EUROPEAN CHEMICALS AGENCY

Helsinki, 17 June 2020

Addressees
Registrant of JS_benzylalkohol listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision
26 May 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Benzyl alcohol
EC number: 202-859-9
CAS number: 100-51-6

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***24 March 2022***.

A. Requirements applicable to all the Registrants subject to Annex VI of REACH

1. Apply the harmonised classification and labelling on the Substance for acute inhalation toxicity (Annex VI, Section 4.);

B. Requirements applicable to 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) with the fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP 2 uvrA (pKM101) with the Substance;

C. Requirements applicable to 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 TG 490) with the Substance;

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 421/422) in rats, oral route with the Substance;

D. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VI, VII, VIII and IX of REACH.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

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 on general considerations

1. Information required in the current decision

In your comments, you have questioned the necessity of providing the information required in the current decision due to the fact that relevant data is already available in the jointly submitted data for the Substance. You also refer to Articles 25 and 26 of REACH Regulation indicating that vertebrate studies should only be undertaken as a last resort and that studies involving vertebrate animals shall not be repeated.

REACH Regulation requires each registrant to provide in accordance with Articles 10 and 11, jointly or separately, information in its dossier to fulfill standard information requirements. Possibility to opt-out from jointly submitted information does not relieve any registrant from the obligation to have compliant dossier.

Your dossier has been found incompliant, and further information is requested in the current decision. Whenever vertebrate testing is requested, it will not result in the duplication of animal testing as there is no relevant study(ies) on the Substance. As already indicated under relevant endpoints, you may either generate it or request it from the other registrant(s) in cases where other registrants have relevant (in vitro) data or relied on an adaptation to meet certain information requirement.

2. Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In your comments on the draft decision you requested ECHA to extend the standard granted time to a total of 24 months based on the complexity of negotions with the Lead Registrant. ECHA notes that the deadline is provided to perform the requested experimental studies. Anyway, it is also sufficient for the possible data sharing purposes. Therefore, the deadline was not extended.

Appendix A: Reasons for the requests to comply with Annex VI of REACH

Under Article 10(a) of REACH, a technical dossier must contain information specified in Annex VI to REACH.

1. **Apply the harmonised classification and labelling on the Substance for acute inhalation toxicity(Annex VI, Section 4.)**

Classification and labelling of the substance, resulting from the application of Title I, II and III of Regulation (EC) No 1272/2008 (CLP), is an information requirement as specified in Annex VI to REACH.

To fulfil the information requirement, the classification and labelling of the substance subject to harmonised classification and labelling through an entry in Part 3 of Annex VI to CLP must be done in accordance with that entry (Annex VI, Section 4 in conjunction with Article 4(3) and Article 21(3) of CLP).

The Substance has the following harmonised classification and labelling entry in Part 3 of Annex VI to CLP for the acute inhalation toxicity: Acute Tox. 4 with hazard statement 'Harmful if inhaled' (H332). However, you have not applied it.

To fulfil the information requirement for the Substance, the harmonised classification and labelling must be applied.

In your comments on the draft decision, you agree to apply the harmonised classification as specified in the decision.

Appendix B: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.) with the fifth strain S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP 2 uvrA (pKM101)

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

You have provided:

i. Ministry of Health & Welfare (Japan), 1996 - Key study, Bacterial reverse mutation assay (similar to OECD TG 471) conducted using benzyl alcohol, EC No. 202-859-9 (CAS No. 100-51-6; i.e. the Substance), using the following strains, *S. typhimurium* TA 98, TA 100, TA 1535, and TA 1537 with and without metabolic activation, which all gave negative results; and

ii. OECD QSAR Toolbox (version 3.3.5.17) - Weight of Evidence, In vitro gene mutation prediction in bacteria for the Substance using S. typhimurium strain TA 100 (Romualdo Benigni, Cecilia Bossa 2013), which 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). The key parameter(s) 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)

The reported data for the studies you have provided did not include the appropriate 5 strains, as the information provided does not include results in the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101.

The information provided does not cover key parameter(s) required by OECD TG 471. Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you explained that the provided study was reported before the issue of the OECD TG 471 (1997) which specifies the requirement for the 5th strain, *S. typhimurium* TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). You refer to the ECHA Guidance R.7a specifying the OECD TG 471 as a suitable study to cover information requierment for bacterial mutagenicity and state that "*it does not cite a specific version*". You also claim that "*in no reference does ECHA insist on the most recent OECD TG to be followed*".

ECHA notes that in accordance with Article 13(3) of REACH tests on substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. In case the data provided is not carried out according to the methods referred to in Article 13(3) of REACH, such test may only be considered as equivalent if the conditions for a general rule for adaptations as set out in Annex XI, Section 1.1.2. 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).

For this information requirement both the EU B.13/14 test method and (updated in 1997) TG 471 require the assessment in five strains.

As the information you provided does not contain the required fifth strain, the study does not meet the current guidelines.

In addition, it has been raised to the attention of the registrants on several occassions, in particular in the Evaluation under REACH - Progress Report 2010[2], and repeated in Evaluation under REACH - Progress Report 2011[3] *"As already detailed in the Evaluation under REACH Progress Report of 2010 in chapter 3.1.3.1 - Use of existing data, ECHA considers that data on four bacterial strains does not fulfil the information requirement for that endpoint. Consequently, when only data from an in vitro gene mutation study in four bacterial strains is available, registrants shall provide data for the fifth strain specified in the current EU B.13/14 test method".*

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) with the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is considered suitable.

The repetition of the full study is not requested, but the *in vitro* gene mutation study in bacteria (OECD TG 471) with the required fifth strain.

Possibility for data sharing

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[4].

[2] ECHA, Evaluation under REACH – Progress Report 2010, page 30. Available at https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_report_2010_en.pdf
[3] ECHA, Evaluation under REACH - Progress Report 2011, section 3.3. page 33. Available at https://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf/0598c959-8fbd-4071-9523-5ca7151f5df5
[4] https://echa.europa.eu/regulations/reach/registration/data-sharing

Appendix C: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

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.

For Annex VIII, 8.4.3., you have not provided any study in your dossier.

You have provided:

(i) inadequate data for the *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1); and
(ii) a negative result for OECD Guideline 474 *in vivo* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2, Column 2 adaption).

The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in Appendix B., Sexction 1. and new data is requested.

The result of the request for information in Appendix B., Section 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. As there is already negative result for bacterial mutagenicity properties in 4 bacterial strains (*S. typhimurium* TA 98, TA 100, TA 1535, and TA 1537 and a negative result for cytogenicity properties of the Substance (Annex VII, Section 8.4.1 and Annex VIII, Section 8.4.2), in case a negative result on the 5th bacterial strain in Annex VII, Section 8.4.1. is obtained, *in vitro* gene mutation study in mammalian cells is required.

In your comments on the draft decision, you noted your intention to strengthen the presented data, if required. However, you have not provided any further information.

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.

Possibility for data sharing
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[4].

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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

You have not provided any Screening for reproductive/developmental toxicity studies with the Substance, however it appears that you have applied a Weight of evidence approach with the following studies:

With the Substance:

i. U.S. Department of Health and Human Services, 1989 – Carcinogenicity study (similar to OECD Guideline 451) conducted in rats;
ii. U.S. Department of Health and Human Services, 1989 – Repeated Dose 90-Day Oral Toxicity in Rodents (similar to OECD Guideline 408) conducted in mice;
iii. OECD QSAR Toolbox (version 3.3.5.17; Database version: 3.8.3/3.1.2) – QSAR prediction for estrogen receptor binding;
iv. ACD/Labs (I-Lab 2.0; Algorithm Version: v5.0.0.184) – QSAR prediction for probability of estrogen receptor binding; and
v. U.S. Department of Health and Human Services, 1989 – Carcinogenicity study (similar to OECD Guideline 451) conducted in mice.

With the analogue substance benzoic acid (EC no.: 200-618-2; CAS no: 65-85-0):

vi. Kieckebusch W & Lang K, 1960 – Four-generation dietary reproductive toxicity study (non-guideline, non-GLP) conducted in rats.

We have assessed this information and identified the following issues:

A. Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. The relative weights of individual sources of information should be assessed and the subsequent conclusions drawn.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the assumption that the substance has or has not a particular dangerous property. In the absence of such documentation, you have not explained how the evidence based approach was used in a reliable, robust and transparent manner.

B. 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.

In order to allow concluding on reproductive toxicity for the Substance in a weight of evidence adaptation, the information must cover the key elements (parameters) foreseen to be investigated in an OECD TG 421/ OECD TG 422 study. The key parameters of these test guidelines include, among others information on fertility, mating behaviour, capacity to mate and offspring development.

The studies (i-ii) inform on whether the Substance causes effects on reproductive organs in adult animals. However, these studies do not address the possibility that the substance may have the capacity to affect fertility, mating behaviour, capacity to mate and offspring development.

The four-generation dietary reproductive toxicity study (vi) provided with the analogue substance benzoic acid addresses above mentioned key parameters. However, as explained in Section C. below, this study on the analogue substance is not considered relevant for the purpose of identification of the hazard of the Substance.

In your comments on the draft decision, you noted your intention to improve the weight of evidence approach but you have not provided any further information.

C. Regarding the '4-generation dietary reproductive toxicity study' (vi), read-across adaptation can be used to adapt the standard information requirement, provided that the criteria in Annex XI, Section 1.5. are fulfilled.

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 ECHA Guidance R.6 and related documents.

You predict the properties of the Substance from the structurally similar substance: benzoic acid, EC No. 200-618-2 (CAS No. 65-85-0; i.e. the source substance).

You have provided the following reasoning for the prediction of toxicological properties:
"Benzyl alcohol will rapidly be metabolized to benzaldehyde and so to benzoic acid.
Therefore the data of benzoic acid can also be supportive to state that benzyl alcohol is not a reproductive (fertility and developmental) toxicant".

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

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

Missing 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 data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[5]. 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).

As indicated above, your read-across hypothesis is based on the formation of common (bio)transformation product. In this context, information characterising the rate and extent of the metabolism of the Substance is necessary to confirm the formation of the proposed common compound and to assess the impact of the exposure to the other compounds than the common compound of interest including parent compounds or intermediate metabolites.

You have not provided information on the rate of biotransformation of your substance to benzoic acid and have not considered the impact of exposure to the intermediate biotransformation product benzaldehyde on the properties of your substance.

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

In your comments on the draft decision, you noted your intention to improve the read-across but you have not provided any further information.

In the absence of such supporting information you have not established why the toxicological properties of the Substance can be determined from information on the analogue substance. Consequently, this information cannot be considered as relevant for the purpose of identification of the hazard of the Substance by means of weight of evidence.

Conclusion on the weight of evidence adaptation

It is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 421/422 study. Your adaptation is rejected and the information requirement is not fulfilled.

Possibility for data sharing

ECHA notes that there are no studies available on the Substance to fulfil the information requirement for Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.). The other registrants of the joint submission relied on an adaptation to meet this information requirement. You may consider sharing this information[4] and ECHA strongly encourages you to do so.

Appendix D: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pre-natal developmental toxicity study in a first species is a standard information requirement in Annex IX to the REACH Regulation.

You have adapted the standard information requirement according to Annex XI, Section 1.2. Weight of evidence of REACH.

You have provided the following information with the Substance:

i. Nair B (Cosmetic Ingredient Review Panel) 2001; Hardin BD et.al. 1987 – Preliminary developmental toxicity test (non-guideline, non-GLP compliant) conducted in mice using a dose of 750 mg/kg bw/day of benzyl alcohol (gavage) between gestation days (GD) 7-14; and
ii. Nair B (Cosmetic Ingredient Review Panel) 2001; Yorck RG, Barnwell PL, Pierrera M, Schuler RL, Hardin BD 1988 – Preliminary developmental toxicity test (non-guideline, non-GLP compliant) conducted in mice using a dose of 550 mg/kg bw/day of benzyl alcohol (gavage) between GD 6-15.

We have assessed this information and identified the following issues:

A. Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. The relative weights of individual sources of information should be assessed and the subsequent conclusions drawn.

However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the assumption that the substance has or has not a particular dangerous property. In the absence of such documentation, you have not explained how the evidence based approach was used in a reliable, robust and transparent manner.

B. 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.

In order to allow concluding on developmental toxicity for the Substance in a weight of evidence adaptation, the information must cover the key elements (parameters) foreseen to be investigated in an OECD TG 414 study. The key parameters of this test guideline include, among others

- the external, skeletal and soft tissue alterations (variations and malformations); and
- the exposure duration at least from implantation to one or two days before expected birth.

The studies provided do not address the key parameters for the property foreseen to be investigated in an OECD TG 414 study. Specifically,

- the external, skeletal and soft tissue alterations (variations and malformations) which

are key investigations in OECD TG 414 have not been addressed; and
- the exposure duration of the provided studies (a single intraperitoneal injection) is less than the required in OECD TG 414.

In your comments on the draft decision, you noted your intention to improve the weight of evidence approach and read-across approach but you have not provided any further information.

Conclusion on the weight of evidence adaptation

It is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 414 study. Your adaptation is rejected and the information requirement is not fulfilled.

Possibility for data sharing

ECHA notes that there are no studies available on the Substance to fulfil ths information requirement. The other registrants of the joint submission relied on an adaptation to meet this information requirement. You may consider sharing this information[4] and ECHA strongly encourages you to do so.

Appendix E: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 29 January 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 amended the request for the *In vitro* gene mutation study in bacteria requiring only a study with the missing fifth strain. ECHA did not amend other requests.

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

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

Appendix F: Observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019/2020.

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

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. Test guidelines, GLP requirements and reporting

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

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

   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: 'How to report robust study summaries'[6].

5. Test material

   Selection of the test material(s)

   While selecting the test material you must take into account 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[7].

6. List of references of the ECHA Guidance and other guidance/ reference documents[8]

   Evaluation of available information

[6] https://echa.europa.eu/practical-guides
[7] https://echa.europa.eu/manuals
[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[9]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[10]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]