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Helsinki, 15 February 2022

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

Date of submission of the dossier subject to this decision
05/10/2010

Registered substance subject to this decision ("the Substance")
Substance name: Butyraldehyde
EC number: 204-646-6
CAS number: 123-72-8

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 ***22 March 2023***.

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)

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

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annex VII of REACH".

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.

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". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

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

1. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have provided studies on the Substance in your dossier:

i. A non-guideline *in vitro* gene mutation study on the Substance, with the following strains, TA 97, TA 98, TA 100, TA 1535, and TA 1537 ([redacted], 1986).
ii. A non-guideline *in vitro* gene mutation study on the Substance, with the following strains, TA 98, and TA 100 ([redacted], 1978).
iii. A non-guideline *in vitro* gene mutation study on the Substance, with the strain TA 1535 (Pool, 1981).

In addition, you have also provided an adaptation under Annex XI, Section 1.5. ('Read-across and grouping of substances'). In support of your adaptation, you provided the following study:

iv. A non-guideline *in vitro* gene mutation study with an analogue identified as "isobutyraldehyde" (EC 201-149-6) with the following strains, TA 98, TA 100, TA 1535, and TA 1537 (Florin, 1980).

We have assessed this information and identified the following issues:

1) Non-conformity with the applicable test guideline

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471[2] (1997). The key parameters of this test guideline include:

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).

None of the studies you provided above did include the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

b) The maximum dose tested must induce a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test dose must correspond to 5 mg/plate or 5 ml/plate.

The reported data for the studies ii., iii., and iv. above, did not include a maximum dose of 5 mg/plate or 5 ml/plate or that induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance.

c) At least 5 doses must be evaluated, in each test condition.

The reported data for the studies i., ii., and iv. above did not include a description of the dose levels used.

d) Triplicate plating must be used at each dose level.

The reported data for studies ii., iii., and iv. above, did not include a description of the number of replicate plating at each dose level.

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

e) One positive control must be included in the study. The positive control substance must produce a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control.

The reported data for the studies i., ii., iii., and iv. above did not include a positive control.

f) The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.

The reported data for the studies i., ii., iii., and iv above did not include the historical control range of the laboratory. In addition, the reported data for the studies i, ii, iii, and iv above, did not include the number of revertant colonies per plate.

g) The mean number of revertant colonies per plate must be reported for the treated doses and the controls.

The reported data in studies i., ii., iii., and iv above did not include data on the number of revertant colonies per plate for the treated doses and the controls.

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

In your comments, you stated that more information on study i. is available, that you will provide at a later stage in an update of your registration dossier. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation").

On this basis the information requirement is not fulfilled.

2) *Invalid read-across adaptation*

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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have not provided a read-across justification document in IUCLID Section 13/CSR.

You predict the properties of the Substance from the structurally similar substance: isobutyraldehyde, EC No. 201-149-6 (CAS No. 78-84-2; i.e. the source substance).

You have provided no reasoning for the prediction of *in vitro* gene mutation.

ECHA assumes that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcoming(s) with regards to prediction(s) of toxicological properties.

Absence of read-across documentation

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

You have provided a robust study summary for study conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance.

In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance(s).

Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3);

Specific reasons why the study on the source substance does not meet these criteria are already explained above under issue 1). Therefore, no reliable predictions can be made for this information requirement.

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.

Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Therefore, the information requirement is not fulfilled.

Study design

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

2. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided the following information:

i. a short-term toxicity study to aquatic invertebrates according to DIN 38412, part 11 on the Substance ([redacted], 1982);
ii. a short-term toxicity study to aquatic invertebrates according to DIN 38412, part 11

on the Substance ([redacted], 1977);

iii. a non-guideline short-term toxicity study to mosquito larvae on the Substance ([redacted], 1983).

We have assessed this information and identified the following issues:

A. Unclear test material identity

To comply with this information requirement, the test material in a study must be representative for the Substance (Article 10 and Recital 19 of REACH; ECHA Guidance R.4.1).

For study i. and ii. above, you have identified the test material as "n-butyraldehyde (butanal)", without further information, including purity. For study iii., you only specified that the test material was equivalent to "reagent grade or better".

In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed and you have not demonstrated that the test material is representative for the Substance.

Therefore, the information provided is rejected.

B. The provided studies are not reliable

To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). However, ECHA identified significant shortcomings regarding the following specifications:

Technical specifications impacting the sensitivity/reliability of the test

- *Daphnia magna* (or other suitable *Daphnia* species) is used as test species;

  However, study iii. was conducted on mosquito larvae.

- the test duration is 48 hours or longer;

  However, for studies i. and ii., the exposure duration was 24 hours while for study iii. it was only 4 hours.

Characterisation of exposure

- the concentrations of the test material are measured at least at the highest and lowest test concentration, at the beginning and end of the test;
- the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within within 80-120% of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1);

  For studies i. to iii., you have expressed the effect values based on nominal concentrations. However, no analytical monitoring of exposure concentrations was conducted in any of these studies.

Reporting of the methodology and results

- the test procedure is reported (*e.g.* composition of the test medium);

For studies i. to iii., you defined the test medium as "freshwater" without providing any further information on the test medium composition.

- the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

  For studies i. to iii., the number of immobilised daphnids is not provided.

Based on the above,

- study iii. is not equivalent to an OECD TG 202. You indicate this study as unreliable (reliability score of 3) and ECHA agrees with this assessment.
- there are critical methodological deficiencies resulting in the rejection of studies i. to iii. More, specifically the test duration in all the above studies is too short which may have significantly impacted the sensitivity of these tests.
- the Substance is difficult to test (due to high volatility) and there are critical methodological deficiencies resulting in the rejection of all the provided studies. More, specifically, no analytical monitoring of exposure concentrations was conducted. Therefore, you have not demonstrated that exposure was satisfactorily maintained throughout the exposure period and that effect values can reliably be expressed based on nominal concentrations.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More, specifically, no information is provided on the test medium composition and therefore an assessment of its adequacy is not possible. Furthermore, you have not provided data on the number of immobilised test animals. As a results, it is not possible to assess mortality in the control and the validity of the study interpretation.

Therefore, the requirements of OECD TG 202 are not met in any of these studies.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision you agree with the request to perform a new study.

Study design

The Substance is difficult to test due to high volatility (vapour pressure of 14.4 kPa at 20°C determined based on OECD TG 104). OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

3. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

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

i. a non-guideline 8 days toxicity study on *Scenedesmus quadricauda* using the Substance ([redacted], 1977);
ii. a non-guideline 8 days toxicity study on *Microcystis aeruginosa* using the Substance ([redacted], 1978);
iii. a 24h toxicity study on an undefined algae mixed population according to DEV L12 1971 (Deutsche Einheitsverfahren) using the Substance (Krebs, 1991).

We have assessed this information and identified the following issue:

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.

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

However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issues.

To fulfil the information requirement, normally a study performed according to OECD TG 201[3] must be provided. OECD TG 201 requires the study to investigate the following key parameters:

- the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated.

For studies i. and ii., you specify that the basis for effects monitored in these studies was growth rate and therefore these studies provide relevant information for this endpoint. For study iii., the basis for effects is not defined and therefore the relevance of this information remains unclear.

Despite study i. to iii. may provide some relevant information on growth inhibition on algae, the reliability of these sources of information is significantly affected by the following deficiencies:

A. Unclear test material identity

[3] ECHA Guidance R.7b, Section R.7.8.4.1

To comply with this information requirement, the test material in a study must be representative for the Substance (Article 10 and Recital 19 of REACH; ECHA Guidance R.4.1).

For studies i. to iii. above, you have identified the test material as "butyraldehyde" with CAS RN 123-72-8, without further information, including purity.

In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed and you have not demonstrated that the test material is representative for the Substance. In the absence of adequate information on the identity of the test material used in these studies, the reliability of these sources of information to conclude on the hazardous properties of the Substance is considered to be low.

B. The studies provided have critical deficiencies

ECHA further identified significant issue regarding the compliance with the specifications of OECD TG 201, as follows:

Validity criteria

- exponential growth in the control cultures is observed over the entire duration of the test;
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata* or *Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%;

For none of the studies above you have provided adequate information to verify whether validity criteria equivalent to those specified in OECD TG 201 were met. In particular you have not demonstrated that exponential growth occur throughout the duration of the test and that growth by the end of the test was adequate. Also the variability among replicate cannot be assessed.

Technical specifications impacting the sensitivity/reliability of the test

- the test is conducted on a culture of a specific algal species/strain.

  For study iii., you specify that the inoculum corresponded to a "*Algae mixed population with mainly Scenedesmus sp.*". Therefore, the study was no conducted on a purified species/strain. You have provided no justification as to why this inoculum is acceptable and why no impact the results is expected.

Characterisation of exposure

- the concentrations of the test material are measured at least at the beginning and end of the test:
  1) at the highest, and
  2) at the lowest test concentration, and
  3) at a concentration around the expected EC_{50}.

  For volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required.
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 80-120% of the nominal or measured initial concentration throughout the test;

For studies i. to iii., you have expressed the effect values based on nominal concentrations. However, no analytical monitoring of exposure concentrations was conducted in any of these studies. Therefore, you have not demonstrated that exposure was satisfactorily maintained throughout the exposure period and that effect values can reliably be expressed based on nominal concentrations.

Reporting of the methodology and results

- the test conditions are reported (*e.g.*, composition of the test medium, test temperature, biomass density at the beginning of the test);

  For studies i. to iii., key information are lacking on test conditions. More specifically, no information on biomass density at the beginning of the test and on the test medium composition is provided. These conditions may significantly impact the reliability of the results. But due to lacking information, no independent assessment can be conducted.

- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

  For studies i. to iii., this information is not provided. Therefore, it is not possible to make an independent assessment whether validity criteria similar to OECD TG 201 were and if the overall interpretation on these studies is acceptable.

Taken together, even if these sources of information provide information on growth inhibition on algae, their reliability is affected so significantly 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 201. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In the comments to the draft decision you agree with the request to perform a new study.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.2.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

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[5].

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

Appendix C: Procedure

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

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

The compliance check was initiated on 04 May 2021.

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

ECHA took into account your comments and did not amend the requests but amended the deadline as described below.

In the comments to the draft decision, you requested an extension of the deadline to provide information from 6 to 10 months from the date of adoption of the decision. You considered that the extension of 4 months is needed due to the high volatility of the Substance and the necessary modifications of the study design and additional work needed to validate an adequate analytical method to conduct aquatic ecotoxicity studies.

ECHA acknowledges the difficulties in conducting the required tests, including the development of an adequate analytical method.

On this basis, ECHA has granted the request and extended the deadline to 10 months.

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

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

Appendix D: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

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

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Appendix E: Addressees of this decision and their corresponding information requirements

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

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