~~Confidential~~

Helsinki, 26 August 2021

Addressees
Registrant(s) of JS_701-308-4 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
30/10/2020

Registered substance subject to this decision ("the Substance")
Substance name: Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane
EC number: 701-308-4
CAS number: NS

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 ***2 December 2024***.

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

Information required from all the Registrants subject to Annex X of REACH

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

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

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity); and
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

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

Reasons for the request(s) are explained in the following appendix

- Appendix entitled "Reasons to request information required under Annexes 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, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII to X to REACH, for registration at more than 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 X of REACH

1. Pre-natal developmental toxicity study in a second species

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

You have provided a PNDT study in a first species (rat) and the following justification for an adaptation of the information requirement of Annex X, 8.7.2 for a PNDT study in a second species: *"The study does not need to be conducted because the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure".*

ECHA understands that you sought to adapt the standard information requirement according to Annex X, Section 8.7., Column 2, third indent.

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

i) that there is no evidence of toxicity seen in any of the tests available and,
ii) that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure and,
iii) that there is no or no significant human exposure.

You justify your adaptation based on:

- no toxicity observed in the 90-day repeated-dose toxicity study (OECD TG 408, GLP, 2016) and PNDT study in rats (OECD TG 414, GLP, 2016); NOAELs = 1000 mg/kg bw/day,
- estimations for teratogenicity (using MultiCASE and the PASS system) with the overall conclusion that the Substance *"may have a low potential to be toxic to reproduction,*
- toxicokinetic data, based on QSAR estimations (using MultiCase (MC4PC v2.1.0.18), and
- a claim that *"all relevant exposures throughout the life cycle of the substance demonstrates the absence of or no significant exposure in all scenarios of the manufacture and all identified uses"*.

In addition, you state that the adaptation is also supported by the following reasons: *"Annex X, 8.7.2, column 1 of the REACH Regulation states that the pre-natal developmental toxicity study shall be initially performed on one species. The outcome of this initial study should form the basis for the decision to perform a study at this tonnage level or the next on a second species as well as all other relevant available data according to Annex IX, 8.7.2, column 2 of the REACH Regulation.*

You also give further arguments for not performing the study in a second species, stating that "*The similarities between rat and human with regards to metabolic pathways coupled with similarities in anatomical and physiological characteristics, the rodent species of choice for pharmacological and toxicological studies is the rat. The use of this species allows for comparisons in absorption, distribution, metabolism and excretion pathways to be conducted"* and that *"There is no reason to suggest that any effects on development are likely in other species given that there was no indication of the substance affecting rat development in the pre-natal study".* You further consider the study scientifically unjustified due to data available

and in terms of animal welfare.

ECHA has evaluated the provided information and identified the following issues:

A. Annex X, Section 8.7., Column 2

With regard to the criteria (i) and (ii) for an adaptation under Annex X, Section 8.7., Column 2, third indent, as stated above, the provided information does not support your claim of no evidence of toxicity and no systemic absorption. ECHA notes that in the 90-day repeated-dose toxicity study a number of dose-dependent and statistically significants effects in haematology, biochemistry and histopathology are reported. Those changes show that the Substance is systemically available as a result of absorption in the organism and exerts some toxicity. Additionally, based on the estimations performed with the MultiCASE human teratogenicity model and the PASS system, you report an indicated potential of the constituents of the Substance for teratogenicity and embryotoxicity in the PASS system.

Further, based on the estimated oral absorption for the main constituent [redacted] and the two main impurities [redacted] and [redacted] (using MultiCase (MC4PC v2.1.0.18) you conclude that "*It is calculated that the Small Vinyl Ester (i.e. the Substance) is absorbed orally by 80%".* Therefore, according to the information provided in your dossier, systemic exposure to the Substance after oral administration does occur.

Based on the above, the first two criteria of the adaptation (i and ii) are not met.

With regard to the criterion (iii), the developed exposure scenarios reported in the Chemical Safety Report (CSR) do not all demonstrate absence or no significant human exposure, in particular for activities such as industrial spraying (PROC 7) and roller application or brushing (PROC 10) in both professional (ES4) and industrial (ES3) uses. You have estimated as high as [redacted] mg/m^3 inhalation exposure and 8.6 mg/kg bw/day dermal exposure for spraying activity (PROC 7) in both professional and industrial uses (ES 3 and 4). For PROC 10 and for PROC 4 (Use in batch and other process where opportunity for exposure arises) in both ES 3 and 4, you have estimated 5.5 mg/kg bw/day and 6.9 mg/kg bw/day for dermal exposure, respectively. Such exposure levels indicate that human exposure to the Substance under these scenarios occurs and that it cannot be considered as not significant.

Therefore, this criterion is also not met.

In the comments to the draft decision you disagree with ECHA's assessment of the provided information. With regards to criteria (i) and (ii), whilst you question ECHA's interpretation of the effects of the 90-day study, arguing that the observed statistically significant changes in different parameters are not considered adverse, you agree that "*there is clear evidence of absorption and systemic exposure following oral dosing*".

With regards to criterion (iii), you argue that the oral exposure is not relevant because "*it is not anticipated or intended from any of the manufacture or use scenarios*" and that while the workplace exposure modelling indicates a potential of dermal and inhalation exposure, they are in practice "*reduced to insignificant levels by a combination of very effective mitigating factors*", such as low vapour pressure, large particle size in spraying, negligible dermal absorption and the used PPE.

Based on the above, you conclude that "*the Substance is of low toxicological activity, there is no systemic absorption occurring via the relevant routes of exposure and there is no significant human exposure in the intended manufacture and use scenarios. Therefore, the PNDT study in a second species should be waived*".

ECHA points out that even though the effects observed at the 90-day study may not be regarded as "toxic", they deviate from the control in a statistically significant manner, and most importantly, they are results of systemic bioavailability of the Substance, fact that you agree with in your comments. Further, criterion (ii) of Annex X, Section 8.7., Column 2, third indent requires that "it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure". You argue that oral is not the relevant route of exposure. However, you have not provided any toxicokinetic data to show that there is no absorption after other routes of exposure: dermal and inhalation. Therefore, you did not substantiate your claim that "*there is no systemic absorption occurring via the relevant routes of exposure",* consequently, the criterion (ii) is not met.

Further, ECHA notes that in addition to inhalation and dermal exposure route, also hands-to-mouth exposure route is relevant in industrial and professional settings e.g. in the conditions when the substance contaminates skin, surfaces or tools (ECHA Guidance Chapter R.14 Occupational exposure assessment Version 3.0 – August 2016). For reducing occupational exposure, the airborne concentration of the substance and contacts with the substance should be minimised. According conditions of use, process categories (PROCs) and calculated exposure estimates in your exposure scenarios, occupational exposure to the registered substance cannot be considered as not significant. Further, as explained in ECHA Guidance Chapter R. 14. (page 25), for omitting standard testing requirement, the use of personal protective equipment is not considered as an appropriate way of describing no or no significant exposure, since it should be used only for residual exposure and as a last risk management measure according the hierarchy of controls (ECHA Guidance Chapter R. 13, page 9). Therefore, the criterion (iii) is not met.

To conclude, ECHA reiterates that, as already explained in the decision above, in order to meet the conditions under Annex X, Section 8.7., Column 2 third indent, all three concomitant criteraia must be met.

Based on the above, you do not meet the general rules for adaptation of Annex X, Section 8.7., Column 2; the three concomitant criteria are not met, and your adaptation is rejected.

B. Other information given in support of the adaptation

Regarding the further reasoning, based on Annex X, 8.7.2*,* column 1 and Annex IX, 8.7.2. column 2, in support of your adaptation in the above, we point out at first that pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH. Therefore, unless one or more specific adaptations in column 2, Section 8.7 of Annex X apply, or any of the general adaptations at Annex XI apply, information on pre-natal devlopmental toxicity in two species is required.
Similarly, your claim that "*Annex X, 8.7.2, column 1 of the REACH Regulation states that the pre-natal developmental toxicity study shall be initially performed on one species*" is not correct. This is indicated in the column 2 of Annex IX, section 8.7.2., it does not stem from Annex X, Section 8.7.2. column 1. Therefore, it does not apply to Annex X, section 8.7.2., column 1, and your statement does not support any adaptation possibility.

Finally, your further arguments on suitability of the rat over other species (such as the rabbit) is of general nature. You do not give justifications with evidence on why a prenatal developmental toxicity study in the rabbit would not provide scientifically reliable information on prenatal developmental toxicity properties of the Substance. Your considerations on the need of the study on a second species is not in line with the information requirements and the adaptation rules. ECHA points out that in order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the

requirements of Annex IX 8.7.2 and Annex X 8.7.2 for pre-natal developmental toxicity in 2 species.

You have not demonstrated that the information on your Substance enable adaptations in accordance with Section 8.7 of Annex X or Annex XI.

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

Study design:

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

The study shall be performed with oral[2] administration of the Substance.

2. Extended one-generation reproductive toxicity study

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

You have sought to adapt the standard information requirement according to Annex XI, Section 3.2(a) - Substance-tailored exposure-driven testing.

According to Annex XI, Section 3, you may adapt the information requirement, provided you fulfil any one of the criteria specified in section 3.2., (a), (b) or (c). In all cases, adequate justification and documentation must be provided, with a justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I.

For an adaptation under the Annex XI, 3.2(a) the manufacturer or importer must demonstrate and document 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.

You provided the following justification for the adaptation: *"An exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrates the absence of or no significant exposure in all scenarios of the manufacture and all identified uses [..] A DNEL has been derived from a recently conducted, reliable 90 day sub-chronic study ([redacted] study number [redacted]) […] and a comparison of the DNEL with the predicted exposures demonstrates that exposures are always well below the derived DNEL".*

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

You also provided a separate document "[redacted]".

ECHA has evaluated the provided information and notes the following deficiencies with regards to your adaptation according to Annex XI, Section 3.2 (a):

(i) Exposure assessment

You have developed exposure scenarios and estimated exposure levels by using Tier 1 modelling (ECETOC TRA) in your CSR. ECHA notes first that the absence of or no significant exposure is not demonstrated for all activities in the CSR. As examples, you have estimated as high as [redacted] mg/m^3 inhalation exposure and 8.6 mg/kg bw/day dermal exposure for spraying activity (PROC 7) in both professional and industrial uses (ES 3 and 4). For PROC 10 and PROC 4 in both ES 3 and 4, you have estimated 5.5 mg/kg bw/day and 6.9 mg/kg bw/day for dermal exposure, respectively and for many ESs you have estimated [redacted] mg/m^3 inhalation exposure. Such exposure levels indicate that human exposure to the Substance under these scenarios occurs and that it cannot be considered as not significant.

Furthermore, ECHA notes that rigorous and thorough exposure assessment that would justify *no or no significant exposure* cannot be achieved by using Tier 1 exposure modelling which is a conservative but also an uncertain exposure tool. As also set out in 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*.

According to Guidance on IRs and CSA, Section R.14.6.1, "*Uncertainty of the exposure estimate needs to be considered to ensure that the conditions of use are sufficiently covered by the exposure estimate. Depending on the level of uncertainty around the various factors contributing to the exposure estimate and resulting RCR, it is recommended to refine (re-iterate) the exposure by alternative means, to reduce the uncertainty. This may include for example modelled exposure from higher tier models, sensitivity considerations regarding input data in models, and by inclusion of or resorting to (additional) measurement data in a weight of evidence approach to increase reliability of the outcome and to guarantee safe use.*" Hence, representative measured data or adequate higher tier exposure modelling should be used to demonstrate absence of or no significant exposure.

In addition, according to the provided separate documentation Small Vinyl Ester is "*produced in closed systems under controlled conditions*" as well as its solutions "*are used under controlled conditions*". Further, you state that "*Small Vinyl Ester will not be systemically bioavailable via occupational exposure (inhalation or skin contact)".* However, ECHA notes that the provided information in the CSR is not in line with those satements. It neither supports nor demonstrates negligible exposure for identified exposure scenarios.

In your comments to the draft decision you disagree with ECHA's assessment, arguing that dermal and inhalation exposure is reduced to insignificant levels by low vapour pressure, large particle size in spraying, negligible dermal absorption and with the use of PPE.

ECHA notes that in addition to inhalation and dermal exposure route, also hands-to-mouth exposure route is relevant in industrial and professional settings e.g. in the conditions when the substance contaminates skin, surfaces or tools (ECHA Guidance Chapter R.14 Occupational exposure assessment Version 3.0 – August 2016). For reducing occupational exposure, the airborne concentration of the substance and contacts with the substance should be minimised. According conditions of use, process categories (PROCs) and calculated exposure estimates in your exposure scenarios, occupational exposure to the registered

substance cannot be considered as no significant. Further, as explained in ECHA Guidance Chapter R. 14. (page 25), for omitting standard testing requirement, the use of personal protective equipment is not considered as an appropriate way of describing no or no significant exposure, since it should be used only for residual exposure and as a last risk management measure according the hierarchy of controls (ECHA Guidance Chapter R. 13, page 9).

Therefore, you did not demonstrate the "*absence of or no significant exposure in all scenarios of the manufacture and all identified uses*".

ii) *DNEL derivation*

In your CSR you have reported the worker, long-term, systemic DNEL for inhalation and dermal effects based on a 90-day oral repeated dose toxicity study. This study does not provide information on mating, fertility, pregnancy, lactation and postnatal development of the fully exposed F1 generation up to the adulthood as required in EOGRT (OECD TG 443). Therefore, the DNEL you have provided is neither relevant nor appropriate for the information requirement to be omitted, i.e. reproductive toxicity, and for risk assessment purposes, alike.

In your comments to the draft decision you disagree with ECHA's assessment, arguing that "*it is not consistent with the intended use of this waiver provision under REACH*".
You aknowledge that the 90-day study, used for derivation of the DNEL, being not a full reproductive toxicity study, "*does not provide information on some reproductive endpoints*", however, it still provides "*some valuable information on reproductive toxicity*", e.g. on the pituitary gland, testes, epididimides, prostate etc. You conclude that "*that it is perfectly justified to compare the estimate esposure estimates with the DNEL derived from the sub-chronic study*".

ECHA reiterates that, as already explained in the decision above, to meet the condition under Annex XI, 3.2(a)(ii), the available test data used to derive the DNEL for an information requirement needs to be "[…] *relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes*".

According to Annex X, section 8.7.3. an Extended one-generation reproductive toxicity (EOGRT) study is a standard information requirement. Relevant information to fulfi this information requirement is provided by the OECD TG 443 as specified in this decision. At general level, this study includes, among other, information on 1) sexual function and fertility on both sexes, that must include: information on mating, fertility, gestation, parturition, lactation, organ weights and histopathology of reproductive organs and tissues, oestrous cyclicity, sperm count, sperm analysis, hormone levels, litter sizes, nursing performance and other potential aspects of sexual function and fertility; on 2) toxicity to offspring that must cover information on deaths before, during or after birth, growth, sexual maturity, oestrous cyclicity, histopathology of reproductive organs in adulthood and other potential aspects of toxicity to offspring.

ECHA reiterates that even though the 90-day repeated dose toxicity study provides some information on the organ weights and histopathology of reproductive organs and tissues, it does not provide any information on the key parameters sexual function and fertility or toxicity to offspring.Based on this, the information from the 90-day oral repeated dose toxicity study does not provide, on its own, the information required to derive a no effect level for reproductive toxicity.

Therefore, criterion 3.2(a)(ii) is not met

(iii) *Comparison of the derived DNEL with the results of the exposure assessment*

The information in your dossier does not fulfill the conditions specified in Annex XI, Section 3.2(a)(i) for exposure assessment or 3.2(a)(ii) for DNEL derivation. Therefore, it is not possible to compare the exposure to the derived DNEL (3.2(a)(iii)), and the conditions under Annex XI, Sections 3.2(a)(i) and 3.2(a)(ii) are not met.

Conclusion on the assessment of the adaptation based on exposure-driven testing

In conclusion, based on above evaluation, your adaptation according to Annex XI, Section 3.2(a) is rejected, and does not fulfil the information requirement.

The specifications for the study design

Premating exposure duration and dose-level setting

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

Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration.

Therefore, the requested premating exposure duration is ten weeks.

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

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

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

Cohorts 1A and 1B

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

Species and route selection

The study must be performed in rats with oral[3] administration. Based on the 90-day oral feeding study in rats provided in the dossier, the Substance in feed interfered with normal nutrition and significantly reduced food intake and body weight gain. In addition, based on the PNDT study provided in rats, oral gavage dosing is suitable for the Substance. Therefore, the study should be conducted using oral gavage dosing.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3

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

(developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[4].

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

Appendix B: 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[5].

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:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex).
c) Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm 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[6].

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

Appendix C: 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 09 October 2020.

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

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

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

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

Appendix D: List of references - ECHA Guidance[7] 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)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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[10]

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