~~Confidential~~

Helsinki, 26 August 2020

Addressees
Registrants of JS_3923-79-3 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
3 February 2020

Registered substance subject to this decision ("the Substance")
Substance name: 4,5-dihydroxy-1,3-dimethylimidazolidin-2-one
EC number: 223-496-2
CAS number: 3923-79-3

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***1 December 2022***.

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

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

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

3. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.)

4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

C. 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)

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

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

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following standard information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5:

- *In vivo* mammalian erythrocyte micronucleus test (Annex IX, Section 8.4., column 2)
- *In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study (Annex VIII, Section 8.4.2)
- *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

A. **Predictions for toxicological properties**

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances, Urea, reaction products with formaldehyde and glyoxal, EC No. 296-664-6 (CAS No. 92908-35-5) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties: *"This read-across is based on the hypothesis that source and target substances have the same type of toxicological effects based on common underlying mechanisms (ECHA, 2017b). [...] Furthermore, the main component of the source substance is likely to be a metabolic sequel product of the target substance"*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

[2] ECHA Guidance R.6
[3] ECHA Read-across assessment framework (RAAF, March 2017)
[4] ECHA Read-across assessment framework (RAAF, March 2017)- considerations on multi-constituent substances and UVCBs

ECHA notes the following deficiencies with regards to prediction of toxicological properties.

1. *Characterisation of the source substance(s)*

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

According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[5] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, whenever the Substance and/or the source substances are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the substances needs to be provided; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[6]

The source substance is a UVCB. In your justification document (Table 2, p. 5) you have identified the source substance by name and numerical identifiers and have provided the typical concentration (ca [redacted]%) of the main constituent (4,5-dihydroxy-1,3-bis(hydroxymethyl)imidazolidin-2-one; EC: 217-451-6). Further, in the same document you state that "*The main component and the other components of the source substance, i.e. condensation products or addition products of urea, glyoxal and formaldehyde, have the target substance 4,5-dihydroxy-imidazolidin-2-one as basic structure*".

Based on this information ECHA understands that the source substance contains "*condensation products*" among the constituents accounting for the remaining [redacted]% of its composition.

You did not provide qualitative and quantitative information on the individual constituents of the source substance other than its main constituent. Without this information, no qualitative or quantitative comparative assessment of the compositions of the source substance and of the Substance can be completed. In the absence of this information, the extent to which differences in the compositions of the substances are likely to influence their overall toxicity cannot be determined and it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

2. *Missing supporting information on the impact of exposure to non-common compounds*

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*"[7]. The set of supporting information should allow

[5] ECHA Guidance R.6: Section R.6.2.3.1
[6] ECHA Guidance R.6: Section R.6.2.5.5
[7] ECHA Guidance R.6: Section R.6.2.2.1.f

to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

Supporting information must include, among others, information on the impact of exposure to non-common compounds.

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, exposure to the Substance and of the source substance(s) may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

The Substance is a mono-constituent substance with its main constituent accounting for 80 to 100% of its composition. Based on the information presented in Table 2 of your read-across justification document, the source substance is a UVCB and the main constituent of the source substance accounts for [redacted]% of its composition. You claim that "*the main constituent of the source substance is likely to be a metabolic sequel product of the target substance*".

No information on bioavailability of the constituents of the source substance and of the Substance is included in your dossier. Therefore, 100% bioavailability is assumed.

Based on the information provided in your dossier, two "*types*" of non-common compounds can be identified: main constituent of the Substance and the other constituents of the source substance than its main constituent.

- main constituent of the Substance, i.e. the parent compound

In order to support your read-across hypothesis, you have indicated in the read-across justification document that "*the main constituent of the source substance is likely to be a metabolic sequel product of the target substance*". In this context, information characterising the rate and extent of the biotransformation of the main constituent of the Substance, i.e. the parent compound, into the main constituent of the source substance, i.e. the common compound, is necessary to confirm the formation of the proposed common compound and to assess the impact of the exposure to the parent compound on the properties of the Substance.

You have not established that the common compound is a biotransformation product, formed from the parent compound as assumed in your read-across justification document. In the absence of information establishing a rapid and extensive biotransformation of the parent compound into the common compound, you have not addressed the impact of exposure to parent compound on your prediction of the properties of the Substance.

- other constituents of the source substance

The source substance is presented as a UVCB in Table 2 of your read-across justification document and its main constituent accounts for [redacted]% of its composition. You have not provided any qualitative and quantitative information on the other constituents of the source substance making up for the remaining [redacted]% of the composition of the substance. Since the Substance is a mono-constituent substance, these remaining constituents of the source substance represent non-common compounds.

No experimental data or other adequate and reliable information addressing the impact of exposure to these non-common compounds on the prediction of the properties of the Substance is included in the documentation of your read-across approach.

In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

3. *Test material identity*

Under Article 10(a)(vii) of the REACH Regulation, a technical dossier must include "*robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I*". Annex I, Section 1.1.4 of REACH states that robust study summaries are "*required of all key data used in the hazard assessment*". When properties of a substance are read-across from a source study conducted with an analogue substance to fulfil an information requirement, this source study provides key data for the hazard assessment. Therefore, a robust study summary providing information allowing to make an independent assessment of the study must be provided for each source study used in read-across approaches. The robust study summary must include information on the composition of the sample tested in the source study.

The information reported in your technical dossier on the composition of the sample tested in the source studies for genotoxicity and developmental toxicity is limited to the generic name of the source substance and/or its numerical identifier. In the source studies for systemic toxicity (90-day) the only additional information is that the test material contains 0.8% formaldehyde.

You have not provided detailed information on the composition of the test sample with which the source studies, used to fulfil the above-mentioned information requirements were conducted. In addition, you did not explain why the presence of formaldehyde in the source test material, used to condusct the 90-day studies would not influence the prediction for systemic toxicity for your Substance. In the absence of such information, the representativity of the sample tested for the source substance cannot be confirmed and the information obtained from that studies cannot be used to reliably predict the properties of the Substance.

Conclusions on the read-across approach

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

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

1. In vitro gene mutation study in bacteria

An *In vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided the following studies performed with the Substance:

(i) *In vitro* gene mutation in bacteria cells (key study, according to OECD TG 471, [redacted], 1995)

(ii) *In vitro* gene mutation in bacteria cells (supporting study, no guideline 1979)

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997), which indicates that the test should be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

You have provided Ames tests with the following strains: TA 98, TA 100, TA 1535, TA 1537 which all gave negative results.

ECHA has assessed this information and identified the following issue:

The studies you have provided were not conducted with the appropriate 5 strains as they do not include results in the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

Therefore, the information provided does not cover a key parameter required by OECD TG 471.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) must be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

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

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

Based on the information provided in your IUCLID dossier, ECHA understands that you sought to adapt this information requirement according to Annex XI, section 1.2. (weight-of-evidence) and has analysed it accordingly.

In order to support your adaptation you have provided the following information:

(i) *In vivo* mammalian erythrocyte micromucleus test (according to OECD TG 474, GLP) with the source substance EC: 296-664-6

(ii) *In silico* prediction, QSAR model, using OASIS TIMES v2.27.19.13

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

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, 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 deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has further assessed the provided sources of information for relevance and reliability and identified the following issues:

A. Relevance of the information

Relevant information that can be used to support the weight of evidence adaptation for information requirement of Annex VIII, Section 8.4.2. includes:

- Detection and quantification of cytotoxicity and the frequency of cells with structural chromosomal aberration(s) or the frequency of micronuclei in cultured mammalian cells *(in vitro*) or in mammals (*in vivo*).

This information is covered by information similar to either *in vitro/in vivo* chromosomal aberration tests (OECD TG 473/OECD TG 474) or *in vitro/in vivo* micronucleus tests (OECD TG 487/OECD TG 475).

The source of information (i) is an *in vivo* micronucleus test (according to OECD TG 474), which provides relevant information on detection and quantification of the frequency of micronuclei in mammals. The source of information (ii) provides relevant supporting information for this endpoint.

However, these sources of information have the following deficiencies affecting their reliability.

B. Reliability of the information

B.1. Studies with analogue substances can contribute to the weight of evidence adaptation only if the read-across is acceptable.

Study (i) is performed with the analogue substance EC 296-664-6. As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected, therefore the information on this analogue substance does not provide reliable information for weight-of-evidence.

B.2. The results obtained from valid QSAR models are considered reliable when cumulative conditions are met, among others: the substance falls within the applicability domain of the QSAR model.

Source of information (ii) is a QSAR model which calculates the applicability domain for the substance you predict as parameter ranges, structural domain and interpolation space. For the structural domain, the model considers the substance to be within domain if 100% of the fragments are correctly predicted. You provide the following information about structural domain: 60% correctly predicted fragments and 40% unknown fragments. Based on this information, you conclude that "*Although the substance does not completely fall into the applicability domain of the model, the model was found to give reliable predictions for industrial chemicals*".

Since the Substance does not completely fall into the applicability domain of the QSAR model, there is an uncertainty on the reliability of the predictions obtained from this model. Therefore, the source of information (ii) does not provide reliable information for weight-of-evidence.

As a conclusion, even though, the sources of information as indicated above provide relevant information, their reliability is affected significantly, therefore, they cannot contribute to the conclusion on cytotoxicity and the frequency of cells with structural chromosomal aberration(s) or the frequency of micronuclei.

C. Conclusion

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 vitro* cytotoxicity study in mammalian cells or *in vitro* micronucleus study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Information on the study design

To fulfil the information requirement for the Substance, either *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

You have provided the following information with the source substance:

(i) *In vitro* gene mutation in mammalian cells (key study, according to OECD TG 476, [redacted])

As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected. Therefore, the information requirement is not fulfilled.

To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

While an adaptation was not specifically indicated by you, ECHA has evaluated the provided information under the rules set out in Annex VIII, 8.6.1, column 2.

Column 2 of Annex VIII, Section 8.6.1. provides that an experimental study for this endpoint is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

You have provided the following information with the source substance:

(i) Sub-chronic (90-day) oral-gavage study in rats ([redacted], 1983).
(ii) Sub-chronic (90-day) oral-gavage study in mice ([redacted], 1983).

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

As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected. Therefore, the information requirement is not fulfilled.

The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see Section C.1). According to Column 2 of Annex VIII, Section 8.6.1., and to prevent unnecessary animal testing, a short term toxicity study (28 days) does not therefore need to be conducted.

Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

4. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You sought to adapt this information requirement in accordance with column 2, section 8.7.2. stating that "*the study does not need to be conducted because a pre-natal developmental toxicity study is available*".

ECHA has assessed this information and has identified the following issue:

According to the first paragraph, fourth indent, the study does not need to be conducted if a pre-natal developmental toxicity study (Annex IX, 8.7.2.) or, either an Extended one-generation reproductive toxicity study (B. 56, OECD TG 443) (Annex X, section 8.7.3.) or a two-generation study (B 35, OECD TG 416) is available.

You have provided a pre-natal developmental toxicity study in rats, performed with the source substance EC: 296-664-6.

As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected. Based on this, your adaptation according column 2, section 8.7.2. is not valid. Therefore, the information requirement is not fulfilled.

Information on study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[8] administration of the Substance.

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

Appendix C. 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 adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

You have provided the following information with the source substance:

(i) Sub-chronic (90-day) oral-gavage study in rats ([redacted], 1983).
(ii) Sub-chronic (90-day) oral-gavage study in mice ([redacted], 1983).

As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected. Therefore, the information requirement is not fulfilled.

Information on the design of the study to be performed (species/route)

Following 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[9]. 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 adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

You have provided the following information with the source substance:

(i) Pre-natal developmental toxicity study in rats, via oral-gavage (key study, according to OECD TG 414, GLP).

As explained above, under Appendix on Reasons common to several requests section, your read-across adaptation has been rejected. Therefore, the information requirement is not fulfilled.

Information on the study design
A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[10] administration of the Substance.

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

Appendix D. 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[11].

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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[12].

[11] https://echa.europa.eu/practical-guides
[12] https://echa.europa.eu/manuals

Appendix E. 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 17 December 2019.

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

ECHA did not receive any comments within the notification period.

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

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

Appendix F. List of references - ECHA Guidance[13] 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)[14]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[14]

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[15]

[13] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[14] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[15] 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 G. Addressees of this decision and the corresponding information requirements applicable to them

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

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

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.