EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 6 May 2021

Addressees
Registrants of JS_6731-36-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
18/03/2020

Registered substance subject to this decision ("the Substance")
Substance name: Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
EC number: 229-782-3
CAS number: 6731-36-8

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***11 August 2022***.

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

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

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

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

C. Information required from all the Registrants subject to Annex IX of REACH

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendices:
- Appendix on "Reasons common to several requests", and
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

Authorised[1] under the authority of 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

1. Assessment of your read across adaptation under Annex XI, Section 1.5

In your comments on the draft decision, you proposed to adapt the following standard information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the specific standard information requirements in this appendix.

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[2,3].

A. Predictions for aquatic toxicity properties

In your comments on the draft decision, you have provided the following reasoning for the prediction of aquatic toxicity:

- "*The hypothesis is* [based on] *structural similarity between* [the target and source substance]" as they both contain a cyclohexane ring with two tert-butylperoxy groups on carbon 1 of the ring. Structural differences reside in the presence of three methyl groups in the cyclo-hexane ring positioned on carbons 3 and 5 for the target substance but not for the source substance. You report that the OECD Toolbox indicates that they share similar organic functional groups;
- "*Most of* [physico-chemical] *properties are similar and would support the similar behavior of these materials in the environment* [and] *bioaccumulation potential*";
- "*The methyl groups in the ring structure do influence the solubility* [...], *the reactivity in its application and temperature stability is slightly lower*". However, "*at environmental temperatures these differences are negligible*";
- "*Methyl groups could promote greater level biological reactivity / DNA interaction and hence make the* [Substance] *a realistic worst case for the group for toxicity endpoints*". You report that the target and source substance share similar profiles as generated with the OECD QSAR Toolbox v4.3.1;
- "*The primary endpoint not supporting a 1:1 read-across is the higher water solubility of 1,1 TBPCH (CAS 3006-86-8) in comparison to 1,1 TBPTMCH (CAS 6731-36-8)* [...]. *This makes 1,1 TBPCH (CAS 3006-86-8) the best candidate as a worst case (source) material for the further assessment of the aquatic compartment*";
- "*For the aquatic compartment, all the available data with 1,1 TBPTMCH (CAS 6731-36-*

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

8) and 1,1 TBPCH (CAS 3006-86-8) does not show any aquatic toxicity up to the solubility limits of both substances". You provide a table which claims the following:

- No toxicity up to the water solubility was observed in OECD TG 201, 202 and 203 for the target and source chemicals;
- No toxicity was observed for the Substance in an OECD TG 211 study (further assessed below in this decision) and you propose to cover the information reauirement on long-term toxicity to fish using a read-across from data on the source substance;
- There is currently no information available on long-term toxicity on aquatic invertebrates and on fish for the source substance and you specify that the test are currently being commissioned.

You read-across between the structurally similar substances, 1,1-di(tert-butylperoxy)cyclohexane, EC No. 221-111-2 (CAS No. 3006-86-8) as source substance and the Substance as target substance.

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 based on a worst-case approach.

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

1. *Relevance of the supporting information*

According to the ECHA Guidance R.6.2.2.1.f "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that your Substance and source substance(s) have similar properties for the endpoints under consideration in the read-across approach, you refer to their:

- similar profiles as generated with the OECD QSAR Toolbox v4.3.1;
- similar absence of effect up to the water solubility in growth inhibition studies on algae;
- similar absence of effect up to the water solubility in short-term toxicity studies on aquatic invertebrates and fish.

Whilst this data set suggests that the substances may have similar overall mode of actions as they share similar functional groups and similar structural profiles according to OECD QSAR Toolbox v4.3.1, this information does not inform on the long-term toxicity to aquatic invertebrates and fish of the target and source substances. Furthermore, the absence of toxicity observed up to the water solubility limit in growth inhibition studies on algae is not relevant supporting information to demonstrate similar properties on other trophic levels. Finally, poorly water soluble substances, such as the Substance and the selected analogue substance, require longer time to reach steady-state conditions. As a result, short-term toxicity tests do not give a true measure of toxicity for this type of substance and this information is therefore not relevant to demonstrate similar properties. Accordingly, these information are not considered as relevant to support prediction of all the endpoints under consideration.

2. *Missing supporting information to substantiate worst-case consideration*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Section R.6.2.2.1.f). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance.

As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance.

However, your worst-case consideration exclusively relies on a slightly higher water solubility of the source substance compared to the Substance. Also, as explained in issue 1 above, the set of supporting information you provided in your justification is not relevant to demonstrate similar properties for long-term toxicity on aquatic invertberates and on fish.

Additionally, in your read-across justification you state that "*Methyl groups could promote greater level biological reactivity / DNA interaction*" and we note that the Substance includes methyl groups while the source substance does not. However, you have not provided any supporting information to explain why information on the selected source substance would provide conservative predictions of toxicity for the Substance.

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

3. Characterisation of the source substance

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 structural similarity may be considered as group.*"

According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance (ECHA Guidance R.6.2.3.1).

Your read-across justification document contains compositional information for the source substance. You report that this substance is "*available as* [redacted] *% in is dodecane*" and that the compositional information was normalized in order to allow a comparision with the composition of the Substance.

You have not addressed in your read-across justification the impact of the presence of [redacted]% dodecane in the composition of the source substance on the predictions and how it

may impact the overall toxicity of this substance. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

B. Conclusions on the read-across approach

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

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

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided a short term OECD TG 202 study by [redacted] (2013) as the key study but no valid information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issues:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

In the provided OECD TG 202 ([redacted] 2013), the saturation concentration of the Substance in water at the applied concentrations was determined to be between 0.00117 and 0.00439 mg/L and below the limit of quantification (LOQ) of the analytical method after 24 and 48 hours in the experiment (LOQ = 0.0083 mg/L).

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

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.1.

In your comments to the draft decision, you propose to adapt the information requirements on long-term toxicity testing on aquatic invertebrates by applying a read-across approach under Annex XI, Section 1.5. However, for the reasons explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

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

1. Long-term toxicity testing on fish

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

You have provided a short term OECD TG 203 by [redacted] (2011) as the key study but no valid information on long-term toxicity on aquatic invertebrates or on Fish for the Substance.

We have assessed this information and identified the following issues:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

In the provided OECD TG ([redacted] 2011), the saturation concentration of the Substance in water was in the range from 0.21 to 0.27 mg/L (arithmetic mean 0.25 mg/L) in the applied flow-through experiment.

As already explained under Section A.1. the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.2.

In your comments to the draft decision, you propose to adapt the information requirements on long-term toxicity testing on fish by applying a read-across approach under Annex XI, Section 1.5. However, for the reasons explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

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

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information:

- OECD TG 211 (*Daphnia magna* reproduction test), key study, test substance: 1,1-bis(tert-butylperoxy)-3,3,5-trimethylcyclohexane (CAS: 6731-36-8, EC: 229-782-3) from [redacted] (2014).

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 211 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

Validity criteria

- the percentage of mortality of the parent animals in control (female *Daphnia*) is ≤ 20% at the end of the test;

Information on the test material

- chemical identification data should be reported, including purity;

Characterisation of exposure

- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
  - an analytical method validation report demonstrating that the analytical method is appropriate, and
  - information on the saturation concentrations of the test material in water and in the test solution, and
  - the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

Your registration dossier provides an OECD TG 211 ([redacted], 2014), showing the following:

Validity criteria

- the reported percentage of mortality of the parent animals in control at the end of the test was 23.3 %;

Information on the test material

- the purity of the test substance is not reported.

Characterisation of exposure

- the Substance is difficult to test (water solubility of 93 µg/L, Log Kow = 7.00 and Log Koc = 5.1). Regarding the applied water accommodated fraction (WAF) method to prepare saturation concentration in the test solutions you did not include the following information:
  - an analytical method validation report was not provided and adequacy of the analytical method is questionable since the reported exposure concentrations

in all the test tanks were below the level of quantification (LOQ = 4 µg/L) from day 2 to day 21;
- information on the saturation concentrations of the test material in the test solution was not provided;
- the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in the test solution was not provided.

Based on the above, the validity criteria of OECD TG 211 are not met. More specifically, the observed mortality in controls was higher than the maximum (20%) acceptable mortality rate specified in the TG 211. As a result the reproductive output in controls may not reflect reproduction in normal conditions and possible effects of the substance on the reproduction cannot be reliably measured. There are also critical methodological deficiencies in the test. For example, purity of the test substance and presence of possible impurities are not reported and therefore possible influence of impurities on the test results cannot be assessed. In addition, the Substance is difficult to test (water solubility 93 µg/L, Log Kow = 7.00 and Log Koc = 5.1) meaning the concentration of the substance is not easily maintained in the test solutions. Therefore, if the substance is tested at or near the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration in the test solutions. In this case the test substance was tested at an assumed saturation concentration, however, no evidence was provided that all reasonable efforts were taken to achieve the saturation concentration in the test solutions. This is summarised in three following points. First, a validation report for the analytical method was not provided and as a result the adequacy of the method cannot be independently assessed and the analytical results cannot be confirmed as reliable. As a result the analytical method could not detect the test substance in the test tanks (i.e. in the test solutions) from day 2 to day 21, since the concentrations were below the LOQ. This means that it is not known what was the exposure concentration for which the test animals were exposed during that time window. Second, the saturation concentration of the test substance in the test solution (i.e. in the test tanks) was not provided and therefore, it is not known what is the solubility of the test substance in the test solutions. Third, the test solution preparation method was not demonstrated (i.e. by a preliminary experiment) to be adequate to maximize the concentration of the test material in the test solution. In conclusion of the three aforementioned points, it was not demonstrated that all reasonable efforts have been taken to achieve a saturation concentration.

Therefore, the requirements of OECD TG 211 are not met.

In your comments to the draft decision, you propose to adapt the information requirements on long-term toxicity testing on aquatic invertebrates by applying a read-across approach under Annex XI, Section 1.5. However, for the reasons explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

As explained above, the Substance is difficult to test. OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results.

If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution. As explained in OECD GD 23, under Section 7.1. you can also use solvents in order to obtain maximized saturation in the test solutions.

2. Long-term toxicity testing on fish

Long term toxicity testing on Fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have adapted this information requirement according to Annex IX, Section 9.1, Column 2 with the following justification: *"No toxicity was found (at the limit of solubility) in fish and at the highest concentration possible to test on algae, and daphnids. In the interest of animal welfare, a long-term study, with daphnids was conducted to demonstrate lack of chronic toxicity as fish were not found to be the most sensitive species."*

We have assessed this information and identified the following issue:

Under Section 9.1., Column 2, Annex IX to REACH, the study may be omitted if the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the manufacture and use of the substance are controlled (Annex I, Section 0.1). The justification for this adaptation must be documented in the Chemical Safety Report (CSR) and include all the following elements:

- the predicted no effect concentrations (PNEC) for the aquatic compartment which must be based on:
  - reliable information on the hazardous properties of the Substance on at least three trophic levels.
  - an appropriate assessment factor (AF) (ECHA Guidance R.10, Section R.10.3),
- a quantitative exposure assessment which leads to derivation of predicted environmental concentrations (PECs),
- the outcome of the risk characterisation ratio (RCR) which demonstrates that the risks are adequately controlled (*i.e.* PEC < PNEC).

Your registration dossier does not provide an exposure assessment for the freshwater/marine water compartments in your CSR because you consider that *"None of the three acute studies (algae, daphnia, fish) and a single daphnia chronic study detected any effects at or greater than the limit of solubility"* and therefore, no hazard to aquatic organisms was identified.

For the reasons explained under requests in appendices A1, B1 and C1, your dossier does not include reliable hazard information for the Substance on at least three trophic levels. Such information includes reliable data on long-term toxicity on at least three trophic levels as the Substance is poorly water soluble.

Therefore, the adaptation submitted in your dossier is rejected.

In your comments on the draft decision, you state that *"Partitioning of the test material in the water treatment plant and specific analysis in the OECD 303A test demonstrate that the test material does not reach surface water"*. However, this statement does modify the outcome of the above assessment.

In your comments to the draft decision, you propose to adapt the information requirements on long-term toxicity testing on fish by applying a read-across approach under Annex XI, Section 1.5. However, for the reasons explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

Study design

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

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section C.1.

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

1. Test methods, GLP requirements and reporting

- 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.

- 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.

- 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[4].

2. Test material

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

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

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

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

Appendix E: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for substance evaluation in 2019.

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

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

The compliance check was initiated on 20 January 2020.

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

ECHA took into account your comments and did not amend the requests.

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 F: List of references - ECHA Guidance[6] and other supporting documents

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

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

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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

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

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

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

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

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

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

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

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

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[9]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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

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

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

Appendix G: 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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