EUROPEAN CHEMICALS AGENCY

Helsinki, 10 February 2020

Addressees
Registrants of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
13/01/2017

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 2-(2-hexyloxyethoxy)ethanol
EC number: 203-988-3
CAS number: 112-59-4

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***15 February 2022.***

A. 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: Bacterial reverse mutation test, EU B.13/14. /OECD TG 471), with the Substance using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102;

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

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

B. 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. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance;

C. Requirements applicable to 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) with the Substance;

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.
To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The 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.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix A: 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.)

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. Gene mutation study in bacteria (2001) with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538 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). 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 study you have provided did not include:

a) the appropriate 5 strains, as the information provided does not include results in TA98/TA100/TA1535/TA1537 or TA97a or TA97/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 to the draft decision you indicate your agreement to conduct the requested test.

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

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

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

You have provided results of two experimental studies, key and supporting, both performed according to OECD TG 202 (test type – static) with the Substance.

We have assessed this information and identified the following deficiencies.

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 202 requires that the following conditions are met:

- analytical monitoring of exposure concentrations is performed;
- effect concentrations are based on the measured values rather than nominal values unless the test concentrations are maintained within 20% of the measured initial

concentrations throughout testing.

The substance is readily biodegradable, i.e. degrades in the test system. Therefore it is expected that considerable losses will occur during the exposure period.

Realibility of the key study
For the key study you reported results based on nominal concentrations and did not demonstrate that the test substance concentration during the test was maintained within the required 20% of the measured initial concentrations. Thus, the second condition, as listed above, is not met for the key study.

Realibility of the supporting study
For the supporting study you reported results based on nominal concentrations and noted in the registration dossier that "*no information on analytical measurements of the tested dose(s)*", so that the deviation from the nominal or measured initial concentration(s) could not be verified. Thus, the aforementioned conditions of the guideline are not met for the provided supporting study.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision you indicate your agreement to conduct the requested test.

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

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

You have provided an adaptation based on a read-across approach using the results of two experimental studies, key study according to DIN 38412, part L9 (with analogue substance CAS number 112-25-4) and supporting study according to OECD TG 201 (with analogue substance CAS number 112-34-5). In addition, you have provided a QSAR adaptation for effect concentration for aquatic plants estimated using ECOSAR v1.00.

We have assessed this information and identified the following deficiencies:

Adaptation according to Annex XI, Section 1.5

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 source study(ies).[2]

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s). Therefore, the information requirement is not fulfilled by the provided experimental studies.

Reliability of experimental studies

[2] ECHA Guidance R.6, Section R.6.2.6.1

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 201 which is the standard test guidelines for aquatic plants toxicity requires that the following conditions are met:

- analytical monitoring of exposure concentrations is performed;
- if the deviation from the nominal or measured initial concentration is not within the range of ± 20 %, analysis of the results should be based on geometric mean concentration during exposure or on models describing the decline of the concentration of the test substance.

The substance is readily biodegradable, i.e. degrades in the test system.Therefore it is expected that considerable losses will occur during the exposure period.

For both experimental studies you reported results based on nominal concentrations and noted in the registration dossier that no analytical monitoring of exposure concentrations was performed, so that the deviation from the nominal or measured initial concentration(s) could not be verified.

The aforementioned conditions of the standard OECD test guideline are not met for neither of the provided experimental studies. Therefore, the information requirement is not fulfilled by the provided experimental studies.

Adaptation according to Annex XI, Section 1.3

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the cumulative conditions, as listed in this section of Annex XI, are met, in particular, when adequate and reliable documentation of the applied method is provided.

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

As noted above you have provided a QSAR prediction for this endpoint.

We have assessed this information and identified the following issue:

You have not provided any documentation for the QSAR prediction. In particular, you have not included a QMRF and/or a QPRF in your technical dossier.

Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment. Thus, the information requirement is not fulfilled by the provided QSAR prediction of effect concentration.

As conclusion, the information requirement is not fulfilled by neither of the provided information.

In your comments to the draft decision you indicate your agreement to conduct the requested test.

Appendix B: 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.

Your dossier contains (i) a negative result for a cytogenicity study in mammalian cells or a micronucleus study, and (ii) inadequate data for the other study (*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 A.1.

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

You have provided a key study and supporting study in your dossier:

i. in vitro mammalian gene mutation test (OECD 476, 2001) with a positive results in the first of two experiments
ii. sister chromatid exchange assay (OECD 479, 2001)

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

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

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

The reported data for the study (i.) you have provided do not include:

a) a maximum tested concentration of 10 mM, 2 mg/mL or 2 µl/mL, or that induced 55+5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance, without metabolic activation.

The information provided (study i.) does not cover key parameters required by the relevant OECD TG.

Therefore, the information requirement is not fulfilled.

ii. To fulfil the information requirement, the study has to be an in vitro gene mutation study conducted in mammalian cells in accordance with OECD TG 476 or OECD TG 490, respectively[3].

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

The information provided (study ii.) is not an *in vitro* gene mutation study in mammalian cells. The information provided in study ii. does not cover the key parameter(s) required by the OECD TG 476 or 490.

Therefore, the information requirement is not fulfilled.

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

In your comments to the draft decision you indicate your agreement to conduct the requested test, in case of a negative result obtained in the aforementioned *in vitro* gene mutation test in bacteria.

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.

2. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

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

You have provided the key study performed according to OECD TG 203 with the Substance.

We have assessed this information and identified the following deficiencies:

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 203 requires that the following conditions are met:

- analytical monitoring of exposure concentrations is performed;
- effect concentrations are based on the measured values rather than nominal values unless the test concentrations are maintained within 20% of the measured initial concentrations throughout testing.

The substance is readily biodegradable, i.e. degrades in the test system.Therefore it is expected that considerable losses will occur during the exposure period.

For the provided study you reported results based on nominal concentrations and noted in the registration dossier that "*the report contains no information on analytical measurements of the tested doses*", so that the deviation from the nominal or measured initial concentration(s) could not be verified. Thus, the aforementioned conditions of the guideline are not met for the provided key study.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision you indicate your agreement to conduct the requested test.

Appendix C: 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. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

You have provided the key study performed according to AFNOR NF T 90-376 with the Substance.

We have assessed this information and identified the following deficiencies:

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 211 which is the standard test guideline for the long-term toxicity testing on aquatic invertebrates requires that the following conditions are met:

- analytical monitoring of exposure concentrations is performed;
- if the deviation from the nominal or measured initial concentration is greater than ± 20 per cent, results should be expressed in terms of the time-weighted mean.

The substance is readily biodegradable, i.e. degrades in the test system. Therefore it is expected that considerable losses will occur during the exposure period.

For the provided study you reported results based on nominal concentrations and noted in the registration dossier that no analytical monitoring of exposure concentrations was performed, so that the deviation from the nominal or measured initial concentration(s) could not be verified. Thus, the aforementioned conditions of the guideline are not met for the provided key study.

In your comments to the draft decision you indicate that you will consider the need to perform requested test if "*evidence arises that the substance poses a risk to the environment (see ITS, ECHA Guidance R.7b, Section R.7.8.5, Figure R.7.8-4)*".

To adapt the information requirement for long-term toxicity testing on aquatic invertebrates based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment (CSA) needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The elements which need to be addressed in the justification are noted in the section C.2 below. As summarised in the same section C.2 below, your CSA does not currently demonstrate that the risks of the Substance are adequately controlled.

Therefore, the information requirement is not fulfilled.

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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

You have provided an adaptation according to Annex IX, Section 9.1.5., Column 2 noting that the the CSA does not indicate the need to investigate further the effects on fish. In addition, you have provided a QSAR adaptation for chronic effect concentration for fish estimated using ECOSAR v1.00.

We have assessed this information and identified the following deficiencies:

Adaptation according to Annex IX, Section 9.1, Column 2

To adapt the information requirement for long-term toxicity to fish based on Annex IX, Section 9.1, Column 2, the CSA needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The CSA needs to assess and document that risks arising from the Substance are controlled and demonstrate that there is no need to conduct further testing (Annex I, Section 0.1; Annex IX, Section 9.1, Column 2).

In particular, you need to take into account of the following elements in your justification:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

As specified in requests for A.2. – A.3., B.2. and C.1. the data on Short-term toxicity testing on aquatic invertebrates, Growth inhibition study aquatic plants, Short-term toxicity testing on fish, Long-term toxicity testing on aquatic invertebrates are not compliant. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance.

Therefore your CSA does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., Column 2.

Consequently, the information requirement is not fulfilled by the provided adaptation.

Adaptation according to Annex XI, Section 1.3

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the cumulative conditions, as listed in this section of Annex XI, are met, in particular, when adequate and reliable documentation of the applied method is provided.

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

As noted above you have provided a QSAR prediction for this endpoint.

We have assessed this information and identified the following issue:

You have not provided any documentation for the QSAR prediction. In particular, you have not included a QMRF and/or a QPRF in your technical dossier.

Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment. Thus, the information requirement is not fulfilled by the provided QSAR prediction of effect concentration.

In your comments to the draft decision you indicate that you will consider the need to perform requested test if "*evidence arises that the substance poses a risk to the environment (see ITS, ECHA Guidance R.7b, Section R.7.8.5, Figure R.7.8-4)*".

As noted above, your CSA does not currently demonstrate that the risks of the Substance are adequately controlled.

As conclusion, the information requirement is not fulfilled by neither of the provided information.

As reliable information neither on the short-term toxicity to fish nor to invertebrates is available, neither fish nor invertebrates are shown to be substantially more sensitive than other trophic levels (i.e., fish, invertebrates, algae). According to the integrated testing strategy (ITS) (ECHA Guidance R.7b,Section R.7.8.5 including Figure R.7.8-4), if necessary, the long-term *Daphnia* toxicity study is to be conducted first. If based on the results of that study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), the long-term fish study may not need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Appendix D: 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 12 July 2018.

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

ECHA took into account your comments and did not amend the 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 E: Observations and technical guidance

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

2. 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.

3. 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'[4].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   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"[5].

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

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

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 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)[7]

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[8]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

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

Appendix F 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.