requests" (where applicable);
- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you. In accordance with Articles 10(a) and 12(1) of REACH, the information specified in VII, VIII and IX of REACHi is required as you have registered a substance at 100-1000 tpa.

How to comply with your information requirements

To comply with your requirements you must submit the information required 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.

In addition, you should follow the recommendations and information provided in:
- the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes";
- the Appendix entitled "List of references".

The studies related to biodegradation and bioaccumulation (requests B.5 to B.8) are necessary for the assessment of the PBT potential. To determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance, you need to follow the guidance described in Appendix entitled "Requirements to fulfil when conducting new tests for REACH purposes", to determine the most appropriate testing sequence.

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.

Approved[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 Reasons common to several requests

(i) Assessment of your QSAR adaptations under Annex XI, Sections 1.3. and 1.2

You seek to adapt the information requirements for the following standard information requirements using data from Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3 or use QSAR predictions as part of a weight of evidence in accordance with Annex XI, Section 1.2:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5)
- Long-term toxicity testing on fish (Annex XI, Section 9.1.6)
- Soil simulation testing (Annex IX, Section 9.2.1.3)
- Sediment simulation testing (Annex IX, Section 9.2.1.4)
- Bioaccumulation in aquatic species (Annex IX, Section 9.3.2)

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

1. the substance falls within the applicability domain of the QSAR model;
2. adequate and reliable documentation of the applied method is provided; and
3. the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

You have not provided appropriate documentation for the QSAR predictions. You have provided QSAR predictions for constituents of the substance for the endpoint listed above in a report entitled [redacted] in Section 13.2 of your IUCLID dossier. However you have not included a QMRF and/or a QPRF in your technical dossier.

Therefore, ECHA cannot establish whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment.

Consequently, your adaptations according to Annex XI, Section 1.3. are rejected and additionally the QSAR predictions are not considered reliable information in support of a weight of evidence adaptation according to Annex XI, Section 1.2.

(ii) Assessment of your exposure-based adaptations under Annex XI, Section 3.

You seek to adapt the following information requirements in accordance with Annex XI, Section 3 (Substance-tailored exposure-driven testing):

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex XI, Section 9.1.6)
- Soil simulation testing (Annex IX, Section 9.2.1.3.)
- Sediment simulation testing (Annex IX, Section 9.2.1.4.)
- Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)
- Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

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:
  - 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 or a PNEC 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 or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
  - iii. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.
- 3.2(b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply; and/or
- 3.2(c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the described conditions are fulfilled.

You have provided the following justification for your adaptations:

- "*BAB is used* [as an intermediate and as a full substance] *only and solely under strictly controlled conditions. The registrant* [...] *advises against all uses and life-cycle stages, which are not used under strictly controlled conditions for the REACH Regulation*";
- "*The use and exposure characteristics of BAB mean that all relevant legal conditions are satisfied, particularly those legal conditions as set out in Section 3.2 Annex XI REACH, ensuring that: (i) there is no legal or scientific need to undertake further vertebrate animal testing particularly as regards Section 8.7.3 Annex IX/X; (ii) that testing on vertebrate animals can be avoided (Article 25 REACH) and that, given the use and exposure characteristics, undertaking further vertebrate animal testing, particularly for 8.7.3 purposes, would be to undertake vertebrate animal testing in breach of the "last resort" requirement (Article 25(1) REACH); (iii) that a requirement to require vertebrate animal testing vis-à-vis 8.7.3 would be disproportionate and not legally necessary or appropriate*";
- "*There is no relevant exposure to the environment. The registrant and the sole importer advise against all exposure/uses where there is, or would be, relevant exposure*";
- A document from two downstream users stating that BAB is used under strictly controlled conditions;
- A endpoint specific justification for the information requirement on extended one-generation reproductive toxicity which further specifies that:
  - "*BAB is a substance which is not incorporated in articles and that such use is advised against*";
  - "*the registrant and the importer confirm that there are no uses outside of, or inconsistent with, uses under strictly controlled conditions*";
  - "*a DNEL has been derived and a risk assessment conducted and assessed*" and

"any possible or hypothetical, exposure is, in any event, well below the DNEL".

We have assessed this information and identified the following issues:

A. As explained above, an adaptation according to Annex XI, Section 3 is only applicable to adapt the information requirement in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X. Therefore, it cannot be used to adapt the information requirement for:
   - Growth inhibition study aquatic plants in accordance to Annex VII, Section 9.1.2.

B. Regarding the criterion 3.2(a), you have not provided adequate and reliable documentation demonstrating the *"absence of or no significant exposure in all scenarios of the manufacture and all identified uses"* (i.e. condition 3.2(a)(i)). Furthermore as explained further below your dossier does not contain adequate information to derive DNELs and PNECs that relevant and appropriate to the information requirement to be omitted and for risk assessment (i.e. condition 3.2(a)(ii)). The reasons for the absence of adequate information to derive a relevant DNEL and PNEC are described under sections B.2., A.1 and B.3-B.4, respectively. Hence, you have not provided appropriate information to demonstrate that exposures are always well below the derived DNEL/PNEC (i.e. condition 3.2(a)(iii)). Therefore the conditions of criteria 3.2(a) of Annex XI, Section 3 are not fulfilled.

C. Regarding the criterion 3.2(b), you claimed SCC according to 18(4)(a) to (f). However you have reported that the Substance is used at industrial sites, as a dielectric fluid in electrical transformers: you report uses according to PROC 8b (Transfer of substance or mixture (charging and discharging) at dedicated facilities), PROC 9 (Transfer of substance or mixture into small containers) and PROC 20 (Use of functional fluids in small devices). This is not consistent with handling under strictly controlled conditions (SCCs). In particular, condition (a) as set out in Article 18(4) does not appear to be fulfilled because it has not been demonstrated that the substance is rigorously contained by technical means during its whole lifecycle. Therefore the conditions of criteria 3.2(b) of Annex XI, Section 3 are not fulfilled.

D. Regarding the criterion 3.2.(c) you stated that *"BAB is a substance which is not incorporated in articles and that such use is advised against"*, therefore we conclude that criteria 3.2(c) of Annex XI, Section 3 does not apply to the Substance.

E. Annex XIII, Section 2.1 of REACH specifies that the generation of additional information listed in Annex IX or X to REACH and required to conclude on the PBT/vPvB properties of the Substance may only be omitted if the conditions set out in Annex XI, Section 3.2(b) or (c) applies. In such case, the Substance must be considered as if it is a PBT/vPvB in the registration dossier.

   As explained above, the criteria 3.2(b) of Annex XI, Section 3 is not fulfilled and the criteria 3.2(c) of Annex XI, Section 3 is not applicable to the Substance. Therefore, your adaptation is rejected for the following endpoints as it is necessary to provide this information to fulfil the requirements of Annex XIII:
   - Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5).
   - Long-term toxicity testing on fish in accordance to (Annex XI, Section 9.1.6)
   - Sediment simulation testing (Annex IX, Section 9.2.1.4.)
   - Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

Based on the above, your exposure-based adaptations are rejected.

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

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3;
b. A statement that "*for a substance with very low water solubility* [...], *REACH guidance R7 Table R. 7.8-2 indicates that aquatic toxicity should be tested on non-pelagic (e.g. sediment) organisms preferentially*". This statement has been evaluated with regard to the provisions of Annex VII, Section 9.1.2., column 2.
c. A weight of evidence adaptation according to Annex XI, Section 1.2 based on the following sources of evidence:
    i. A category read-across including branched alkyl benzene (BAB) and linear alkyl benzene (LAB) substances;
    ii. A statement that the predicted lack of toxicity of the Substance "*is consistent with ECOSAR predictions*" and a report entitled "Data collection of QSAR estimations done for BAB (branched alkyl benzene)" including predicted 96h-EC50 for algae.

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your adaptation according to Annex XI, Section 3 is rejected

b. Statement on low solubility and aquatic toxicity test organisms

This information requirement can be adapted based on Annex VII, Section 9.1.2., column 2 if the Substance is highly insoluble in water. ECHA Guidance, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which no toxicity occur. It might be possible to decide on a case-by-case basis, that aquatic toxicity is unlikely to occur due to very low water solubility and unlikelihood to cross biological membranes. Supporting information may include the indicators used for low likelihood of a high bioaccumulation potential (ECHA Guidance, Figure R.11-4), for instance:

- physico-chemical indicators support hindered uptake due to large molecular size (e.g. D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- there are supporting experimental evidence of hindrance of uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

When such indicators are used in the context of triggering a derogation from toxicity testing on aquatic organisms however a cautious approach must be used. If it cannot be demonstrated that aquatic toxicity is unlikely to occur, the substance should be considered as "*poorly water soluble*", not as "*highly insoluble in water*".

To justify your adaptation you explain that the water solubility is "*0.8-2.6 µg/L for the main, C12-substituted fraction, once corrected by available experimental values of*

analogues" and you refer to ECHA Guidance R.7b, Table 7.8-2 to justify that sediment organisms should be tested preferentially. You have not provided any justification as why aquatic toxicity is unlikely to occur.

Table 7.8-2 of ECHA Guidance R.7b explains that water solubility in the low µg/L range could be used as a reason to significantly modify a standard test or to test non-pelagic organisms preferentially. However, it does not mandate testing in sediment organisms or justify adapting the information requirement for this endpoint. In the absence of a valid justification that aquatic toxicity is unlikely to occur, your adaptation is rejected.

c. Weight of evidence adaptation

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, normally a study performed according to OECD TG 201[2] must be provided. OECD TG 201 requires the study to investigate the following key parameter: inhibition of growth, expressed as the logarithmic increase in biomass (average specific growth rate) during the 72h exposure period.

The sources of information (i.) and (ii.) may provide relevant information on this key parameter.

However, the reliability of these sources of information is significantly affected by the following deficiencies:

A. 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 (addressed under

[2] ECHA Guidance R.7b, Section R.7.8.4.1

'Scope of the grouping'). 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.

In your registration dossier you have formed a group (category) of 'alkyl benzene' substances. You have provided a read-across justification document attached to a study record for this endpoint and in IUCLID Section 13.

You define the applicability domain of the category as follows: "*The category applies to BAB and alkyl benzenes with alkyl chain between 8 and 24 carbons*".

You have provided the following reasoning for the prediction of aquatic toxicity within the category: "*They show similar toxicological and ecotoxicological properties*" and "[...] *the acute aquatic toxicity (daphnia, algae and fish) do not show differences between several alkylbenzenes: LC50 or EC50 was > water solubility or > 1000 mg/L. Therefore, LC50 and EC50 for BAB should be considered to be > water solubility*".

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 prediction of toxicity to aquatic algae and cyanobacteria:

i) Characterisation of the group members

Annex XI, Section 1.5 of the REACH Regulation provides that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group.*"

According to the ECHA Guidance, "*in identifying a category, it is important that all potential category members are described as comprehensively as possible*", because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[3] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[4]

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

Your read-across justification document contains no compositional information for the members of your category, although you have defined the applicability domain of the category as *"alkyl benzenes with alkyl chain between 8 and 24 carbons"*. The category members are UVCBs including branched and/or linear alkyl of various carbon chain lengths. The degree of branching is not provided for the category members.

Without consideration of the distribution of the carbon chain length and degree of branching amongst category members, no qualitative or quantitative comparative assessment of the compositions of the different category members can be completed. Therefore, the category membership cannot be confirmed.

ii) *Omission of source study*

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should be included in the dossier in order to be assessed and to support the read-across justification. In addition they should:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3);
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

You refer to a growth inhibition study to aquatic plants on Benzene C10-C13 alkyl derivates with CAS No. 67774-74-7 in your read-across justification document but you have not included this source study in the IUCLID dossier. Therefore, the omission of this information from the dossier does not allow ECHA to assess and conclude on the relevance of this information regarding the read-across.

iii) Data density

Annex XI, Section 1.5. provides that "*substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances.*

According to the ECHA Guidance, one of the factors in determining the robustness of a category is the density and distribution of the available data across the category[5]. To identify a regular pattern and/or to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

Furthermore in larger categories there may be breaks in trends which could affect the reliability of interpolation[6]. To confirm that there are no such

[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.1.5.
[6] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.2.

breakpoints, adequate and reliable information needs to cover also substances within a range of homologous series.

In your read-across justification document you refer to a growth inhibition study to aquatic plants on Benzene C10-C13 alkyl derivates with CAS No. 67774-74-7. Based on this study you claim that all category members should be regarded as exhibiting no toxicity to aquatic plants at their limit of water solubility.

Information for a single category member is not sufficient to establish similar properties across the category consisting of 8 substances. Furthermore, in the absence of information on substances between the upper and lower borders of the category, it cannot be confirmed that there is no breakpoint in toxicity trend within the given range of chain length and potential degree of branching. Therefore, the information provided is not sufficient to conclude that ecotoxicological properties are likely to follow a regular pattern.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance(s). Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and cannot be considered as providing reliable information in support of your weight-of-evidence adaptation.

B. For the reasons explained in the "Appendix on Reasons common to several requests", the reported QSAR predictions are not considered as reliable sources of information.

As a conclusion, none of the sources of information described above provide reliable information on inhibition of growth for the Substance. Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 201 study. Hence, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study design

The substance is difficult to test due to the low water solubility (0.0026 mg/L) and/or adsorptive properties (log kow = 8.5). OECD TG 201 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented. Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

The Substance is a UVCB comprising constituents with different properties (i.e. water solubility, lipophilicity). OECD GD 23 describes various techniques appropriate for aquatic toxicity testing of UVCBs. If you select the Water Accommodated Fraction (WAF) approach, you must in addition to the above:

- Provide full description of the method used to prepare the WAF (including among others loading, use of solvent, stirring speed and duration, any centrifugation or filtration step)
- Prepare WAFs in a consistent manner (including e.g. the same co-solvents and the stirring methods in all test solutions preparations).
- Choose/develop appropriate analytical methods for your substance, and conduct chemical analysis of the test medium including the changes in constituents' ratios.

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

1. Extended one-generation reproductive toxicity study (Annex IX, 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 IX to REACH, if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. Furthermore column 2 defines the conditions under which the study design needs to be expanded.

1.1 Assessment of the triggers at Annex IX

Adverse effects on reproductive organs or tissues or other concerns in relation with reproductive toxicity are observed in available studies. More specifically, in a repeated dose (28-day) toxicity study (2010, OECD TG 407, GLP-compliant), performed on the Substance, Benzene, reaction product with propylene tetramer (or BAB, previously identified with EC number 246-772-4, before you adapted the substance identification and registered it under EC number 810-801-4) you reported that the "*male reproductive organs were the target organs (Leydig cell and prostate acinus atrophy, degenerated stage VII/VIII sperm cells, decreased secretion content in seminal vesicles)*" and that effects were seen at 800 mg/kg bw/day, but also at 400 mg/kg bw/day (but with lower frequency and/or severity).
In addition at 800 mg/kg bw/day, lower body weight gain, lower ovaries and spleen weights were noted. Other post-mortem changes were noted in the liver (higher weight, enlargement, hepatocellular hypertrophy: hepatic induction i.e. adaptive effect), forestomach (yellow deposit: undigested substance; hyperplasia and hyperkeratosis: irritation due to local concentration at gavage site), adrenals (higher weight, cortical hypertrophy likely stress-related), thymus (lower weight, atrophy likely stress-related) and kidneys (grade 2 tubular mineralization in males).

These findings were confirmed in the sub-chronic repeated dose (13-week) toxicity study by [redacted] (2014), conducted according to OECD TG 408 with spermiological examination), performed on the Substance. The study showed adverse effects in the testis (degeneration seminiferous tubules) and epididymis (mononuclear cell infiltration, reduced sperm with cell debris). In addition a significant lower motility and significant higher frequencies of altered morphology of sperm cells was noted.

An EOGRT study according to OECD TG 443 as specified in this decision is therefore an information requirement for your registration, because the Column 1 criteria at Annex IX, section 8.7.3 are met.

1.2 Assessment of the information provided

To fulfil the information requirement of Section 8.7.3 of Annex IX, you have provided the following information:

- an adaptation based on exposure considerations, claiming that "*because: (1) relevant human exposure can be excluded as demonstrated in the relevant exposure assessment; and/or (2) it is not scientifically necessary, in accordance with Sections 1.3 etc of Annex XI REACH*".
- a publication by [redacted] (1992) for a non-guideline non-GLP two-generation reproductive toxicity study with the analogue substance Alkylate 215, in Sprague-Dawley rat via oral route;
- a key sub-chronic repeated dose toxicity study (13-week) with the Substance in Sprague-Dawley rats via oral (feed) route, by [redacted] (2014), according to OECD TG

408 with spermiological examination);

We have assessed this information and identified the following issues:

A. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your exposure based adaptation according to Annex XI, Section 3 is rejected.

B. Read across two-generation reproductive toxicity study

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.

Predictions for toxicological properties (your hypothesis)

You have provided a read-across justification document in IUCLID Sections 7.8.1. and 13.2 of your registration dossier entitled [redacted]

According to your justification you predict the properties of the Substance from the structurally similar substance: Benzene, C10-C13 alkyl derivatives, EC No. 267-051-0 (CAS RN.67774-74-7; i.e. the source substance).

The source study that you have used in your read-across approach, a non-guideline non-GLP two-generation reproductive toxicity publication by [redacted] (1992) is performed with Alkylate 215 (a linear alkyl benzene mixture containing alkyl substituent with <1% C9, 16% C10, 43% C11, 40% C12, <1% C14; boiling point : 279-295°C).

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

- The selected source substance and the Substance are structurally similar and only differ by the side alkyl chains on the benzene ring. You state that: "*they are geometric isomers, having the same number of carbons, hydrogens, and electrons but differ in the geometric arrangement and chemical bonding pattern between the atoms*" and that "*no multiple bonds that could modify the reactivity of the side functional groups are present*";
- "*All substances are UVCB substances characterised by a high purity, more than 85 %*". You state that "*no impurities were identified for the target substance*". For the selected source substances "*contain two types of non-linear alkylates as co-products, mainly tetralins (< 0.5 – 8 %) and isoalkylbenzenes (1 – 6 %), that, however, are not considered as hazardous for the chemical safety assessment of the target and source substances. The most common LAB on the*

market (ca.75 %) has a low tetralin content (<0 .5 %)";
- *"Physico-chemical data [...] shows that the profiles of the target and source substances are similar"*;
- *"The substances are expected to have a similar metabolic pathway due to the structural similarity and comparable physicochemical properties. They are therefore deemed to have a similar toxicological profile and the Read Across hypothesis is justified"*.

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's assessment of your read across hypothesis

ECHA notes the following shortcomings with regards to the predictions of reproductive toxicity:

1. *Missing information on structural similarity*

As explained above the first condition that must be fulfilled in any read-across approach is that there needs to be structural similarity between the substances subject to the read across adaptation. Accordingly the *"chemical composition, including structural information should be well defined* for both the Substance and the source substance."

For the two-generation reproductive toxicity study you report that the test material *"Alkylate 215 is a linear alkyl benzene mixture containing alkyl substituent with <1% C9, 16% C10, 43% C11, 40% C12, <1% C14"*. No further compositional information is available.

The compositional information of the source substance tested in the two-generation study is insufficient for applying read-across. Furthermore, the side chains of the source substance are claimed to be linear and not branched as in the case of the Substance. You did not provide any information on what impact this difference in branching has on the prediction of toxicological properties. Hence, ECHA considers that there is not an adequate basis for predicting the toxicological properties of the Substance based on the properties of this source substance

2. *Supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that *"physicochemical properties, human health effects and [...] 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"*[7]. 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 analogues.

Supporting information must include bridging studies to compare properties of the substances subject to the read across justification.

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

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the substances is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration.

You have not reported in the technical dossier any relevant, reliable and adequate information derived from bridging studies to support your read-across hypothesis.

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

3. Read-across hypothesis contradicted by existing data

As explained above, supporting information to verify the crucial aspects of the read-across is required. The observation of differences in the toxicological properties among substances subject to read-across is a crucial aspect of any read-across and should be carefully examined. Any such difference which contradicts the similarity claimed in the read-across hypothesis needs to be documented and its impact on the prediction of toxicological properties explained.

The non OECD test guideline two-generation study with Alkylate 215 (a linear alkyl benzene) showed no treatment-related effect on fertility, while the OECD TG 408 repeated dose toxicity study with the Substance clearly indicated treatment-related adverse effects on the reproduction system.

The available data indicates differences in the toxicological properties of the substances. This contradicts your read-across hypothesis and you have not explained what impact this difference has on the prediction of toxicological properties.

Conclusion

Therefore, the information requirement is not fulfilled.

C. Sub-chronic repeated dose toxicity study

To be considered compliant and enable concluding if the Substance is a reproductive toxicant, the information provided has to meet the requirements of OECD TG 443 as specified in this decision.

The sub-chronic repeated dose toxicity study (13-week) study, performed according to OECD TG 408 and with the Substance does not meet the requirements of OECD TG 443 because effects on mating, fertility, pregnancy, lactation and postnatal development of the fully exposed F1 generation up to the adulthood are not investigated. Hence the study does not cover all relevant life stages because the animals were not exposed during gestation/ during lactation/*in utero*/postnatally.

Therefore, the information requirement is not fulfilled.

1.3 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 is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance[8]. In this specific case, a ten-week exposure duration is supported by the lipophilicity of the Substance (logKow calculated to be above 8) 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. You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

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.

Cohorts 1A and 1B

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

Cohort 3

The developmental immunotoxicity Cohort 3 needs to be conducted in case of a particular concern on (developmental) immunotoxicity.

Existing information on the Substance itself derived from available studies, namely a repeated dose (28-day) toxicity study (2010, OECD TG 407) and sub-chronic repeated dose (13-week) toxicity study by [redacted] (2014) show evidence of adverse effects on the immune system. More specifically, both studies available in the dossier revealed effects on essential organs of the immune system, i.e. they both showed reduced weights of spleen and thymus.

From the (OECD TG 407) 28-day study on the Substance: Mean thymus and spleen weights were decreased in males at all doses. Although microscopic correlations were seen only in 1/5 mid-dose and in 1/5 high-dose male in the thymus (lymphoid atrophy), these changes were attributed to treatment.

High absolute and relative adrenals weights were seen in all treated females. Only the relative adrenals weights were increased in treated males. Despite a poor dose-relationship, these changes were considered to be related to treatment.

In addition, in the (OECD TG 408) 13-week study on the Substance, the red and white blood cell values were decreased, multifocal epithelial hyperplasia and decreased lymphocyte cortex was observed in thymus and decreased cellularity in lymphoid follicles was seen in the spleen. These findings can only be partially explained by the reduced food consumption and, therefore can be attributed to the treatments.

[8] ECHA Guidance R.7a, Section R.7.6.

Therefore, the developmental immunotoxicity Cohort 3 must be conducted.

Species and route selection

The study must be performed in Sprague-Dawley rats with oral[9] administration, gavage, for the following reasons:
The available repeated dose toxicity studies were performed in Sprague-Dawley rats and indicated adverse findings on reproductive organs resulting in triggering the EOGRT study. Therefore, the Sprague-Dawley rat strain must also be used in the EOGRTS.

In the 90-day repeated dose toxicity study the substance was administered as dietary feed while it was administered by oral gavage in the OECD TG 407. Adverse effects on reproductive organs were noted independently from the type of oral administration.

In addition, via dietary administration, reduced feed consumption was reported and explained as "*associated to the low palatability of the diet*". This was confirmed by the introduction of an extra control group (pair-fed).

Hence to avoid unnecessary challenges in interpretation of the results due to palatability issues, the administration route must be oral gavage.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no trigger for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) were identified. However, you must expand the study by including the extension of Cohort 1B, and/or Cohorts 2A and 2B 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 IX. 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[10].

2. 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 in Annex IX to REACH.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3;
b. A statement that "*for a substance with very low water solubility* [...], *REACH guidance R7 Table R. 7.8-2 indicates that aquatic toxicity should be tested on non-pelagic (e.g. sediment) organisms preferentially*".
c. A weight of evidence adaptation according to Annex XI, Section 1.2 based on the following sources of evidence:
    i. A non-guideline study for chronic (14 d) sub-lethal toxicity to *Mytilus edulis* by Scarlett *et al.* (2008) with clearance rate as the measured endpoint.
    ii. A statement that "*ECOSAR indicates that [...] no chronic toxicity effects are*

[9] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[10] ECHA Guidance R.7a, Section R.7.6.

predicted at saturation" and a report entitled *"Data collection of QSAR estimations done for BAB (branched alkyl benzene)"* including predicted ChV for Daphnia for C9 to C15 constituents of the Substance using ECOSAR.

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your adaptation according to Annex XI, Section 3 is rejected.

b. Statement on low solubility and aquatic toxicity test organisms

As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity study on aquatic invertebrates must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). Any such justification must be documented in the Chemical Safety Assessment and must take into account all relevant hazard information from your registration dossier.

You did not submit in your dossier any specific justification demonstrating that the risks of the substance are controlled. However, to reach the conclusion that the risks are controlled, we understand that you rely on the fact that the Substance has *"very low water solubility"*.

As explained in section 1 of Appendix A above there is no valid justification in your dossier to demonstrate that aquatic toxicity is unlikely to occur and consequently your substance is considered poorly water soluble rather than highly insoluble. Most of the constituents of the Substance are poorly water soluble (i.e. water solubility < 1 mg/L).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, short-term tests may not give a true measure of toxicity for your substance and the long-term test is required.

Your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled and your adaptation is rejected.

c. Weight of evidence adaptation

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, a long-term toxicity to aquatic invertebrates must provide information on the impact of the test material on the life cycle of the tested species (e.g. reproduction eficiency, offspring survival).

With regard to the provided information, the source of information (i) is irrelevant as it does not provide any information on life cycle.

Source of information (ii) might provide relevant information to fulfil this information requirement. However, for the reasons explained in the "Appendix on Reasons common to several requests", this source of information (i.e. the reported QSAR predictions) is not considered as reliable.

As a conclusion, none of the sources of information described above provide reliable information on reproduction in Daphnia for the Substance. Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 211 study. Hence, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study design

The substance is difficult to test due to the low water solubility and adsorptive properties as explained above. OECD TG 211 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.1. If you decide to use Water Accommodated fraction (WAF) approach, you must follow the conditions described above under request A.1.

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

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3;
b. A statement that "*for a substance with very low water solubility* [...], *REACH guidance R7 Table R. 7.8-2 indicates that aquatic toxicity should be tested on non-pelagic (e.g. sediment) organisms preferentially*".
c. A statement that "*ECOSAR indicates that [...] no chronic toxicity effects are predicted at saturation*" and a report entitled "*Data collection of QSAR estimations done for BAB (branched alkyl benzene)*" including predicted ChV for fish QSAR predictions for 96h-

EC50ChV for algae for C9 to C15 constituents of the Substance using ECOSAR.

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your substance-tailored exposure-driven adaptation according to Annex XI, Section 3 and your QSAR adaptation according to Annex XI, Section 1.3 are rejected.

b. **Statement on low solubility and aquatic toxicity test organisms**

As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity to study on fish must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). Any such justification must be documented in the Chemical Safety Assessment and must take into account all relevant hazard information from your registration dossier.

You did not submit in your dossier any specific justification as to why the risks of the substance are controlled. However, to reach the conclusion that the risks are controlled, we understand that you rely on the fact that the Substance has *"very low water solubility"*.

As explained in section 1 of Appendix A above there is no valid justification in your dossier to demonstrate that aquatic toxicity is unlikely to occur and consequently your substance is considered poorly water soluble rather than highly insoluble. Most of the constituents of the Substance are poorly water soluble (i.e. water solubility < 1 mg/L).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, short-term tests may not give a true measure of toxicity for your substance and the long-term test is required.

Your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled and your adaptation is rejected.

Study design

The substance is difficult to test due to the low water solubility and adsorptive properties as explained above. OECD TG 210 specifies that for difficult to test substances, the OECD GD 23 is to be followed, as described above under request A.1. If you decide to use Water Accommodated fraction (WAF) approach, you must follow the conditions described above under request A.1.

4. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Soil simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to soil. The Substance includes constituents with low water solubility (the C12 branched alkylbenzene constituent has an estimated water solubility of 0.8 - 2.6 µg/L at 25 °C using WATERNT v1.01), high partition coefficient (the C12 branched alkylbenzene constituent has an estimated log Kow of 8.4 - 8.5 at 25 °C using KOWWIN v1.67a) and high adsorption coefficient (the C12 branched alkylbenzene constituent has an estimated log Koc of 5.0-6.7 using KOCWIN), indicating high adsorptive properties.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3.
b. An adaptation according to Annex IX, Section 9.2.1.3, column 2 as you consider that soil is not the critical compartment. In support of your adaptation you provided the following statement: *"In accordance with ECHA's R11 Guidance, the persistence has only to be assessed in the critical compartment. The critical compartment is the sediment and not the soil based on persistence data (based on QSAR half-lives) and distribution modelling".*
c. A weight of evidence adaptation according to Annex XI, Section 1.2 based on the following sources of evidence:
    i. QSAR predictions from the Level III Fugacity Model (output soil) on C9 to C15 branched typical structures using BioHCWIN v 1.01 (EPI Suite v4.11). You have provided a document in Section 13 of your technical dossier summarizing the outputs of the model (entitled "[redacted]");
    ii. A publication by Eganhouse and Pontolillo (2008) reporting the result of a field study to monitor the biodegradation of tetrapropylene-based alkylbenzenes (TABs) and the linear alkylbenzenes (LABs) in reducing marine sediments. You assign a reliability of 4 to this study.

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your substance-tailored exposure-driven adaptation according to Annex XI, Section 3 is rejected.

b. Annex IX, Section 9.2.1.3, column 2 adaptation

According to Annex IX, Section 9.2.1.3, column 2 a soil simulation testing does not need to be conducted if direct and indirect exposure of soil is unlikely.

In your Chemical Safety Report you report uses of the Substance which involve Environmental Release Categories (ERCs) 2, [redacted] and therefore release to drain is foreseen. Based on the output of the Simple Treat model, it is predicted that 67.36% of the substance reaching STPs will adsorb to sewage sludge. This is further substantiated by a PEC for agricultural soil of $5.56E^{-3}$ mg/kg dw associated to the use of the Substance in as a dielectric fluid in electrical transformers.

On the basis that contaminated sewage sludge may be spread on land, indirect exposure of the soil compartment cannot be excluded. Therefore your adaptation is rejected.

c. Weight of evidence adaptation

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, normally a study performed according to OECD TG 307[11] must be provided. OECD TG 307 requires the study to investigate the following key parameters:

- soil samples are treated with the test substance and incubated in the dark in biometer-type flasks or in flow-through systems under controlled laboratory conditions
- at least four soils must be used representing a range of relevant soils
- mass balance during and at the end of the studies

With regard to the provided information, the source of information (i) is irrelevant as it does not provide any information on biodegradation in soil. Furthermore, it reports results of a field study and therefore it was not conducted under controlled laboratory conditions and no mass balance can be determined.

Source of information (ii) might provide relevant information to fulfil this information requirement. However, for the reasons explained in the "Appendix on Reasons common to several requests", this source of information (i.e. the reported QSAR predictions) is not considered as reliable.

As a conclusion, none of the sources of information described above provide reliable information on degradation rates in soil. Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 307 study. Hence, your adaptation is rejected.

Therefore, this information requirement is not fulfilled.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore, you must perform the test at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8).

[11] ECHA Guidance R.7b, Section R.7.9.4.1

Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 307.

5. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Sediment simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to sediment. The Substance includes constituents with low water solubility (the C12 branched alkylbenzene constituent has an estimated water solubility of 0.8 - 2.6 µg/L at 25 °C using WATERNT v1.01), high partition coefficient (the C12 branched alkylbenzene constituent has an estimated log Kow of 8.4 - 8.5 25 °C using KOWWIN v1.67a) and high adsorption coefficient (the C12 branched alkylbenzene constituent has an estimated log Koc of 5.0-6.7 using KOCWIN), indicating high adsorptive properties.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3.
b. An adaptation according to Annex IX, Section 9.2.1.3, column 2 as you consider that "direct and indirect exposure of sediment is unlikely".
c. An adaptation according to Annex XI, Section 2 by stating that the study is not technically feasible as '*the substance is highly insoluble in water*'.
d. QSAR predictions, labelled as a key study, from the Level III Fugacity Model (output sediment) on C9 to C15 branched typical structures using BioHCWIN v 1.01 (EPI Suite v4.11). You have provided a document in Section 13 of your technical dossier summarizing the outputs of the model (entitled "[redacted]");
e. As part of Section 5.2.3. of your technical dossier (soil simulation testing), you have provided publication by Eganhouse & Pontolillo (2008) reporting the result of a field study to monitor the biodegradation of tetrapropylene-based alkylbenzenes (TABs) and the linear alkylbenzenes (LABs) in reducing marine sediments. This information was considered an attempt to adapt this information requirement based on Annex XI, Section 1.1.2.

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your substance-tailored exposure-driven adaptation according to Annex XI, Section 3 is rejected.

b. Annex IX, Section 9.2.1.3, column 2 adaptation

According to Annex IX, Section 9.2.1.3, column 2 a sediment simulation testing does not need to be conducted if direct and indirect exposure of sediment is unlikely.

In your Chemical Safety Report you report uses of the Substance which involve Environmental Release Categories (ERCs) 2, [redacted] and therefore release to drain is foreseen. Based on the output of the Simple Treat model, it is predicted that 4.375% of the substance reaching STPs will pass to water.

On this basis there will be exposure to sediment. Therefore your adaptation is rejected.

c. Testing not possible adaptation

Annex XI, Section 2 specifies that testing for a specific endpoint may be omitted, if it is not possible to conduct the study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, must always be respected. In this case, the recommended method is OECD TG 308.

You have justified the adaptation by stating that the Substance is "highly insoluble in water". However, OECD TG 308 specifies that "*the method is generally applicable to chemical substances (unlabelled or labelled) for which an analytical method with sufficient accuracy and sensitivity is available*" and that it is applicable to "*poorly water-soluble compounds*". As poorly water soluble compounds are within the aplicability domain of OECD TG 308, your adaptation according to Annex XI, Section 2 is rejected.

d. QSAR based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your QSAR-based adaptation according to Annex XI, Section 1.3 is rejected.

e. Use of existing data

The adaptation rule in Annex XI, Section 1.1.2 imposes a number of cumulative conditions for an adaptation to be valid, in particular the study must provide an adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 308. In particular:

- sediments should not be used if they have been contaminated with the test substance or its structural analogues within the previous 4 years;
- biodegradation kinetics is to be monitored under under controlled laboratory conditions

In the study by Eganhouse & Pontolillo (2008), sediment cores where sampled near a submarine wastewater outfall system in July 1992 and July 2003. Wastewater effluent sampled in 1979 and 1990 was also analysed to "*present data on the LAB composition [of the effluent]*". The study is limited to the monitoring the composition of long-chain alkylbenzenes in sediment core.

The study aims at monitoring the presence of long-chain alkylbenzenes in sediments known to be subject to long-term contamination. It addition, the objective of the study is not to monitor the degradation kinetics of long-chain alkylbenzenes under standardized conditions. Hence, it does not provide an adequate coverage of the key parameters of OECD TG 308 and your adaptation is rejected.

Therefore, this information requirement is not fulfilled.

Study design

OECD TG 308 is an appropriate method for studying the degradation in sediment. The requested simulation tests shall be performed under relevant conditions (12°C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section C.2. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable,

shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance Chapter R.11).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the persistence of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

6. Identification of degradation products (Annex IX, 9.2.3.)

Identification of the degradation products is a standard information requirement at Annex IX of REACH. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

You have not provided any information on the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement. You admit that the Substance is not readily biodegradable.

Therefore, this information requirement is not fulfilled.

Test design

Regarding appropriate and suitable test method, the methods will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation may be investigated. You may obtain this information from the two degradation simulation studies also requested in this decision or by some other measure. If any other method than the tests requested under B4 or B5is used for identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

Bioaccumulation in aquatic species, preferably fish is a standard information requirement at Annex IX of REACH.

You have provided multiple independent adaptations for this information requirement including:

a. A substance-tailored exposure-driven adaptation according to Annex XI, Section 3.
b. An adaptation according to Annex IX, Section 9.2.1.3, column 2 as you consider that "direct and indirect exposure of the aquatic compartment is unlikely".
c. An adaptation based on Annex XI, Section 2 as you consider that "testing is technically

not possible".

d. A weight of evidence adaptation according to Annex XI, Section 1.2 based on the following sources of evidence:
   i. QSAR predictions on C9 to C15 branched typical structures using BCFBAF v3.00 (EPI Suite v4.11). You have provided a document in Section 13 of your technical dossier summarizing the outputs of the model (entitled "[redacted]");
   ii. A publication by Scarlett *et al.* (2008) for a non-guideline bioaccumulation study in mussels.
   iii. A publication by Scarlett *et al.* (2009) for a non-guideline bioaccumulation study in crabs fed with contaminated mussels.
   iv. A publication by [redacted] (1991) for a non-guideline fish bioaccumulation study with the source substance 2-Phenyldodecane (no EC or CAS number reported).

We have assessed this information and identified the following issues:

a. Exposure based adaptation

For the reasons explained in the "Appendix on Reasons common to several requests", your substance-tailored exposure-driven adaptation according to Annex XI, Section 3 is rejected.

b. Annex IX, Section 9.3.2, column 2 adaptation

According to Annex IX, Section 9.3.2, column 2 a bioaccumulation study in aquatic species does not need to be conducted if direct and indirect exposure of the aquatic compartment is unlikely.

In your Chemical Safety Report you report uses of the Substance which involve Environmental Release Categories (ERCs) 2, [redacted] and therefore release to drain is foreseen. Based on the output of the Simple Treat model, it is predicted that 4.375% of the substance reaching STPs will pass to water.

On this basis there will be exposure of the aquatic compartment. Therefore your adaptation is rejected.

c. Testing not possible adaptation

Annex XI, Section 2 specifies that testing for a specific endpoint may be omitted, if it is not possible to conduct the study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, must always be respected. In this case, the recommended method is OECD TG 305.

To justify your adaptation you provide the following arguments:
- A dietary study would be required in view of the low water solubility of the substance and this would result in determination of a biomagnification factor (BMF) from which only a tentative bioconcentration factor (BCF) can be estimated.
- The substance would be impossible to differentiate analytically from metabolites and therefore the BMF and derived BCF values would not be pertinent to the substance itself.
- Consequently you argue that '*the OECD 305 study would produce, at best,*

tentative results of questionable relevance to actual risk to the environment.'

The OECD TG 305 includes a method for the determination of the dietary bioaccumulation (BMF) which is applicable to substances with very low water solubility. The method also addresses the issues of estimating a BCF from a measured BMF and of metabolites. Therefore, based on the above justification you have not demonstrated that the study is not technically feasible and your adaptation is rejected.

d. Weight of evidence adaptation

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, normally a study performed according to OECD TG 305[12] must be provided. OECD TG 305 requires the study to investigate the following key parameters:

- For OECD TG 305-I, the bioconcentration factor (BCF) calculated preferably both as the ratio of concentration in the whole test organism (C_f) and in the water (C_w) at steady-state (BCF_{SS}) and as a kinetic bioconcentration factor (BCF_K), which is estimated as the ratio of the rate constants of uptake (k_1) and depuration (k_2) assuming first order kinetics.
- For OECD TG 305-III, the kinetic biomagnification factor (BMF_K) (if necessary growth corrected, BMF_{Kg}), its lipid-corrected value (BMF_{KL} or BMF_{KgL}, if corrected for growth dilution) based on whole test organisms.

The source of information (iii.) does not provide relevant information on bioaccumulation because in this dietary study (i.e. similar to OECD TG 305-III) no information is provided on the kinetic biomagnification factor. The sources of information (i.), (ii.) and (iv.) may provide relevant information on either of these key parameters.

[12] ECHA Guidance R.7b, Section R.7.10.4.1

However, the reliability of these sources of information is significantly affected by the following deficiencies:

A. For the reasons explained in the "Appendix on Reasons common to several requests", the reported QSAR predictions are not considered as reliable sources of information.

B. To comply with this information requirement, a study must fulfil the validity criteria and cover the key parameters of the corresponding TG (Article 13(3) of REACH), in this case OECD TG 305-I study (i.e. aqueous exposure) or OECD TG 305-III study (i.e. dietary exposure) which include (among others):
   - The exposure concentrations should not exceed the range of water solubility of the test substance in the test media.
   - The means of the measured test concentrations and their standard deviations in the test vessels and the method and frequency by which these were attained must be provided.
   - The uptake phase is run for 28 days in fish. Shorter duration can be used if it is demonstrated that steady-state has been reached earlier.
   - A complete description of all chemical analysis procedures employed including limits of detection and quantification, variability and recovery must be provided.

   The source of information (ii.) does not provide a reliable coverage of the key parameters foreseen to be investigated in an OECD TG 305-I study because:
   - The study was conducted at 5µg/l, i.e. above the water solubility limit of 0.8-2.6 µg/l for C12 fraction of the substance
   - No analytical monitoring of exposure concentrations is reported.
   - The update phase was 14d and there is no information available to verify if steady-state was reached at the end of the uptake phase.
   - The performance parameters of the analytical method used to quantify the test substance in the aqueous phase and in the mussel tissues are not reported.

C. 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 'alkyl benzene' substances. You have provided a read-across justification document attached to a study record for this endpoint and in IUCLID Section 13.

   You define the applicability domain of the category as follows: "*The category applies to BAB and alkyl benzenes with alkyl chain between 8 and 24 carbons*".

   You have not provided a specific reasoning for the prediction of bioaccumulation

in aquatic species within the category, including a read-across hypothesis.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues:

i) Characterisation of the group members

Annex XI, Section 1.5 of the REACH Regulation provides that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group.*"

According to the ECHA Guidance, "*in identifying a category, it is important that all potential category members are described as comprehensively as possible*", because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[13] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[14]

Your read-across justification document contains no compositional information for the members of your category, although you have defined the applicability domain of the category as *"alkyl benzenes with alkyl chain between 8 and 24 carbons*". The category members are UVCBs including branched and/or linear alkyl of various carbon chain lengths. The degree of branching is not provided for the category members.

Without consideration of the distribution of the carbon chain length and degree of branching amongst category members, no qualitative or quantitative comparative assessment of the compositions of the different category members can be completed. Therefore, the category membership cannot be confirmed.

ii) Adequacy and reliability of the source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). In the case of an OECD TG 305-I study (i.e. aqueous exposure), the key parameters include (among others):

- number and size of test chambers,
- water volume replacement rate,
- loading rate,
- number of replicates,

[13] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[14] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

- number of fish per replicate,
- number of test concentrations,
- sampling frequency for fish and water samples
- mortality of the control fish and the fish in each exposure chamber and any observed abnormal behaviour,
- complete description of all chemical analysis procedures employed including limits of detection and quantification, variability and recovery
- the lipid content of the fish,
- tabulated fish weight (and length) data and calculations for derived growth rate constant(s),
- tabulated test substance concentration data in fish,
- curves of growth and uptake and depuration.

The study by [redacted] (1991) conducted with the source substance 2-Phenyldodecane used to adapt this information requirement does not provide an adequate coverage of the key parameters foreseen to be investigated in the relevant study.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance(s). Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and cannot be considered as providing reliable information in support of your weight-of-evidence adaptation.

As a conclusion, none of the sources of information described above provide reliable information on bioconcentration factor (BCF) or on kinetic biomagnification factor (BMF_K). Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 305 study. Hence, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA *Guidance, Chapter R.7c, R.7.10.3.1*). Whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) must be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility. In case you conduct the study using the dietary exposure route (OECD 305-III), you must also attempt to estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you must report all data derived from the dietary test as listed in the OECD TG 305-III.

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the persistence of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

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

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[15].

Test material

1. *Selection of the Test material(s)*

   The Test Material used to generate the new data must be selected taking into account the following:
   a) the boundary composition(s) of the Substance
   b) 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*

   a) 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.
   b) The reported composition must include a careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,
   c) The reported composition must also include other parameters relevant for the property to be tested, in this case the distribution of carbon chain length and on adequate infomration on the dregree of branching of constituents.

   With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

   Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[16].

[15] https://echa.europa.eu/practical-guides
[16] https://echa.europa.eu/manuals

Further considerations

1. Strategy for the assessment of the PBT/vPvB potential

ECHA Guidance R.7b, Section R.7.9., R.7c, Section R.7.10 and R.11 on PBT assessment gives considerations to determine the sequence of the tests and the necessity to conduct all of them. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

You must first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also must consider the intrinsic properties of the Substance, its identified use and release patterns since these could significantly influence the environmental fate of the Substance. You must revise the PBT assessment when the new information is available.

2. PBT assessment of UVCB substances

The environmental effects assessment of UVCBs under REACH are needed for the PBT assessment and/or for classification and labelling purposes and/or to perform the risk assessment (e.g. for PNEC derivation).

Your Substance is a complex UVCB and, based on the information you provided, it includes constituents with different properties (including poorly water soluble constituents).

As indicated in the ECHA Guidance R.11, to fulfil information requirements for persistency, bioaccumulation and aquatic toxicity, you can consider the following approaches:
- The "known constituents approach" (by assessing specific constituents), or
- The "fraction/block approach" (performed on the basis of fractions/ blocks of constituents), or
- The "whole substance approach", or
- various combinations of the approaches above.

The choice of the assessment approach will depend on several factors, such as knowledge of constituents and/or fractions in the whole substance, differences in properties amongst them and the ability to characterise these.

Appendix F Procedure

This decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision under Article 50(1) of REACH.

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 07 November 2018.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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 G: List of references - ECHA Guidance[17] and other suporting 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.

ECHA Read-across assessment framework (RAAF, March 2017)[18]

Guidance on information requirements and chemical safety assessment, Chapter R.5: Adaptation of information requirements (Version 2.1, December 2011), referred to as ECHA Guidance R.5. in this decision.

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.

OECD Guidance documents[19]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[17] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[18] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[19] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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 H: Addressees of this decision and the corresponding information requirements applicable to them

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]

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.