~~Confidential~~

Helsinki, 10 January 2022

Addressees
Registrants of Dodecane-12-lactam as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
14/10/2016

Registered substance subject to this decision ("the Substance")
Substance name: Dodecane-12-lactam
EC number: 213-424-8
CAS number: 947-04-6

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 ***16 April 2024***.

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

A. 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)

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

1. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by oral route, in rats, specified as follows:

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

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes IX to X of REACH", respectively.

Information required depends on your tonnage band

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

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

100 tpa

- 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 Mike Rasenberg, 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 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 adapted this information requirement claiming that '*The substance was not classified as dangerous according to Directive 67/548/EWG due to low acute aquatic toxicity and ready biodegradability (>60% in 10 day-window). In view of this the testing of longterm toxicity to aquatic organisms does not seem to be necessary, since long term effects might only occur if the substance is not readily biodegradable or bioaccumulative*.' We understand that you intended to rely on Annex IX, Section 9.1., Column 2.

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 fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected. In your comments on the draft decision, you agree that the Annex IX, Section 9.1., Column 2 adaptation does not apply.

Additionally, in your comments on the draft decision, you have sought to adapt the standard information requirement according to Annex XI, Section 3. Substance-tailored exposure-driven testing. You have provided exposure scenarios (ESs) and risk characterisation ratios (RCRs) for [redacted].

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 criteria 3.2.(a),(b) or (c) shall be met. In particular :

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

However, in your dossier you state that the substance is used as a monomer in a polycondensation polymerisation process resulting in formation of polyamide. In addition, you have not provided an ES for release of the substance from polyamide polymer. Therefore you

have not established an absence of exposure or no significant exposure for all the identified uses.

Therefore, the adaptation you provided in your comment on the draft decision is not in line with the conditions specified in Annex XI, Section 3 (a) and this adaptation is also rejected

Consequently, the information requirement is not fulfilled.

In your comments on the draft decision you agree to conduct the long-term toxicity testing on aquatic invertebrates (OECD TG 211) if your Annex XI, Section 3. (Substance-tailored exposure-driven testing) is rejected.

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 requirementclaiming that '*The testing of longterm toxicity to aquatic organisms does not seem to be necessary, since long term effects might only occur if the substance is not readily biodegradable or bioaccumulative. Furthermore fish were not the most sensitive species*.' We understand that you intended to rely on Annex IX, Section 9.1., Column 2.

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 fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected. In your comments on the draft decision, you agree that the above Annex IX, Section 9.1., Column 2 adaptation does not apply

However, in your comments on the draft decision, you have instead sought to adapt the standard information requirement based on two different grounds:

- Firstly you invoke the same adaptation under Annex XI, Section 3. (Substance-tailored exposure-driven testing) as analysed under section A.1 above. However, for the reasons already described in section A.1 above, your adaptation is rejected.

- secondly you propose a stepwise testing if your adaptation under Annex XI Section 3 is rejected. Your proposed testing strategy begins with a long-term toxicity testing on aquatic invertebrates (OECD TG 211). You then propose to conduct the long-term toxicity testing on fish (OECD TG 210) only if the NOEC or EC10 is > 1mg/l in the long-term toxicity testing on aquatic invertebrates (OECD TG 211).

A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

However, your proposal to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

Therefore, you have not demonstrated that this information can be omitted.

On this basis, the information requirement would not be fulfilled.

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

1. Extended one-generation reproductive toxicity study

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

You have adapted this information requirement under Annex XI, Section 1.2 (Weight of evidence). In support of your adaptation, you provided the following sources of information:

i. a non-guideline 3-generation study via oral route (feed) in rats with an analogue substance, ε-caprolactam, (EC No. 203-313-2) (DFG 1990)
ii. a study according to OECD 408 via oral route (gavage) in rats with the Substance ([redacted] 1993)
iii. a study similar to OECD 409 via oral route (feed) in dogs with the Substance ([redacted] 1974)
iv. a study according to OECD 414 via oral route (gavage) in rats with the Substance ([redacted] 2001)

In addition, you have provided the following statement: *"According to section 1.2 of Annex XI, the study need not be done if there is a weight of evidence to conclude the substance does not have a particular property, and further testing on vertebrate animals may be omitted. The toxicological information regarding effects on fertility of lauryl lactam and of the structurally related ε-caprolactam leading to the assumption/conclusion that effects on fertility and lactation of the substance lauryl lactam at doses, which do not cause parental toxicity, are rather unlikely. Furthermore a developmental toxicity study conducted with lauryl lactam in rats showed no relevant toxic effects to reproduction indicating that the substance is not a reproductive toxicant ([redacted], 2001). Therefore further studies regarding effects on fertility are not necessary for lauryl lactam."*

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

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

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

You have not included a justification for your weight of evidence adaptation for the information requirement, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Irrespective of the above mentioned deficiency on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

To fulfil the information requirement, normally a study performed according to OECD TG 443 design as specified in this decision must be provided. OECD TG 443 requires the study to investigate the following key parameters: 1) sexual function and fertility, 2) toxicity to offspring and 3) systemic toxicity.

1) Sexual function and fertility

Sexual function and fertility on both sexes must include information on mating, fertility, gestation (length), maintenance of pregnancy (abortions, total resorptions), 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.

The sources of information (ii) and (iii) only provide relevant information on organ weights and histopathology of reproductive organs and tissues. Source (iii) provides only limited information on sperm parameters such as the sperm maturation. Source (iv) only provides relevant information on the maintenance of pregnancy. The other key aspects of sexual function and fertility are not covered in sources of information (ii) – (iv).

Source (i) could provide information on the aspects described above.

However, significant deficiencies affect the reliability of source (i). Your documentation does not describe the method, and it also provides very little information on the examinations performed and the results observed. As the source (i) is based on secondary literature, you have rated the reliability of the study as not assignable. You have only indicated that the birth behaviour of dams was not affected, but detailed information on the key parameters of sexual function and fertility is missing. In addition, the source study (i) is performed with an analogue substance. More specifically, you read-across between ε-caprolactam (EC No. 203-313-2) as a source substance and the Substance as a target substance. You have not provided any read-across justification document and you have not provided any reasoning for the prediction of toxicological properties in your registration dossier.

In your comments on the draft decision, you indicate your intention to revise your read-across adaptation according to the read-across assessment framework (RAAF) scenario 2, and provide the following reasoning for the prediction of reproductive toxicity of the Substance:

- *"[…] the lead registrant and the other addressees in Annex X propose to revise the current read-across after the RAAF particularly in regards of the missing weight of evidence, sufficient documentation of the read-across, the study report of the source study (i) and current QSAR models."*
- *"[…] the QSAR Toolbox (Appendix 4) shows the best ratio in regards of structural similarities between the target and source substance would be between ε-Caprolactam (CAS 105-60-2) as a source substance and Dodecane-12-lactam (CAS 947-04-6) as the target substance."*
- *"The technical requirements (scenario 2) for the conduction analogue of the read-across between the source ε-Caprolactam (CAS 105-60-2) and the target Dodecane-12-lactam (CAS 947-04-6) are fulfilled […]"*
- *"[…] the results of the OECD 414 in rats and rabbit show that the source ε-Caprolactam (CAS 105-60-2) can be considered as a worst-case approach in the read-across for reproductive toxicity according to the RAAF."*

Regarding your read-across adaptation, ECHA has identified the following issues:

a) *Read-across documentation*

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies) (ECHA Guidance R.6.2.6.1).

You have provided a study (i) conducted with another substance than your Substance in order to comply with the REACH information requirements. You have not provided documentation in your registration dossier as to why this information is relevant for your Substance.

In your comments on the draft decision, you indicate that the requirements of scenario 2 in RAAF for analogue approach are fulfilled. In your assessment, you refer to further toxicokinetic profiling and QSAR models (VEGA and ToxCast) without providing any further information. In addition, you have provided Derek predictions without any explanation how they are relevant for your read-across justification and prediction of reproductive toxicity of the Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance.

b) *Supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

As indicated above, you argue in your comments on the draft decision that your read-across hypothesis for reproductive toxicity 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. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and for the source substance.

In your comments on the draft decision, you refer to studies equivalent to OECD 414 performed in rats and rabbits with the source substance and claim "*[…] the source ε-Caprolactam (CAS 105-60-2) can be considered as a worst-case approach in the read-across for reproductive toxicity according to the RAAF. Therefore, the use of OECD 416 of the source ε-Caprolactam (source (i)) in the read-across indicates that the expected effect in the target substance could be expected to be lower. Consequently, the prediction constitutes would not lead to an underestimation of the effect(s).*"

ECHA notes that you have provided some supporting information regarding pre-natal developmental toxicity, but neither your comments on the draft decision nor the registration dossier includes any robust study summaries or descriptions of data for

the source substance that would confirm a conservative prediction of the properties of the Substance on the fertility-related parameters.

In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In addition, the source study (iii.) indicates that the Substance decreased weights of reproductive organs (testes, ovaries and prostate) and caused an impairment of the sperm maturation in dogs. You have not reported similar findings with the source substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

c) *Adequacy and reliability of source study*

Under Annex XI, Section 1.5., the results to be read across must provide adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 443. Therefore, the following specification must be met:

- at least 20 pregnant females per dose group in parental P0 generation
- examination of key parameters for sexual function and fertility
- examination of key parameters for pre/peri/postnatal developmental toxicity
- examination of key parameters for endocrine modes of action
- examination of key parameters for systemic toxicity

However, the study (i) does not meet the above mentioned specifications because:

- no information provided on how many pregnant females per dose group in parental P0 generation were used;
- functional fertility, sperm parameters and oestrus cyclicity have not been examined in P0 generation, and also histopathology of the gonads in P0 generation is missing;
- developmental toxicity has not been examined as required in OECD TG 443 as e.g. no information on litter size, postnatal survival, clinical signs, distribution of males and females, and sexual maturation is provided;
- investigations of endocrine mode of action, such as oestrus cycle, endocrine organ weights and histopathology, anogenital distance, nipple retention, sexual maturation (vaginal opening and preputial separation, time from vaginal opening to first oestrous cycle, and thyroid hormone measurements have not been performed; and
- investigations for full clinical chemistry, full haematology, and full histopathology of organs and tissues have not been performed.

In your comments on the draft decision, you propose the following actions to address the above-mentioned missing specifications in the study (i):

- *"[…] a letter of access (LoA) needs to be purchased from the study owner of source study (i) to provide reliable information to conduct a sufficient read-across."*
- *"[…] to conduct an OECD 421 Reproduction/Developmental Toxicity Screening Test to address the current endocrine disruptor mode of action endpoints and gain additional information on sexual function and fertility. […] an endocrine mode of action (such as oestrus cycle, endocrine organ weights and histopathology, anogenital distance, nipple retention, sexual maturation and thyroid hormone measurements) have not been evaluated in the source study (i) due to the Guideline of the OECD 416 Two-Generation Reproduction Toxicity Study "*

While ECHA acknowledges your intention to complete the information on the study (i), this information does not change the assessment as currently you have not provided any new information regarding the missing study specifications indentifed above in your comments or in the registration dossier.

Therefore, the source (i) does not have adequate and reliable coverage of the key parameters of the OECD TG 443.

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.

Therefore, source (i) does not provide any reliable information on sexual function and fertility.

Taken all these sources of information together, there is no reliable information on mating, fertility, gestation (length), parturition, lactation, oestrus cyclicity, sperm count, full sperm analysis, and nursing performance.

Due to lack of significant amount of relevant and reliable information on sexual function and fertility, it is not possible to conclude on that property.

2) *Toxicity to offspring*

Toxicity to offspring must cover information on deaths before, during or after birth, growth, external malformations, clinical signs, sexual maturity, oestrous cyclicity, organ weights and histopathology of reproductive organs in adulthood and other potential aspects of toxicity to offspring.

The sources of information (ii) and (iii) do not provide any relevant information on toxicity to offspring. Source (iv) provides relevant information on toxicity to the offspring only before birth.

Only source (i) could provide relevant information on toxicity to the offspring. However, source (i) is not reliable due to significant deficiencies in the provided information as explained under sexual function and fertility.

Taken together, there is no reliable information on toxicity to offspring after birth (deaths, growth, clinical signs, sexual maturity, oestrous cyclicity, organ weights and histopathology of reproductive organs in adulthood).

Due to lack of significant amount of relevant and reliable information on toxicity to offspring, it is not possible to conclude on that property.

3) *Systemic toxicity*

Systemic toxicity must include information on clinical signs, survival, body weights, food consumption, haematology (full-scale), clinical chemistry (full-scale), organ weights and histopathology of non-reproductive organs (full-scale) and other potential aspects of systemic toxicity in the parental P and F1 generation up to adulthood.

The sources (ii) and (iii) provides relevant information on several aspects of systemic toxicity in P generation, including clinical signs, survival, body weights, food consumption, haematology, clinical chemistry, organ weights and histopathology of non-reproductive

organs. However, there is no information on systemic toxicity in F1 generation up to adulthood.

Source (iv) provides relevant information on clinical signs, survival and body weights but only in P generation females during pregnancy. However, several aspects of systemic toxicity are not covered in source (iv).

Source (i) could provide relevant information on systemic toxicity in P and F1 generations. However, source (i) is not reliable due to significant deficiencies in the provided information as explained under sexual function and fertility.

Due to the lack of all reliable information on systemic toxicity in F1 generation, it is not possible to conclude on that property.

Conclusion on weight of evidence

The sources of information (ii) to (iv) provide relevant and reliable information on
- sexual function and fertility: weight and histopathology of reproductive organs (in P generation) and maintenance of pregnancy
- toxicity to offspring: toxicity to the offspring before birth
- systemic toxicity: P generation

However, the provided sources of information (i) to (iv) lack reliable information on
- functional fertility
- toxicity to offspring after birth
- systemic toxicity in F1 generation

Therefore, a significant amount of essential investigations are limited or totally lacking that would inform on sexual function and fertility, toxicity to offspring and systemic toxicity in order to conclude on these aspects, and totally on properties of reproductive toxicity.

It is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 443 study.

Based on the above, your adaptation is rejected and the information you provided does not fulfil the information requirement.

<u>Study design</u>

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 (ECHA Guidance R.7.6.).

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 administration (ECHA Guidance R.7.6.2.3.2.).

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/or Cohort 3 (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 Annex X, Section 8.7.3., Column 2. 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 R.7.6.

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[2].

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 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.

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 and whether it is suitable for use by all members of the joint submission.

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

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 8 May 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 request(s).

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

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

Appendix E: List of references - ECHA Guidance[3] 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)[4]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[4]

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[5]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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

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

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

Appendix 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]
[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.