EUROPEAN CHEMICALS AGENCY

Helsinki, 21 January 2021

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

Date of submission of the dossier subject to this decision
28/10/2011

Registered substance subject to this decision ("the Substance")
Substance name: Benzoic acid, C9-11 , C10-rich, branched alkyl esters
EC number: 421-090-1
CAS number: NS

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 ***28 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)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; 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. 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 (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

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)

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

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD

TG 414) by oral route, in a second species (rabbit)

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

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

Information required depends on your tonnage band

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

- the information specified in 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.

Approved[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 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. OECD TG 471 (1996) with the following strains, TA 98, TA 100, TA 1535 and TA 1537 which all gave negative results.

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

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997) and cover the key parameters of the corresponding TG (Article 13(3) of REACH). 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)
b) The mean number of revertant colonies per plate must be reported for the treated doses and the controls.

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

a) results for the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).
b) data on the number of revertant colonies per plate for the treated doses and the controls.

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

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision you attached the tabulated results of an OECD TG 471 study, made with isodecyl benzoate, using five relevant strains and presenting data on the number of revertant colonies per plate. You indicate that you intend to update the technical dossier to include this data. ECHA agrees that the submitted information is sufficient to fulfil the information requirement, however it is not in the technical dossier. You are responsible to provide the necessary information to comply with the decision by the set deadline.

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

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided a key study (1996) conducted according to "Title 40 of the Code of Federal Regulation Par 797, Section 1050" with the Substance

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex XI, Section 1.1.2. This adaptation rule enables registrants to claim that the data from

experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

Adequate and reliable coverage of the key parameters foreseen to be investigated and the validity criteria to be met in the corresponding test methods referred to in Article 13(3), in this case, an OECD TG 201 which include (among others):

1. The mean coefficient of variation for section-by-section specific growth rate in the control cultures not exceeding 35%,
2. The biomass in the control cultures should increase exponentially by a factor of at least 16 within the 72-hour test period,
3. The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with Pseudokirchneriella subcapitata,
4. The test design must include three replicates at each test concentration and at least three replicates for controls,
5. The pH of the control medium must not increase by more than 1.5 units during the test

You provided the key study showing the following:

- You did not specify whether validity criteria were fulfilled and you did not provide any raw data such as initial biomass concentration in the control to demonstrate that all the validity criteria were fulfilled.
- You did not report number of replicates used,
- pH is reported to have increased from 7.4-7.5 to 8.7-9.1. without justification

In your comments to the draft decision, you agree that key information is missing in the information submitted in the technical dossier. You consider that the information provided in your comments to the draft decision is sufficient to fulfill the information requirement. In addition, you indicate that you intend to update the technical dossier to include this data.

In your comments to the draft decision, you provided the calculated values for the points 1-3 above. However, you still did not provide raw data used for calculations to allow for the verification of the calculated values.

Regarding the point 4, you state that three replicates were used for the study. ECHA notes that you have now addressed point 4 of this request.

Regarding the point 5 above, you state that the pH did not increase more than 1.5 units for the negative and solvent controls. However, ECHA notes that this information contradicts the pH values (7.4-7.5 to 8.7-9.1) currently reported in the technical dossier. In this regard, actual pH values of the control medium must be provided with explanation of this contradiction. In addition, justification must be provided in case the pH values of the control medium increased more than 1.5 units during the study.

You are responsible to provide the necessary information to comply with the decision by the set deadline. ECHA notes you must provide all of this information in your updated dossier by the set deadline of this decision. ECHA notes that the information submitted will be evaluated after the set deadline of the present decision.

Based on the currently available data and information provided in your comments to the draft decision, it is still not possible for ECHA to verify whether the validity criteria were fulfilled.

Hence, the information provided does not cover the key parameters required by OECD TG 201.

Therefore, the information requirement is not fulfilled.

3. Ready biodegradability

Ready biodegradability is a standard information requirement at Annex VII of REACH.

You have provided a key study (2006) conducted according to OECD TG 301F with the Substance.

We have assessed this information and identified the following issue(s):
To comply with this information requirement, an OECD TG 301 A, B, C, D, E, F, or 310 study must be provided and cover the key parameters and the validity criteria to be met of the corresponding TG (Article 13(3) of REACH), which include:

- variation between the replicates of less than 20%,- percentage degradation of the reference compound above 60 in 14 days,
- acceptable source of the inocula: for Manometric Respirometry (301 F) methods if activated sludge is used, it must be taken from a treatment plant or laboratory-scale unit receiving predominantly domestic sewage, and suspended solids concentration ≤30 mg/L.
-number of flasks and samples: at least two flasks or vessels containing the test substance plus inoculum, and at least two containing inoculum only must be used.

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

a) Data on each replicate to verify the difference of extremes of replicate values of less than 20%,
b) percentage degradation of the reference compound,
c) Specification of the inoculum source and suspended solid concentration,
d) Number of flasks and samples.

The information provided does not met the validity criteria or cover the key parameters required by OECD TG 301F.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you provided the following additional information:

1. You confirm that the variation between the replicates of less than 20% and provide the replicate results at the end of the study.
2. The percentage degradation of the reference compound after 14 days was 86.64%.
3. Fresh activated sludge taken from a waste water treatment (predominantly domestic sewage) was used for the study, with the mean total suspended solids concentration was determined to be 3.6 g/L.
4. The test substance, positive control and blank test systems were run in triplicate.

In your comments to the draft decision, you agree that key information is missing in the technical dossier and you provide the missing information outlined above. You consider that the information provided in your comments is sufficient to fulfill the information requirement. In addition, you indicate that you intend to update the technical dossier to include this information. ECHA agrees that the submitted information is sufficient to fulfil the information requirement, however it is not in the technical dossier. You are responsible to provide the necessary information to comply with the decision by the set deadline.

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 *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study, and (ii) inadequate data for *in vitro* gene mutation study in bacteria.

The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in section A1.

The result of the request for information in section A1 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.

Your dossier does not contain any study or adaptation in accordance with column 2 of Annex VIII, Section 8.4.3. or with the general rules of Annex XI for this standard information requirement.

In your comments to the draft decision you state that you intend to fulfil the information requirement for this endpoint by using a Weight of Evidence approach according to Annex XI, Section 1.2. You argue that your Substance belongs to a class of substances which are not anticipated to be genotoxic. You state that the Substance is rapidly metabolised to benzoic acid and isodecanol, and that there is data available regarding the genotoxicity of these metabolites.

You have not provided information on the rate of hydrolysis to benzoic acid and isodecanol in your comments to the draft decision. You are responsible to provide the necessary information i.e. adaptatation(s) and/or data to comply with the decision by the set deadline.

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

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

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 the REACH Regulation.

You have provided a key study (1995) conducted according to EPA OTS 797.1330. GLP

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex, Section XI 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 211 which include:

1. The mean number of living offspring produced per parent animal surviving at the end of the test is ≥ 60;
2. The dissolved oxygen concentration at the end of the test must be > 3 mg/L in all test vessels,
3. The nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels must be reported
4. if the deviation from the nominal or measured initial concentration is greater than ± 20 per cent, that results should be expressed in terms of the time-weighted mean;
5. The coefficient of variation around the mean number of living offspring produced per parent animal in the control(s) is reported,
6. For flow-through tests, at least 20 animals must be used per concentration: They must be divided into two or more replicates with an equal number of animals
7. Reproductive outputs as 1) the total number of living offspring per parent animal and /or 2) the production of living offspring by the surviving parent organism at the end of the test are reported, the time to production of first brood is reported,

You provided the key study showing that no significant effect on reproductive capacity in Daphnia magna was observed at the maximum test material water solubility under the conditions of the test, which was measured as 39 µg/L.

The above validity criterion and key parameters of a OECD TG 211 are not met by the provided study, because:

- you did not provide data on the mean number of living offsprings produced per parent animal surviving at the end of the test
- You only stated that dissolved oxygen was exceed 60% of saturation throughout test but did not provide concentration
- you did not provide data on analytical monitoring and you did not specify how the effect concentrations are derived. Hence it is not possible for ECHA to verify if the effect concentrations are derived according to the TG
- You did not report the coefficient of variation around the mean number of living offspring produced per parent animal in the control(s)You did not report the coefficient

of variation around the mean number of living offspring produced per parent animal in the control, numer of organisms used, the time to production of first brood.
- You did not specify nor provide data on the reproductive output. Hence it is not possible ECHA to verify the validity of your conclusion.

Based on above, information provided does not cover the key parameters required by OECD TG 211.

In your comments to the draft decision, you agree that key information is missing in the technical dossier and you provide the missing information outlined above. You consider that the information provided in your comments is sufficient to fulfill the information requirement. In addition, you indicate that you intend to update the technical dossier to include this information. ECHA agrees that the submitted information is sufficient to fulfil the information requirement, however it is not in the technical dossier. You are responsible to provide the necessary information to comply with the decision by the set deadline.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

2. Long-term toxicity testing on fish

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

You have provided a key study (1995) conducted according to "Title 40 of the Code of Federal Regulation Par 797, Section 1600".

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

Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex XI, Section 1.1.2. This adaptation rule enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:

Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case OECD TG 210 which include;

- the overall survival of fertilised eggs and post-hatch success in the controls and, where relevant, in the solvent controls should be greater than or equal to the limits (70 % for hatching success and 75 % for post-hatch success),
- at least 80 eggs, divided equally between at least four replicates used per concentration
- when the measured concentrations do not remain within 80-120% of the nominal concentration, that the effect concentrations should be determined and expressed relative to the arithmetic mean concentration for flow-through tests,
- weight and length of surviving fish at the end of the test, any abnormal appearance and behaviour, stage of embryotic development are reportd.

You provided the key study showing that no effects were observed at the highest concentration achievable under the condition of the test with the nominal loading rate of 100 µg/L and mean measured concentration of 47 µg/L.

The above validity criterion and key parameters of a OECD TG 210 are not met by the provided study, because:

1. You did not provide data on overall survival of fertilised eggs and post-hatch success in the controls and you did not specify whether the validity criteria were fulfilled.
2. You did not provide data on the number of the eggs used and on loading rate,
3. you only provided highest nominal concentration and its mean measured value. You did not provide full analytical monitoring data and you did not specify how the effect concentrations are derived. Hence it is not possible for ECHA to verify if the effect concentrations are derived according to the test guideline,
4. You did not provide information on the key parameters such as, data on mortality at each stage (embryo, larval and juvenile) and cumulative mortality, days to hatch, numbers of larvae hatched each day, and end of hatching, weight and length of surviving fish at the end of the test.

Based on above, information provided does not cover the key parameters required by OECD TG 211.

In your comments to the draft decision, you agree that key information is missing in the technical dossier. You provided the following additional information in your comments to the draft decision.

a. the hatching success in the negative and solvent controls (as well as all treatments) were 100%. Post-hatch survival in the negative and solvent controls were 97% and 98%,
b. 60 embryos per treatment was used for the study,
c. nominal and men measured concentrations,
d. the date of hatching in controls and treatments and that hatching success were 100%,
e. post-hatch survival in the treatments (low to high) were 95, 95, 98,93, and 100%, respectively,
f. A table including number of surviving larvae, as well as mean and standard deviations for standard length and dry weights for each treatment level and control atthe end of the test will be added to the endpoint study record.

You consider that the information provided in your comments is sufficient to fulfill the information requirement. In addition, you indicate that you intend to update the technical dossier to include this information as well as a table including number of surviving larvae, mean and standard deviation for standard length and dry weights for each treatment levels at the end of the test.

ECHA has assessed the provided information and notes that regarding point 2 above, lower number of test organisms were used in the study. You do not provide a justification for the deviation and how the study may still be considered as equivalent to an OECD TG 210. Furtheremore, you still do not provide information on the loading rate. You are responsible to provide the necessary information to comply with the decision by the set deadline.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

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

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have provided a prenatal developmental toxicity study in rat.

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

You have not provided information on a second species. In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

In your comments to the draft decision you state that a substance-tailored exposure-driven adaptation may substitute for the requested PNDT study in a second species as outlined under Annex XI 3.2(a) of REACH. In order to consider such an adaptation ECHA would expect all relevant exposure scenarios throughout the life cycle of the substance to demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5 of REACH. As you have not included any exposure scenarios or RCRs in your CSR, this adaptation cannot be assessed.

In your comments to the draft decision you state that comparison of the derived DNEL with the results of the exposure assessment yield RCRs up to 0.19. For the purposes of a substance-tailored exposure-driven adaptation this would not be considered as insignificant exposure when taking account of the increased uncertainty resulting from the omission of the information requirement. In the exposure assessment that you refer to in your comments to the draft decision, you could consider using input parameters that reflect the actual conditions of use such as the actual risk management measures deployed in the use of the Substance. You could also consider using higher tier exposure modelling tools, and/or providing representative workplace measurement data as a means of demonstrating that the exposure is not significant. Based on the above, the information you provided do not fulfil the information requirement.

Information on study design

The test in the first species was carried out by using a rodent species (rat). A PNDT study according to the test method OECD TG 414 must be performed in rabbit as preferred non-rodent species.

The study shall be performed with oral[2] administration of the Substance.

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

Appendix E: 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[3].

B. Test material

1. *Selection of the Test material(s)*

   The Test Material used to generate the new data must be selected taking into account the following:

   a) the boundary composition(s) of the Substance,
   b) 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*

   a) 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.
   b) The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

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

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 9 July 2019.

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

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

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

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

Appendix G: 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.

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]

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.