Helsinki, 15 May 2020

Addressees
Registrant(s) of JS_Diphenylsulfone as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
10 February 2016

Registered substance subject to this decision ("the Substance")
Substance name: Diphenyl sulphone
EC number: 204-853-1
CAS number: 127-63-9

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 ***21 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

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

3. Ready biodegradation (Annex VII, Section 9.2.2.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

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

1. Only if a negative result in Annex VII, Section 8.4.1. 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

2. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

C. 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)

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C

4. Identification of degradation products (Annex IX, 9.2.3.; test method: OECD TG 309)

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

- 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, 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 Schillinger-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

Deadline in the decision

The timeline indicated in the draft decision to provide the information requested was 24 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the deadline. You justified your request stating that due to the very low water solubility of the Substance, currently there is no analytical method available to analyse the Substance in water for ecotoxicity studies. You request 4 months more for the selected CRO to develop such a method.

ECHA agrees to your request.

Therefore, ECHA has granted the request and set the deadline to 28 months.

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 a key study in your dossier:

i. In vitro gene mutation study in bacteria, [redacted], 1989, with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538 which all gave negative results.

Furthermore you have adapted this information requirement by applying a read-across approach in accordance with Annex XI, Section 1.5.

ii. OECD QSAR Toolbox was used to identify the three analogue substances.

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

i) Key study

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997). One of the key parameters of this test guideline includes:

a) 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 study (i) you have provided did not include:

a) results for the appropriate 5 strains, that is TA98, TA100, TA1535, TA1537 or TA97a or TA97 and the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

The information provided does not cover one of the key parameters required by OECD TG 471.

Therefore, the information requirement is not fulfilled.

ii) Analogues identified with OECD QSAR Toolbox

You seek to adapt the following standard information requirements by 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.) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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 with three analogue substances which have experimental data for the 5th bacterial strain for the Ames test, using qualitative prediction of mutagenicity on Escherichia coli WP2 vrA and Salmonella typhimurium TA102 with OECD QSAR Toolbox in IUCLID Section 7.6.1.

You read-across between the structurally similar substances
- 4,4'-sulfonyldiphenol, CAS Number: 80-09-1,
- bithionol sulfone, p-chlorophenyl, CAS Number: 4568-36-9,
- 2,4,5-trichlorophenyl sulfone, CAS Number: 116-29-0

as source substances and the Substance as target substance.

You have provided the following justification for use of this information to predict the properties: *"QSAR toolbox was applied for the endpoint of bacterial reverse mutagenicity, with specification of the 2 strains (TA102 Salmonella typhimurium and, WP2 vrA of Escherichia coli) that can detect cross-linking mutagens. This information, together with the results of the Ames test, will give the necessary information for the IUCLID file, so no other tests will be acquired".*

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

Read-across hypothesis

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on your Substance[5]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

You have not provided a read-across hypothesis which enables establishing a reliable prediction for the toxicological properties, based on recognition of the structural similarities and differences between the source substances and the substance.

Additional considerations

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*

[2] ECHA Guidance R.6
[3] ECHA RAAF
[4] ECHA RAAF UVCB
[5] ECHA Guidance R.6

data for reference substance(s)". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[6]. 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 the source substance(s).

In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substances.

To support your predictions, you have provided QSAR Toolbox prediction reports detailing the structural and mechanistic criteria used for identifying the similar substances and providing high level information on the identity of these substances.

No further endpoint-specific scientific explanation is provided. These descriptions of criteria do not constitute on their own reliable scientific justifications. More specifically, due to the complexity and amount of information needed from various function and parameters to evaluate bacterial gene mutation, QSAR predictions alone do not establish that structurally similar substances have similar properties for these endpoints. You have not provided robust scientific information, including relevant and reliable studies of comparable design, establishing why the toxicological properties of the Substance can be determined from information on the similar substances.
Therefore, this information cannot support the prediction of the endpoint under consideration.

Source studies documentation

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 1.1.4/3.1.5 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.

You identified three analogue substances and refer to different source studies with negative outcome.

You have not provided robust study summaries for any of these source studies. In particular you have not provided detailed information on the methods, results and conclusions of these studies allowing for an independent assessment of the studies. In the absence of such information, we cannot assess the reliability of the information used to predict the properties of the Substance.

B. 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

[6] ECHA Guidance R.6, Section R.6.2.2.1.f

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, the information requirement is not fulfilled.

Information on the study design

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.

In your comments to the draft decision you agreed to perform the requested test.

2. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing a calculation as a key study (US EPA ECOSAR v1.10, 2000).

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. the results are adequate for classification and labelling and/or risk assessment.

Regarding point 1, for a substance to be included in the applicability domain of a QSAR model it has to, among others, fall within the structural fragments domain (ECHA Guidance R.6).

You have provided a QSAR prediction using model ECOSAR v1.10 (in software US EPA EPISuite). You have provided the following information on the structural applicability domain: "*Diphenyl sulphone contains no additional structural fragments that are not represented by the scope of the neutral organics*".

However, we note that sulphones are not listed among the chemical functional groups covered by the model in ECOSAR "*Neutral Organics - QSAR Equation Document*" (available in the Help files of ECOSAR v1.10). In more detail, sulfones that are similar to the Substance are not present in the training set of the model.

As a consequence, the Substance falls outside the structural fragments domain, and consequently the applicabilty domain of the model. The prediction is then considered not adequate for the purposes of classification and labelling and/or risk assessment

Therefore, your adaptation according to Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

3. Ready biodegradability

Ready biodegradability is a standard information requirement in Annex VII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing a calculation as a key study (US EPA BioWin v.4.10, 2000).

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. the results are adequate for classification and labelling and/or risk assessment.

Regarding point 1, for a substance to be included in the applicability domain of a QSAR model it has to, among others, fall within the structural fragments domain (ECHA Guidance R.6).

You have provided a QSAR prediction using model BioWin v.4.10 (in software US EPA EPISuite). You have provided the following information on the structural applicability domain: "*Diphenyl sulphone contains no additional structural fragments that are not represented in the training set*".

However, sulfones are scarcely represented in the training sets of the Biowin models (only one sulfone is present in the training set of Biowin 3 and Biowin 4). Furthermore, we note that sulphones are not listed among the contributing chemical fragments of the biodegradation model(s) in the ECOSAR "*Fragment Coefficients for Biodegradation Models*" (available in the Help files of BioWin v.4.10).

As a consequence, the Substance falls outside the structural fragments domain, and consequently the applicabilty domain of the model. The prediction is therefore considered not adequate for the purposes of classification and labelling and/or risk assessment.

Therefore, your adaptation according to Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

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

1. 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.

Your dossier contains (i) a negative result for an *in vitro* cytogenicity study in mammalian cells, (ii) inadequate data for an *in vitro* gene mutation study in bacteria:

i. *In vitro* chromosome aberration study in mammalian cells, Diphenylsulphone: An evaluation in the in vitro Cytogenetic Assay in Human Lymphocytes, [redacted], 1994.
ii. *In vitro* gene mutation study in bacteria, [redacted], 1989, with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538 which all gave negative results.

The result of the request for information in section A.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.

For Annex VIII, 8.4.3., you have provided the following study in your dossier:

- *In vitro* gene mutation study in mammalian cells, [redacted] 1994. According to OECD 476.

We have assessed this information and identified the following issues:

To fulfil the information requirement, the *in vitro* gene mutation study on mammalian cells has to meet the requirements of OECD TG 476 or OECD TG 490. The key parameters of these test guidelines include:

a) The maximum concentration tested must induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.

The reported data for the study you have provided does not include:

a) a maximum tested concentration of 10 mM, 2 mg/mL or 2 µl/mL, or that induced 55+5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance.
You justified the selected concentration regime by claiming that the highest concentration of diphenyl sulphone tested was based on the solubility of the test sample in the culture medium, treatment with diphenyl sulphone at 125 µg/mL being just in excess of the limit of solubility. In the aforementioned study, neither cytotoxicity compared to the negative control, nor precipitation was reported. Furthermore, ECHA noted that for the *in vitro* cytogenicity study in mammalian cells, performed in human lymphocytes ([redacted] 1994), the reported maximum dose tested was 500 µg/mL. It was not explained why such maximum concentration level was not tested in the gene mutation test on mammalian cells.

The information provided does not cover a key parameter required by the relevant OECD TG.

Therefore, the information requirement is not fulfilled.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria provide a negative result.

In your comments to the draft decision you agreed to perform the requested test.

2. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing a calculation as a key study (US EPA ECOSAR v1.10, 2000).

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. the results are adequate for classification and labelling and/or risk assessment.

Regarding point 1, for a substance to be included in the applicability domain of a QSAR model it has to, among others, fall within the structural fragments domain (ECHA Guidance R.6).

You have provided a QSAR prediction using model ECOSAR v1.10 (in software US EPA EPISuite). You have provided the following information on the structural applicability domain: "*Diphenyl sulphone contains no additional structural fragments that are not represented by the scope of the neutral organics*".

However,we note that sulphones are not listed among the chemical functional groups covered by the model in the ECOSAR "*Neutral Organics - QSAR Equation Document*" (available in the Help files of ECOSAR v1.10). In more details, sulfones that are similar to the Substance are not present in the training set of the model.

As a consequence, the Substance falls outside the structural fragments domain, and consequently the applicabilty domain of the model. The prediction is then considered not adequate for the purposes of classification and labelling and/or risk assessment

Therefore, your adaptation according to Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

Appendix C: 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 a standard information requirement in Annex IX to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing a calculation as a key study (US EPA ECOSAR v1.10, 2000).

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. the results are adequate for classification and labelling and/or risk assessment.

Regarding point 1, for a substance to be included in the applicability domain of a QSAR model it has to, among others, fall within the structural fragments domain (ECHA Guidance R.6).

You have provided a QSAR prediction using model ECOSAR v1.10 (in software US EPA EPISuite). You have provided the following information on the structural applicability domain: "*Diphenyl sulphone contains no additional structural fragments that are not represented by the scope of the neutral organics*".

However,we note that sulphones are not listed among the chemical functional groups covered by the model in the ECOSAR "*Neutral Organics - QSAR Equation Document*" (available in the Help files of ECOSAR v1.10). In more details, sulfones that are similar to the Substance are not present in the training set of the model.

As a consequence, the Substance falls outside the structural fragments domain, and consequently the applicabilty domain of the model. The prediction is then considered not adequate for the purposes of classification and labelling and/or risk assessment

Therefore, your adaptation according to Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing a calculation as a key study (US EPA ECOSAR v1.10, 2000).

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:

1. the substance falls within the applicability domain of the QSAR model;
2. the results are adequate for classification and labelling and/or risk assessment.

Regarding point 1, for a substance to be included in the applicability domain of a QSAR model it has to, among others, fall within the structural fragments domain (ECHA Guidance R.6).

You have provided a QSAR prediction using model ECOSAR v1.10 (in software US EPA EPISuite). You have provided the following information on the structural applicability domain: "*Diphenyl sulphone contains no additional structural fragments that are not represented by the scope of the neutral organics*".

However,we note that sulphones are not listed among the chemical functional groups covered by the model in the ECOSAR "*Neutral Organics - QSAR Equation Document*" (available in the Help files of ECOSAR v1.10). In more details, sulfones that are similar to the Substance are not present in the training set of the model.

As a consequence, the Substance falls outside the structural fragments domain, and consequently the applicabilty domain of the model. The prediction is then considered not adequate for the purposes of classification and labelling and/or risk assessment

Therefore, your adaptation according to Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

3. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is a standard information requirement in Annex IX to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.3., Qualitative or Quantitative structure-activity relationship ((Q)SAR), by providing the following calculations as key studies:

i. simulation half-life in water predicted with model PBT profiler (US EPA);
ii. biodegradation probability predicted with models Biowin1 and Biowin2 (part of Biowin v4.10 module in software US EPA EPISuite).

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

In order to adapt this standard information requirement, the information provided has to be adequate to conclude on P/vP. Using QSAR models requires that the conditions described under Annex XI, Section 1.3. have to be met. In addition, as explained in ECHA Guidance R.11, Section R.11.4.1.1.4, QSAR results alone are not sufficient to conclude on non-persistence in accordance with Section 3.2.2 of Annex XIII.

Under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met:
1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. the results are adequate for classification and labelling and/or risk assessment; and
4. adequate and reliable documentation of the applied method is provided.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model and to assess the adequacy of the prediction for the purposes of classification and labelling and/or risk assessment.

You have provided a QSAR prediction for simulation half-life in water (study i.) using model PBT profiler. As input to the model, you have used the ultimate biodegradation estimated with the model Biowin3 v4.10 (in software US EPA EPISuite). In addition, you have provided QSAR predictions for biodegradation probability using models Biowin1 and Biowin2 (study ii.).

Finally, you conclude that the Substance is not P/vP based on the results from QSAR models Biowin2 and Biowin3 (PBT assessment, IUCLID Section 3.2).

For the PBT profiler prediction (study i.) you did not provide QSAR Model Reporting Formats (QMRF) or a QSAR Prediction Reporting Formats (QPRF). In addition, the Biowin predictions (used as input to the PBT profiler model as well as in study ii.) are not adequate, as explained in request A.3 above. Therefore, the conditions according to Annex XI, Section 1.3. are not met.

Finally, you have provided only QSARs. In absence of any other data, QSAR alone are not sufficient to conclude on non-persistence, as explained above.

ECHA notes that there is currently no information to conclude on P/vP. In addition, the Substance could be bioaccumulative or very bioaccumulative for air-breathing organism since LogKow > 2 and LogKoa = 7.39 (> 5) based on ECHA's calculations. Therefore, the PBT/vPvB assessment is currently not complete.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

In your comments to the draft decision you agreed to perform the requested test.

4. Identification of degradation products

Identification of degradation products is a standard information requirement in Annex IX to REACH.

You have not provided any information on the identification of degradation products of the Substance, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3 or with the general rules of Annex XI for this standard information requirement.

Therefore, the information requirement is not fulfilled.

Study selection and design

You must obtain this information while performing the simulation study(ies) requested in this decision (request C.3). You must provide a scientifically valid justification for any other method you have used for identification of the transformation/degradation products.

Identity, stability, behaviour, and molar quantity of the degradation/ transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, potential for bioaccumulation and toxicity of the transformation/degradation product must be investigated.

In your comments to the draft decision you agreed to perform the requested test.

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[7].

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[8].

[7] https://echa.europa.eu/practical-guides
[8] https://echa.europa.eu/manuals

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

Appendix F: 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 31 July 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

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

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 G: List of references - ECHA Guidance[9] 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)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[10]

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.

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

OECD Guidance documents[11]
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.

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

Appendix H: 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]

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.