EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 20 April 2021

Addressees
Registrants of JS_Ethylmethacrylate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
11/02/2020

Registered substance subject to this decision ("the Substance")
Substance name: Ethyl methacrylate
EC number: 202-597-5
CAS number: 97-63-2

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 ***26 July 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. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells;

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 VIII of REACH", respectively.

Information required depends on your tonnage band

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

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

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

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

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- In vivo mammalian erythrocyte micronucleus test (Annex IX, Section 8.4., column 2)
- In vivo mammalian bone marrow chromosomal aberration test (Annex IX, Section 8.4., column 2)

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

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 (addressed under 'Scope of the grouping'). 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 R.6 and related documents.

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have formed a group (category) of 'Lower Alkyl (C1-C8) Methacrylates'. You have provided a read-across justification document in IUCLID Section 7.1.

For the purpose of this decision, the following abbreviations are used for the group members:
[1] MMA for Methyl methacrylate (EC No. 201-297-1);
[2] EMA for Ethyl methacrylate (EC No. 202-597-5); and
[3] nBMA for nButyl methacrylate (EC No. 202-615-1).

You provide the following reasoning for the grouping the substances: *"the rationale of this category approach, is based on the chemical reactivity of the esters and the common primary metabolic pathway".*

You define the applicability domain of the category as follows: methacrylate esters of linear and branched C1 to C8 alcohols. However, in your justification document you focus only on the two immediate neighbours, methyl methacrylate (MMA; C1) and butyl methacrylate (nBMA; C4).

B. Assessment of prediction(s)

a. Prediction for toxicological properties

You explain that your prediction follows scenario 6 of the Read-across assessment framework (RAAF, March 2017). You predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects.

You intend to predict the properties for the category members from information obtained from the following source substances:

In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- Schweikl (1994), with MMA
- [redacted] (1987), with MMA

In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Moore (1988), with MMA
- Schweikl (1998), with MMA

In vivo mammalian erythrocyte micronucleus test (Annex IX, Section 8.4., column 2)
- [redacted] (1982), with MMA
- [redacted] (1999), with nBMA

In vivo mammalian bone marrow chromosomal aberration test (Annex IX, Section 8.4., column 2)
- [redacted] (1976), with MMA
- [redacted] (1979), with MMA

ECHA notes the following shortcomings with regards to predictions of toxicological properties.

1. *Read-across hypothesis contradicted by existing data*

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances.In the context of the conditions set out under Annex IX, section 1.5. ECHA Guidance[2] indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on category members.

The observation of differences in the toxicological properties among some members of a category is a warning sign. An explanation for such a difference resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties needs to be provided and supported by scientific evidence.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effect(s).

[2] Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.6, Section R.6.2.2.1.f

However, the results of mutagenicity studies submitted for the category members vary. Specifically, positive results are observed in the *in vitro* chromosomal aberration studies conducted with MMA while negative results are reported for equivalent studies conducted with nBMA and the Substance (EMA).

In addition, weakly positive results are observed in the *in vitro* gene mutation studies conducted with MMA and the Substance (EMA), while negative results are reported in a similar study conducted with nBMA ([redacted] 2016).

The *in vitro* chromosomal aberration studies conducted with MMA and nBMA and the *in vitro* gene mutation study conducted with nBMA are not provided in the technical dossier but referred to in the category justification document.

The available set of data on the category members indicates differences in the toxicological properties of the substances, more specifically the mutagenicity properties. These mutagenicity properties are directly relevant for your predictions and contradict your read-across hypothesis that the structurally similar category members cause the same type of effect(s). Therefore, you have not demonstrated and justified that the properties of the category members are likely to be similar despite the observation of these differences.

No experimental data or other adequate and reliable information addressing the impact of exposure to these non-common compounds 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 target 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.

In your comments on the draft decision you acknowledge the variation in the outcomes of the available for *in vitro* mutagenicity studies and commit to conduct further *in vitro* studies before considering any further adaptation possibilities.

C. Conclusions on the grouping of substances and 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.

2. Assessment of your weight-of-evidence adaptation under Annex XI, Section 1.2

You have adapted the following standard information requirements by applying weight-of-evidence approaches in accordance with Annex XI, Section 1.2:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- In vivo mammalian erythrocyte micronucleus test (Annex X, Section 8.4., column 2)

Your weight of evidence adaptation has certain decifiencies that are common to all of the information requirements for which it is used. Accordingly, ECHA has addressed these common deficiencies in the present Appendix, before assessing specific issues with your weight of evidence adaptations under the corresponding standard information requirements in the other appendices.

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.4.4, a weight-of-evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, 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.

In that context, we identified the following issue recurrent for all the information requirements relying on a weight of evidence adaptation:

Reliability of the read across approach

Section A of the present Appendix identifies deficiencies of the grouping and read across approach used in your dossier. These findings apply equally to the sources of information relating to analogue substances submitted under your weight of evidence adaptations.

Additional issues related to weight of evidence are addressed under the corresponding information requirements in the following Appendices.

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 adapted this standard information requirements by applying weight-of-evidence approaches in accordance with Annex XI, Section 1.2. In support of your adaptation you have provided the following sources of information with the Substance:

i. [redacted](1987), with the following strains, S. typhimurium TA 1535, TA 1537, TA 98 and TA 100.
ii. Waegenmaekers (1984) with the following strains, S. typhimurium TA 1535, TA 1537, TA 1538, TA 98, TA 100.

In addition, you have provided several sources of information performed with the analogue substance MMA (EC No. 201-297-1):

iii. Schweikl (1994), supporting study with the following strains, S. typhimurium TA 97a, TA 98, TA 100, TA 102 and TA 104.
iv. [redacted](1987) with the following strains, S. typhimurium TA 1535, TA 98 and TA 100.

To fulfil the information requirement, normally a study performed according to OECD TG 471 must be provided. OECD TG 471 requires the study to investigate gene mutations in bacteria using 5 different bacterial strains.

The sources of information (i.) to (iv.) provide relevant information on *in vitro* gene mutations in bacteria.

However, the reliability of these sources of information is significantly affected by the following deficiencies:

1. *Test specifications of OECD TG 471*

   One of the specifications of this test guideline is that the test must 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).

   The reported data for the studies (i.), (ii.) and (iv.) you have provided did not include results for the appropriate 5 strains, that is the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101). Therefore these sources of information do not investigate the specificity of the the fifth strain with regards to the types of mutations that can be induced. As indicated in OECD TG 471, this information is required as the fifth strain may detect certain oxidising mutagens, cross-linking agents and hydrazines, which the other four strains cannot detect. Therefore, in absence of information of the fifth strain, the provided studies (i.), (ii.) and (iv.) cannot be considered as reliable sources of information that could contribute to the conclusion on gene (point) mutations in the five bacterial strains.

2. *Deficiencies of the read-across approach*

Information from source substance(s) can contribute to weight of evidence adaptation only if the read-across is acceptable.

Studies (iii.) and (iv.) are performed with an analogue substance.

However, for the reasons explained under Appendix on Reasons common to several requests, there are deficiencies identified with the read across adaptation. These deficiencies affect significantly the reliability of the sources of information relating to analogue substances and relied upon in your weight of evidence adaptation. Therefore, the sources of information (iii.) and (iv.) cannot contribute to the weight of evidence adaptation.

Taken together, even if these sources of information provide information on gene mutations in bacteria, their reliability is affected so significantly by the deficiencies as described above that they cannot be taken into consideration in a weight of evidence approach.

Therefore, 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 property foreseen to be investigated in an OECD TG 471. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments on the draft decision you acknowledge the guideline conformity issues and the contradictory evidence in support of your read across adapation with regard to the available *in vitro* mutagenicity studies. You commit to conduct further *in vitro* studies before considering any further adaptation possibilities.

Information on the study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should 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.

You have adapted this standard information requirement by applying weight-of-evidence approaches in accordance with Annex XI, Section 1.2. In support of your adaptation you have provided the following sources of information with the Substance:

i. [redacted] (2002), similar to OECD 473.

In addition, you have provided several sources of information (*In vivo* studies) performed with analogue substances:

ii. [redacted] (1976), similar to OECD 478 with the analogue MMA.
iii. [redacted] (1982), similar to OECD 474 with the analogue MMA.
iv. [redacted] (1976), similar to OECD 475 with the analogue MMA.
v. [redacted] (1979), similar to OECD 475 with the analogue MMA.
vi. [redacted] (1999), similar to OECD 474 with the analogue nBMA.

To fulfil the information requirement, normally a study performed according to OECD TG 473/487 must be provided. OECD TG 473/487 requires the study to investigate the following: Detection and quantification of structural or numerical chromosomal aberrations in cultured mammalian cells including data on the cytotoxicity and the frequency of cells with chromosomal aberrations or micronuclei.

Source of information ii. is an *in vivo* study that investigates chromosomal aberrations in germ cells. The ECHA Guidance R.7.7.3.1. clarifies that the *in vivo* cytogenicity test that can be used to omit the study according to OECD TG 473/487 must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively[3]. OECD TGs 474/475 investigate chromosomal aberrations in somatic cells. Though this source of information ii. may provide information on chromosomal aberrations, it does not provide relevant information on somatic cells as the study is on germ cells only. Therefore, this source of information cannot contribute to the weight of evidence adaptation.

The sources of information (i.) and (iii.) to (vi.) provide relevant information on chromosomal aberrations in cultured mammalian cells, as required by OECD TG 473/487 and in somatic cells, as required by OECD TG 474/475.

However, the reliability of these sources of information is significantly affected by the following deficiencies:

1. The specifications of OECD TG 473/487 include the following:
   - Data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures must be reported.

   The reported data for study (i) you have provided did not include:
   - data on the cytotoxicity and/or the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures.

[3] ECHA Guidance R.7a, Table R.7.7-3, p.558

As indicated in OECD TG 473 this information is required to conclude whether a test chemical is clearly negative. Therefore the acceptability criteria of the OECD TG 473 are not met and the provided study cannot be considered as a reliable source of information that could contribute to the conclusion on this information investigated by the required study.

2. Information from source substances can contribute to weight of evidence adaptation only if the read-across is acceptable.

Studies ii. to vi. are performed with an analogue substance.

However, for the reasons explained under Appendix on Reasons common to several requests, there are deficiencies identified with the read across adaptation. These deficiencies affect significantly the reliability of the sources of information relating to analogue substances and relied upon in your weight of evidence adaptation. Therefore, the sources of information ii. to vi. cannot contribute to the weight of evidence adaptation.

In the absence of reliable information on all key elements and key investigations, no conclusion can be drawn on structural or numerical chromosomal aberrations in cultured mammalian cells as required by the information requirement.

Taken together, even if these sources of information (i.) and (iii.) to (vi.) provide information on structural or numerical chromosomal aberrations in cultured mammalian cells, their reliability is affected so significantly by the deficiencies as described above in points 1) and 2) that they cannot be taken into consideration in a weight of evidence approach.

On the basis of the information provided in the Appendix on Reasons common to several requests and on the above, 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 473 or 487 study. Therefore, your adaptation is rejected and the information requirements is not fulfilled.

In your comments on the draft decision you acknowledge the guideline conformity issues and the contradictory evidence in support of your read across adapation with regard to the available *in vitro* mutagenicity studies. You commit to conduct further *in vitro* studies before considering any further adaptation possibilities.

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. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490), with the Substance

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.

Triggering of the study

Your dossier contains an adaptation for an *in vitro* gene mutation study in bacteria, and an adaptation for an *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study.

The information for the *in vitro* gene mutation study in bacteria and for the *in vitro* cytogenicity study in mammalian cells provided in the dossier are rejected for the reasons provided in sections A.1 and B.1 of Appendices A and B.

The result of the requests for information in sections A.1 and B.1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Information provided in the dossier

You have adapted this standard information requirement by applying weight-of-evidence approaches in accordance with Annex XI, Section 1.2. In support of your adaptation you have provided the following sources of information:

i. Moore (1988), similar to OECD TG 476, with the Substance.
ii. [redacted] (1989), similar to OECD TG 476, with the Substance.
iii. Moore (1988), WoE similar to OECD TG 476 with the analogue MMA.
iv. Schweikl (1998), WoE similar to OECD TG 476 with the analogue MMA.
v. [redacted] (1986), similar to OECD 479 with the Substance.

To fulfil the information requirement, normally an *in vitro* gene mutation study conducted in mammalian cells in accordance with OECD TG 476 or OECD TG 490, respectively[4], must be provided. OECD TGs 476/490 investigate the detection and quantification of gene mutations (point mutations, frame-shift mutations, small deletions, etc.) in cultured mammalian cells including data on the frequency of mutant colonies.

The source of information (v.) does not provide relevant information on *in vitro* gene mutations in cultured mammalian cells as it is an *in vitro* Sister Chromatid Exchange assay in mammalian cells. This study provides only an indication of induced damage to DNA through sister chromatid exchange, but not direct evidence of mutation. Therefore, this study does not provide information that would contribute to the conclusion on the information investigated by OECD TGs 476/490.

The sources of information (i.) to (iv.) provide relevant information on *in vitro* gene mutations in cultured mammalian cells.

However, the reliability of these sources of information is significantly affected by the following deficiencies:

1. The specification(s) of test guidelines OECD TG 476 or OECD TG 490 include:
- Two separate test conditions must be assessed: in absence of metabolic activation and in presence of metabolic activation.
- One positive control must be included in the study. The positive control substance must produce a statistically significant increase in the response compared with the concurrent negative control.

The reported data for studies (i) and (ii) do not include:

[4] ECHA Guidance R.7a, Table R.7.7-2, p.557

- two separate test conditions: Both studies were conducted only in the absence of metabolic activation, therefore not addressing the impact of the metabolites on toxicity.
- one positive control: in study (ii) a positive control was not indicated.

As indicated in OECD TGs 476/490 this information is required to conclude whether a test chemical is clearly negative. Therefore the acceptability criteria of the OECD TGs 476/490 are not met and the provided studies cannot be considered as reliable sources of information that could contribute to the conclusion on this information investigated by the required studies.

2. Information from source substance(s) can contribute to weight of evidence adaptation only if the read-across is acceptable.

   Studies (iii.) and (iv.) are performed with an analogue substance. However, for the reasons explained under Appendix on Reasons common to several requests, there are deficiencies identified with the read-across adaptation. These deficiencies affect significantly the reliability of the sources of information relating to analogue substance and relied upon in your weight of evidence adaptation. Therefore the sources of information (iii.) and (iv.) cannot contribute to the weight of evidence adaptation.

Taken together, even if these sources of information (i. to iv.) provide information on gene mutations in mammalian cells, their reliability is affected so significantly for the reasons explained in 1) and 2) above that they cannot be taken into consideration in a weight of evidence approach.

On the basis of the information provided in the Appendix on Reasons common to several requests and on the above, 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 476 or 490 study. Therefore, your adaptation is rejected and the information requirements is not fulfilled.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

In your comments on the draft decision you acknowledge the guideline conformity issues and the contradictory evidence in support of your read across adapation with regard to the available *in vitro* mutagenicity studies. You commit to conduct further *in vitro* studies before considering any further adaptation possibilities.

Study design

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.

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[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:
   - 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[6].

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

Appendix D: Procedure

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

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

The compliance check was initiated on 11 September 2019.

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

In your comments you agreed to the draft decision. ECHA took your comments into account 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[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.

[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

OECD Guidance documents[10]
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.

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

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

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

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

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