~~Confidential~~

Helsinki, 15 November 2021

Addressees
Registrant(s) of DMBPC Joint Submission as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
13/11/2015

Registered substance subject to this decision ("the Substance")
Substance name: 4,4'-cyclohexylidenedi-o-cresol
EC number: 219-110-7
CAS number: 2362-14-3

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 in A.1. below by ***23 May 2022*** and all other information listed below by ***22 May 2023***.

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. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method)

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

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

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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

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

Reasons for the requests are explained in the following appendix/appendices:

- Appendix/Appendices entitled "Reasons to request information required under Annexes VII and 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 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.

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

1. Partition coefficient n-octanol/water

Partition coefficient in n-octanol/water is an information requirement under Annex VII to REACH (Section 7.8).

You have provided the following information in the dossier:

i. OECD TG 107, key study, [redacted] (2001).

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 107 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The analytical method used for the quantification of the substance is described. The specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range are reported;
- The concentrations measured in each phase for each duplicate vessel used in each run (i.e. 12 concentrations) are reported in a tabular form.
- The maximum concentration of the test substance in each phase (i.e. ≤ 0.01 mol/L) is reported
- The test design is reported, The test consists of three runs:
    1- A first run where a volume ratio of n-octanol to water and a quantity of substance are chosen taking into account the preliminary estimate of the log Pow, the limit of quantification of the analytical method and the fact that the maximum concentration of the test substance in each phase must be ≤ 0.01 mol/L, and
    2- A second run where the chosen volume ratio in the first run is divided by two, and
    3- A third run where the chosen volume ratio in the first run is multiplied by two;

In your dossier you have provided the following:

- you indicate that the high-performance liquid chromatography was used as analytical method. However no information on the performance parameters were provided (i.e. specificity, recovery efficiency, precision, limits of determination).
- you have not provided any information on the concentration of the Substance.
- you have not reported the amount of test substance introduced in the test vessels. volume of each phase in each vessel under tabulated form.
- You have not reported any information on the test design.

On this basis, the reporting of the study is not sufficient to conduct an independent assessment.

In your comment to the draft decision, you clarified that you conducted a preliminary study according to the OECD TG 107 but the definitive study was conducted according to the OECD TG 117. You have provided in your comments the corresponding study report for the OECD TG 117 study and you state that you will update your registration dossier accordingly. ECHA has assessed this information against the requirements of the OECD TG 117 and considers that the information provided as part of your comments on the draft decision meets the information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

Therefore, the information requirement is not fulfilled.

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

1. Sub-chronic toxicity study (90-day)

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

You have provided a key study for this endpoint in your dossier:

i. [redacted] 2002 (OECD 422).

Furthermore, you have provided adaptations according to Annex XI, Section 3 and Column 2 of Annex IX, Section 8.6.2. in your dossier.

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

i. Provided study inadequate to fulfil the information requirement

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

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

The Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) you have submitted does not have the required exposure duration of 90 days as required in OECD TG 408, because the exposure duration of the screening test is approximately 63 days (for females) and 28 days (for males). Furthermore the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 408.

ii. Adaptation according to Annex XI, Section 3

You have provided an adaptation in Section 7.5.1 of your dossier, and you conclude that "*In accordance with point 3 of section 3 of REACH Annex XI, it is considered justified to omit the repeated dose toxicity study (required in section 8.6.2 of Annex IX) on the basis that there will be extremely minimal exposure to the substance. The substance is not manufactured or imported as such on the EU market, but it is only available as a reacted monomer in an imported polymer with residual levels below 0.1 %; it is therefore considered justified to omit the 90 day repeated dose toxicity testing via the oral route.*"

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

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

- 3.2 (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled, where two conditions are that:

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

- 3.c (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
- 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 following conditions are fulfilled, where two conditions are:
  i. the substance is not released during its life cycle;
  ii. the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible.

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

i) Exposure assessment

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

ECHA notes that you have not identified any use for the Substance, nor have you created any exposure scenario in the CSR. The CSR does not contain a chemical risk assessment covering all relevant exposures of the entire life-cycle of the monomer substance subject to this decision. Instead, you state that as polymerisation takes place outside the EU, there is no identified use within the EU and no exposure assessment needs to be addressed.

Moreover, you have not provided documentary evidence (e.g. laboratory report, confirmation from your supplier or reference to literature) confirming that the total concentration of the residual unreacted monomer in the polymer is always below 0.1%.

You have neither considered the possibility that the unreacted monomer might be released from the polymer upon degradation or the polymer might be decomposed to the monomer and result in exposure to man. In this respect, you are also referred to the ECHA Guidance for monomers and polymers (April 2012, Version 2.0), in particular Sections 2.2, 3.2.1 and 4.2, and the judgement of the European Court of Justice in EU Case C 558/07 of 7 July 2009, paragraph 51.

ii) DNEL derivation

REACH Annex XI, section 3.2(a)(ii) contains a footnote which explicitly states "… *a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.*"

You have used the OECD TG 422 study ([redacted] 2002) to derive the worker long-term systemic DNEL for inhalation effects and worker long-term, systemic DNEL for dermal effects.
The duration of the combined repeated dose and reproduction/developmental screening study (OECD TG 422) serves as an alternative for the short-term repeated dose toxicity (28-day) study. In that study, males were dosed for 28 days. Therefore, the duration of the provided studies is not appropriate to derive the relevant and appropriate DNEL for the 90-day repeated dose toxicity study (Section 8.6.2 at Annex IX).

ECHA concludes that reliable documentation and justification for the premise that there is no exposure to the registered substance is currently missing. In particular, the following requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled:

a) you have not provided relevant exposure scenario(s) in the chemical safety report (cf. Annex XI, Section 3.1 of the REACH Regulation) with thorough and rigorous exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation covering whole life cycle of the Substance (cf. Annex XI, Section 3.2 of the REACH Regulation);
b) you have not provided relevant life-cycle information and exposure scenarios relating to the unreacted monomer (cf. Annex XI, Section 3.2.(a)(i) of the REACH Regulation);
c) you have not provided an appropriate study for derivation of the DNEL
d) you have not provided any description of exposure scenarios, nor strictly controlled conditions throughout the life cycle (cf. cf. Annex XI, Section 3.2.(b) of the REACH Regulation);
e) you have not demonstrated and documented that the registered substance (the monomer) is not released during its life cycle e.g. via decomposition or degradation (cf. Annex XI, Section 3.2.(c)(i) of the REACH Regulation).

Therefore, several requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled.

In the comments to the draft decision you disagree with the request and propose to address the above information requirement with the exposure-based waiving. You consider that "*applications of the polymer have limited potential for direct contact with people or with environmental media other than air. The polymer is itself highly resistant to degradation*", there is negligible "*potential leaching or bioavailability of the residual monomer*" and "*there is no reason to expect any generation of residual monomer.*" Regarding the latter you refer to a literature reference on depolymerisation of polycarbonate wastes but you have not provided it nor explained how it substantiates your claim regarding the Substance.
In summary, you propose to conduct a full and comprehensive exposure assessment and risk characterisation based on a conservative measure of the level of residual monomer in polymer, and to provide further information on residual levels, end-applications of the polymer, as a means of demonstrating lack of risk to human health and the environment. You indicate your intention to provide it in a future update of your registration dossier.
You have not specified whether you are planning to address the criteria under Annex XI, Section 3.2 (a), (b) or (c) and how exactly you plan to meet all the relevant conditions specified therein (e.g. regarding the derivation of a suitable DNEL according to Annex XI, Section 3.2 (a)).

ECHA reiterates that in order to omit the standard information requirement under Section 3 of Annex XI the conditions of either Annex XI, Section 3.2 (a), (b) or (c) have to be met. As indicated above, this includes (among others) a thorough and rigorous exposure assessment of the Substance covering all relevant exposures throughout the life-cycle of the Substance, including the potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer.

You have not provided in your comments a thorough and rigorous exposure assessment nor addressed other shortcomings identified above. Based on the information provided in the comments, there is currently no information to satisfy the conditions of either Annex XI, Section 3.2 (a), (b) or (c). Please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3.
Therefore, based on the information provided in your dossier and in your comments, your adaptation is rejected, and the information requirement is not fulfilled.

iii. Adaptation according to Annex IX, 8.6.2, Col 2

Furthermore, we understand that you have provided an adaptation according to Column 2 of Annex IX, Section 8.6.2. in Sections 7.5.1 of your dossier for the inhalation route and 7.5.2 of your dossier for the dermal route.

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement, and omit the repeated dose toxicity study (required in 8.6.2) if the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure.

For inhalation and dermal route you indicate that "*In accordance with Column 2 of REACH Annexes VIII and IX, the repeated dose toxicity study (required in Section 8.6.1 and 8.6.2, respectively) by the inhalation/dermal route does not need to be conducted as exposure of humans via inhalation/the dermal route is extremely unlikely/is considered to be unlikely. The substance is not manufactured or imported as such on the EU market, but it is only available as a reacted monomer in an imported polymer with residual levels below 0.1 %; consequently the potential exposure is minimal and it is therefore considered justified to omit repeated dose toxicity testing via the inhalation/dermal route.*"

ECHA notes that in Section 7.1 of the dossier you state for inhalation that "*It is likely that DMBPC will be absorbed if it is inhaled, based on available toxicity data showing a degree of bioavailability after oral exposure. As a worst-case assumption, inhalation absorption of DMBPC is considered high (100 %) for risk assessment purposes."* as well as for dermal absorption that "*The molecular weight is not excessive and the lipophilicity is appropriate for allowing the substance to cross the stratum corneum of the skin. However the low water solubility suggests that permeation through the stratum corneum into the epidermis would be low to moderate. In the absence of quantitative information and absence of effects in the acute dermal toxicity study, estimation of mammalian dermal absorption is made at 25 % in accordance with principles adopted by the EFSA guidance on estimating dermal absorption of pesticide active substances.*"
Based on physical-chemical information in the dossier and your argumentation for absorption, the Substance is not insoluble, it is inhalable according to particle size distribution and you consider that absorption after oral, inhalation and dermal exposure is likely. Furthermore, systemic parental toxicity was reported at the dose of 1000 mg/kg bw/day in the OECD TG 422 study ([redacted] 2002).

Therefore, your adaptation is rejected.

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

Information on the design of the study to be performed

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity.

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

2. Pre-natal developmental toxicity study in one species

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

You have provided (i.) a study conducted according to OECD TG 422 ([redacted] 2002) and (ii.) a justification for data waiving.

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

i. In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species, e.g external, skeletal and visceral malformations and variations has to be investigated as described in OECD TG 414.

You have not provided information following OECD TG 414. Instead, you have provided a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). This study does not inform on skeletal and visceral malformations and variations as required by OECD TG 414.

Therefore, this study does not fulfil the information requirement.

ii. You have further provided a justification for data waiving "*in accordance with section 1 of Annex XI*" of REACH, claiming that the "*OECD 422 screening study showed minimal toxicity and no effects on reproductive parameters at the maximum dose level of 1000 mg/kg bw/day"*. You therefore consider it "*appropriate to waive the developmental toxicity study at this tonnage level as it is considered unlikely that further information would be yielded by a new study addressing this endpoint*".

You may adapt the standard information requirement according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation, provided you fulfil the specific criteria, and submit a scientifically-supported justification.

However, you do not further clarify to which adaptation under Annex XI you are referring to. Therefore, based on your claim and the information provided in your registration dossier ECHA cannot identify any applicable legal basis for an adaptation under Annex XI.

While this adaptation was not specifically indicated by you, for sake of completeness ECHA has evaluated the above information under the rules set in Annex IX, Section 8.7., Column 2.

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

- that there is no evidence of toxicity seen in any of the tests available and
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure.

In your adaptation, you have not substantiated your claim on no toxicity. In the OECD TG 422 study ([redacted] 2002) systemic parental toxicity was reported at the dose of 1000 mg/kg bw/day.
In addition, you have not provided any toxicokinetic data to show that there is no systemic absorption. On the contrary, in section 7.1 of your dossier you indicate moderate oral absorption based on physical chemical properties.

Therefore, the adaptation under Annex IX, Section 8.7., Column 2 is rejected.

In your comments to the draft decision you indicate your intention to adapt this information requirement based on exposure considerations, according to Annex XI, Section 3 of REACH Regulation. You have not specified whether you are planning to address the criteria under Annex XI, Section 3.2 (a), (b) or (c).

In summary, you propose to conduct a full and comprehensive exposure assessment and risk characterisation based on a conservative measure of the level of residual monomer in polymer, and to provide further information on residual levels and end-applications of the polymer, as a means of demonstrating lack of risk to human health and the environment. You indicate your intention to provide it in a future update of your registration dossier.

As explained for the endpoint of sub-chronic toxicity study (90-day) under Appendix B.1, in order to omit the standard information requirement under Section 3 of Annex XI the conditions of either Annex XI, Section 3.2 (a), (b) or (c) have to be met. Currently, for the same reasons as explained under Appendix B.1. in points a-e, the specific requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled.

In your comments you have not provided a thorough and rigorous exposure assessment of the Substance covering all relevant exposures throughout the life-cycle of the Substance, including the potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer nor addressed other specific requirements of Annex XI, Section 3 of the REACH Regulation. Based on the information provided in the comments, there is currently no information to satisfy the conditions of either Annex XI, Section 3.2 (a), (b) or (c).

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

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

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[2] administration of the Substance.

3. 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 a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "*The substance is not manufactured or imported as such on the EEA market, but it is only available as a reacted monomer in an imported polymer with residual levels below*

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

0.1 %; consequently the exposure and emissions to the environment are considered to be negligible".

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018)

For the sake of completeness, ECHA also evaluated your adaptation under Annex XI, Section 3.2 (c) (Substance-tailored exposure-driven testing).

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report.

For substances incorporated in articles with no intended releases, the following conditions, among others, must be met:

i. the substance is not released during its life cycle and,
ii. the likelihood that workers and the general public are exposed to the substance under normal or reasonable foreseeable conditions is negligible.

On condition i. above., you have not provided any supporting information establishing that the substance is not released from the polymer throughout its life cycle.

On condition ii. above., the registration dossier does not provide an exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation (cf. Annex XI, Section 3.2, 2nd sentence of the REACH Regulation; Annex XI, Section 3.2.(c)(ii) of the REACH Regulation). Furthermore, you have not provided documentary evidence (e.g. laboratory report, confirmation from your supplier or reference to literature) confirming that the total concentration of the residual unreacted monomer in the polymer is always below 0.1%.

In the absence of this information, you have not demonstrated that the conditions set out in Annex XI, Section 3.2(c) are met and your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you disagree with the request and propose to address the above information requirement with the exposure-based waiving.

While the details of your arguments are presented in section B.1. above, in summary, you propose to conduct a full and comprehensive exposure assessment and risk characterisation based on a conservative measure of the level of residual monomer in polymer, and to provide further information on residual levels and end-applications of the polymer, as a means of demonstrating lack of risk to human health and the environment. You indicate your intention to provide it in a future update of your registration dossier.

ECHA reiterates that in order to omit the standard information requirement under Section 3 of Annex XI the conditions referred there have to be met. As indicated above, this includes a thorough and rigorous exposure assessment of the Substance covering all relevant exposures throughout the life-cycle of the Substance, including the potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer.

You have not provided in your comments a thorough and rigorous exposure assessment so you have not demonstrated that the conditions set out in Annex XI, Section 3.2(c) are met.

Please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

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

4. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (9.1.6., repectively).

As for the long term testing for aquatic invertebrate (i.e. Section B.3. Above), you have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: " *The substance is not manufactured or imported as such on the EEA market, but it is only available as a reacted monomer in an imported polymer with residual levels below 0.1 %; consequently the exposure and emissions to the environment are considered to be negligible".*

We have assessed this information and identified the following issue:

For the same reasons explained in Section B.3. above, your adaptation is rejected.

In the comments to the draft decision, as for long-term toxicity testing on aquatic invertebrates, you disagree with the request and you propose to conduct a full and comprehensive exposure assessment and risk characterisation to demonstrate lack of risk to human health and environment. You indicate your intention to provide it in a future update of your registration dossier.

As already explained in Section B.3. above, based on the information provided in the comments, there is currently no information to assess whether your adaptation fulfils the requirements of Section 3.2 (c) of Annex XI to the REACH Regulation, as you have not provided a thorough and rigorous exposure assessment. Please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

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

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

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

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[3].

B. Test material

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

1. Selection of the Test material(s)

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

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

This information is needed to assess whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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

Appendix D: Procedure

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

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

The compliance check was initiated on 14 October 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 decision.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: List of references - ECHA Guidance[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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

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

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

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

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

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

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

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

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

OECD Guidance documents[8]

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

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

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

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

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

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

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

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

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.