ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 13 May 2020

Addressee
Registrant of JS_701-255-7 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
02/08/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction products of methyloxirane with formaldehyde, oligomeric reaction products with aniline and reaction products of methyloxirane with 2,2'-oxydiethanol
EC number: 701-255-7
CAS number: NS

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 deadlines provided.

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

1. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method) with the Substance;

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. 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

3. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; using an appropriate test method) with the Substance

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance

2. 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

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance

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

D. Requirements applicable to 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) in a second species (rat or rabbit), oral route with the Substance.

Conditions to comply with the requested information

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 of the jointly submitted dossier.

Therefore you have to comply with the requirements of Annexes VII to X of REACH, because you have registered a substance at above 1000 tpa.

When a study is required under several Annexes of REACH, the reasons are provided in the corresponding appendices of this decision.

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 points A.1. - A.3.; B.1. – B.3. ; C.1. above in an updated registration dossier by ***20 May 2021*** and the information requested in points C.2. – C.4. ;D.1. above in an updated registration dossier by ***22 November 2021***.

You must 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.

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 on general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

ECHA has considered the scientific and regulatory validity of your read-across approaches in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance within the group (addressed under 'Predictions for toxicological properties').

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

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You read across to your Substance from the structurally similar substance, 1,2-Diaminotoluene, propoxylated (EC no. 918-139-9, CAS No. 1228577-90-9; i.e. the source substance).

You have provided the following reasoning for the prediction of toxicological properties: *"The target and source substances have similar structural features of the core molecules and the same functional groups. Based on this, the target and source substances are likely to have similar biological reactivity when in contact with target tissues because each contain tertiary amines and alkoxyl side chains."*

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

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

1) *Read-across hypothesis - Similarity in structure and physicochemical data*

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. 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 (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance and your Substance[2]. It should explain why the differences in the chemical structures should not influence the toxicologicalproperties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structure and in some of the physico-chemical properties between the source substance and your Substance is a sufficient basis for predicting the properties of your Substance for other endpoints. Your justification includes that the core molecule are similar (Aniline *versus* Diaminotoluene) and that those molecules have the same side chains attached to tertiary amines.

Furthermore, you explain that the Substance and the source are similar in size (300 – 600 Da versus 166-615 Da) and that the water solubility is comparable.

Similarity in chemical structure and similarity of some of the physico-chemical does not necessarily lead to predictable or similar human health properties in other endpoints. Your justification does not explain the impact of differences in core structure. In particular, the source consist of one aromatic ring, whereas in the Substance there are up to four aromatic subunits. Furthermore, differences in the water solubility by a magnitude of two orders are not taken into account. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological property, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

2) Characterisation of the composition of the source substance

Annex XI, Section 1.5 of the REACH Regulation provides that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group.*"

According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[3] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

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[2] *Guidance on information requirements and chemical safety assessment*, Chapter R.6: QSARs and grouping of chemicals.

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1

Furthermore, the provided information on an analogue substance consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[4]

Your read-across justification document does not contain any compositional information for the source substance.

Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

3) *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).

a. *Missing supporting information to compare properties of the source substance and the Substance*

Supporting information must include bridging studies to compare properties of the Substance and source substances.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar target and source substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the target and source substance is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the target and the source substances.

For the endpoint of repeated dose toxicity, you have provided one study OECD TG 407 (2009, [redacted]) with the source substance. There is no comparable study with the Substance available.

For reproductive toxicity endpoint you provided one study OECD TG 421 (2009, [redacted]) with the source substance. There is no comparable study with the Substance available.

In summary you have not provided any information on the Substance that would allow comparison of the toxicity profile of the Substance with that of the source substance.

Therefore, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the target to compare with source substance studies for

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

repeated dose toxicity and reproductive toxicity to support your read-across hypothesis.

In the absence of such information, you have not established that the target and the source substances are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

b. Impact of exposure to non-common compounds on the prediction

Supporting information must include toxicokinetic information on the formation of the common compound and non-common compounds.

In addition to what you have indicated above, your read-across hypothesis is also based on the (bio) transformation of the target and source substances to a common compound(s). In this context, exposure to the target and source substance may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds (different aromatic cores) on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

In your read across justification document, you state that: "*The metabolic pathways proposed for the target and analogue substances are the same* ". The *in vitro* study in the dossier with human liver microsomes shows that glucuronidation of the Substance occurs. However, there is no study demonstrating the degree of metabolism and identifying metabolites of the Substance (e.g. toxicokinetic study).

Furthermore, you have not provided information characterising the exposure to the non-common core part of the compound [redacted] resulting from exposure to the target and source substance. No experimental data or other adequate and reliable information addressing the impact of exposure to these non-common compounds is included in the documentation of your read-across approach.

In the absence of such information, you have not established that a reliable prediction of the property under consideration of the target substance can be derived on the basis of your read-across hypothesis. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

B. Conclusions on the read-across approach

As explained above, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. Therefore, your adaptation is rejected and it is necessary to perform testing on your Substance.

In your comments on the draft decision, you acknowledge that the information provided in your technical dossier is not sufficient to judge on the Read-across.

(ii) Assessment of the Qualitative or quantitative structure-activity relationships adaptations, in light of the requirements of Annex XI, Section 1.3

You have adapted the following standard information requirements by using data derived from Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3:

- Coefficient n-octanol/water (Annex VII, Section 7.8);
- Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

We have assessed this information and identified the following issues:

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:
- the substance falls within the applicability domain of the QSAR model;
- 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.

a) You have not included QMRFs and a QPRFs in your dossier for any of the endpoints listed above. Therefore, ECHA cannot verify whether the cumulative conditions of Annex XI, Section 1.3 listed above are met.

b) You reported predictions for two structures that you state represent the Substance. However, these two structures represents only one type of the constituents, namely Oligomeric reaction product of formaldehyde, aniline and 2-methyloxirane. You have not included the other two types of constituents ([redacted]) in the prediction nor did you provide a justification why these constituents do not need to be considered in the prediction.

Furthermore, the shorter molecular structure used in the prediction is not indicated as a constituent of the Substance, based on the information you provided on the constituents of the Substance in section 1.2 of IUCLID. The average number of propoxy groups according to section 1.2 of IUCLID is four and in the shorter molecular structure it is two, only.

Finally, the predictions with the model used (KOCWIN, V.2.00) for partitioning coefficient of Substance can not be considered reliable. Based on a model applicability these type of structures cannot be reliably predicted with KOCWIN, partly because they exceed the molecular weight range of the model and the structures exceed the number of ether fragments covered by the training set. Therefore ECHA cannot verify whether the cumulative conditions of Annex XI, Section 1.3 listed above are met.

Your adaptations do not comply with the general rules of adaptation as set out in Annex XI, Section 1.3. Therefore, your adaptations are rejected.

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. Partition coefficient n-octanol/water (Annex VII, Section 7.8.)

Partition coefficient n-octanol/water is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement by using
- data derived from Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3 for the Substance (key study, 2010)
- An OECD TG 117 study (2010) with the Substance (supporting study).

We have assessed this information and identified the following issues:

A: key study with QSAR
You have adapted this information requirement by using a QSAR approach under Annex XI, Section 1.3. As explained in the Appendix on general considerations sections (ii) above, your adaptation is rejected.

In your comments to the draft decision, you indicated that you recognise that no QMRFs and QPRFs are included in the technical dossier. You agree that the models used for the QSAR predictions (KOCWIN, V.2.00) for partitioning coefficient cannot be considered reliable for this Substance. You indicate that the QSAR predictions will be excluded from your updated technical dossier.

B: Supporting study with the Substance
OECD TG 117 require(s) that the following conditions are met (among others):

> For mixtures, UVCBs which result in an unresolved band, upper and lower limits of log Pow, and the area % of each log Pow peak should be reported. For mixtures, which are a group of homologues, the weighted average log Pow should also be stated, calculated based on the single Pow values and the corresponding area % values. Mixtures can be measured with meaningful results, provided that the analytical detector used has the same sensitivity towards all the substances in the mixture and can be adequately resolved.

The partition coeficient study was performed according to OECD Guideline 117 (Partition Coefficient (n-octanol / water), HPLC Method). You determined log Pow by averaging all the peaks at pH 8 to generate a single Log Pow value of 3.48 at 21°C.

The registered substance is a UVCB, composing predominantly of two structurally distinct groups: [redacted]. Each group (a) and (b) is a mixture of constituents with varying degrees of propoxylation.

The constituents of the Substance vary considerably in structure and hence will have differing physico-chemical properties. This is not a substance or mixture consisting of homologue groups, thus a weighted average log Pow value should not be reported but a range and the area % of each log Pow peak should be reported.

In your comments to the draft decision, you submitted a revised Robust Study Summary (RSS) as an attachment outlining a Key experimental study performed in accordance with OECD TG 117 (2009), on the Substance. You provided a range as well as area % of each log Pow peak. ECHA has assessed the provided information in the revised RSS. ECHA agrees that the submitted information is sufficient to fulfil the information requirement. However you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process.

Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

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 an OECD TG 202 study (2010) as a key study with the Substance.

We have assessed this information and identified the following issue:

Under Articles 3(28) and 10(a) (vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 202, it includes:

- a clear description of the test material, including purity, impurities, EC& CAS number;
- a description of test conditions, including number of daphnids per vessels, number of test vessels per concentration;
- a description of the preparation of test solutions, including the justification on the deviation from the TG (i.e. use of a solvent (dimethylformamide) for water soluble substance (reported WS of the Substance is 225 mg/L));
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);

However, in the study summary of your key study (2010), you have not provided the above listed critical elements.

Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

In your comments to the draft decision, you agree that key information is missing in the RSS. However you have now provided it. You consider that the information provided is sufficient to fulfill the information requirement and hence you do not agree to perform the test. In addition, you indicate that you intend to update the technical dossier to include this data. ECHA notes that you have now addressed this request with your newly submitted information, however you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process.

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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 OECD TG 201 study (2010) as a key study with the Substance.

We have assessed this information and identified the following issue:

Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 201, it includes:

- a clear description of the test material, including purity, impurities, EC& CAS number;
- a description of the test organism including initial biomass;
- a description of the preparation of test solutions, including the justification on the deviation from the TG (i.e. use of a solvent (0.1 mg/l dimethylformamide) for water soluble substance (reported WS of the Substance is 225 mg/L));
- a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used);
- a description of test conditions including hardness, dissolved oxygen
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
- reporting of adequate raw data to allow a verification that the validity criteria of the method were fulfilled.

However, in the study summary of your key study (2010), you have not provided the above listed critical elements.

Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

In your comments to the draft decision, you agree that key information is missing in the Robust Study Summary. However, you have now provided some further information. You consider that the information provided is sufficient to fulfill the information requirement and hence you do not agree to perform the test. In addition, you indicate that you intend to update the technical dossier to include this data.

ECHA notes that you have now addressed all the above aspects of this request except
-the reporting of adequate raw data to allow a verification that the validity criteria of the method were fulfilled. In particular, 1) the mean coefficient of variation for section-by-section specific growth rate in the control cultures not exceeding 35%, and 2) 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* are not provided, but is described as requirements in paragraph 11 of the OECD GT 201.

ECHA notes you must provide all of this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process. Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

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

In accordance with 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/in vivo* cytogenicity test.

Your dossier contains negative results for both Ames and *in vivo* cytogenicity studies. Therefore, the information requirement is triggered.

You have provided a read across supporting study in your dossier:

i. *in vitro* gene mutation study in mammalian cells HPRT (2008) with the analogue substance Diaminotoluene, propoxylated (EC no. 500-158-5)

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

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. The requirements for such an adaptation are described in Appendix on general considerations above.

As explained in the Appendix on general considerations above, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study.

Information on the study design

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 an OECD TG 203 study (2010) as a key study with the Substance.

We have assessed this information and identified the following issue:

Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 203, it includes:

- a clear description of the test material, including purity and impurities;
- a description of test fish, including the total length of the fish;
- a description of test conditions including the loading and number of fish used;
- a description of the preparation of test solutions, including the justification on the deviation from the TG (i.e. use of a solvent (0.1 mg/l dimethylformamide) for water soluble substance (reported WS of the Substance is 225 mg/L));
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
- adequate raw data on the % dissolved oxygen concentration relative to the air saturation value, and mortality in controls, to allow a verification that the validity criteria of the method were fulfilled.

However, in the study summary of your key study (2010), you have not provided the above listed critical elements.

Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

In your comments to the draft decision, you agree that key information is missing in the Robust Study Summary. However you have now provided it. You consider that the information provided is sufficient to fulfill the information requirement and hence you do not agree to perform a test. In addition, you indicate that you intend to update the technical dossier to include this data. ECHA notes that you have now addressed this request with your newly submitted information, however you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process.

3. Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

Adsorption/desorption screening is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using

- Data derived from Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3 for the Substance (key study, 2010),
- An OECD TG 121 study (2010) with the Substance (supporting study).

We have assessed this information and identified following issues:

A: key study with QSAR
You have adapted this information requirement by using a QSAR approach under Annex XI, Section 1.3. As explained in the Appendix on general considerations sections (ii) above, your adaptation is rejected.

In your comments to the draft decision, you indicated that you recognise that no QMRFs and QPRFs are included in the dossier. You indicate that the QSAR predictions will be excluded from your dossier.

B: Supporting study

- Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 121, it includes (among others):
  - identity of test and reference substances and their purity, and pK_a values if relevant;
  - description of equipment and operating conditions, e.g. type and dimension of analytical (and guard) column, means of detection, mobile phase (ratio of components and pH), temperature range during measurements;
  - dead time and the method used for its determination;
  - quantities of test and reference substances introduced in the column;
  - retention times of reference compounds used for calibration;
  - details of fitted regression line (log k' *vs* log K_{OC}) and a graph of the regression line;
  - average retention data and estimated d log K_{OC} value for the test compound;
  - chromatograms.

  You have submitted a study according Guideline 121 (Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)). You report values (2.64-3.42) for logKoc at pH3-9.

  However, in the study summary of your supporting study (2010), you have not provided the above listed critical elements.

Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

In your comments to the draft decision, you submitted a revised RSS, as an attachment outlining a Key experimental study performed in accordance with TG OECD 121, (2010). You have provided all necessary documentation so that the validity and reliability of the study and its results for use in hazard assessment are fulfilled. ECHA has assessed the provided information in the revised RSS. ECHA agrees that the submitted information is sufficient to fulfil the information requirement. However you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process."

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

In accordance with 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-IX to REACH.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.);

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

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

You have provided the following information in your dossier:

[1] an experimental study (short-term repeated dose toxicity) according to guideline OECD TG 407 with the analogue substance Diaminotoluene, propoxylated (EC no. 500-158-5);

You have justified the weight of evidence adaptation as follows:

a) Toxicity shown is not sufficient for classification and that a longer study might produce information to refine the dose response relationship and allow a more robust estimation of DNELs but it would not generally change the hazard characterization
b) There is sufficient information on the physical, chemical, and biological properties of the components and the analogue substance Diaminotoluene, propoxylated (EC no. 500-158-5) to conclude that further developmental toxicity testing is not necessary.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence (WoE) from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion. According to ECHA Guidance R.4.4, a WoE adaptation involves an assessment of the relative values/weights of different pieces of the available information which is defined by e.g. the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory endpoint. Subsequently, the lines of evidence should be integrated considering their relative values or weights in order to draw a conclusion. Adequate and reliable documentation shall be provided to describe your WoE approach, the assessment of relative weights of individual piece of information and the subsequent conclusions drawn.

We have assessed this information and identified the following issue:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence "*from several independent sources of information*".

You have only provided one source of information.

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

Additionally, you have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 REACH by providing an

OECD 407 study (2009), [1] with the analogue substance Diaminotoluene, propoxylated EC no. 500-158-5. As explained in the Appendix on general considerations (i) your adaptation is rejected and the information requirement is not fulfilled.

In your comments on the draft decision, you acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study. Please see also section C.2. regarding your proposed combination of the 90 day repeated dose toxicity study (OECD TG 408) with a screening for reproductive toxicity study (OECD TG 421).

Information on the design of the study to be performed

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity[6]. The Substance is a liquid with a low vapour pressure and subsequently the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance. The human exposure to the Substance by the inhalation route are low (maximum 0.06 mg/m^3 at 25° C).

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

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

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

You have provided the following information in your dossier:

an experimental study (screening for reproductive / developmental toxicity) according to OECD TG 421 with the analogue substance Diaminotoluene, propoxylated (EC no. 500-158-5);

Weight of evidence

You have justified the weight of evidence adaptation as follows:

a) There is sufficient information on the physical, chemical, and biological properties of the components and the analogue substance Diaminotoluene, propoxylated (EC no. 500-158-5) to conclude that further developmental toxicity testing is not necessary.
b) This conclusion is supported by results from the screening study OECD TG 421 study [2]

Annex XI, Section 1.2 states that there may be sufficient weight of evidence (WoE) from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion. According to ECHA Guidance R.4.4, a WoE adaptation involves an assessment of the relative values/weights of different pieces of the available information which is defined by e.g. the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory endpoint. Subsequently, the lines of evidence should be integrated considering

[6] ECHA Guidance R.7a, R.7.5.6.3.4

their relative values or weights in order to draw a conclusion. Adequate and reliable documentation shall be provided to describe your WoE approach, the assessment of relative weights of individual piece of information and the subsequent conclusions drawn.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence "*from several independent sources of information*".

You have only provided one source of information.

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

In your comments on the draft decision you agree that there is insufficient evidence from the proposed read-across substance to support a weight of evidence (WoE) adaptation for the target substance for both the sub-chronic toxicity study and pre-natal developmental toxicity study. To improve the WoE you propose a tiered testing by conducting an OECD TG 408 study in rats via the oral route of exposure combined with the reproductive endpoints of an OECD TG 421 study, to fulfil the key information requirements of repeated dose, reproductive, and developmental toxicity. The proposed strategy includes carrying out a full 90 day study according to OECD TG 408 but additionally address parameters of an OECD TG 421 study in 10 animals, dosed for 14 days prior to mating. At weaning, the pups would be examined for developmental delays and other abnormalities.

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, the study has to meet the requirements of OECD TG 414. The key parameter of this test guideline include e.g.

- 20 female animals with implantation sites for each test and control group,
- examination of the foetuses for external, skeletal and soft tissue alterations (variations and malformations)

However, neither in an OECD TG 421 nor in an OECD 408 study structural malformations and variations are investigated as required in the PNDT study (OECD TG 414). Therefore your proposed study design does not provide information to a pre-natal development toxicity study. In addition, the criterion of 20 pregnant females for each test group set in OECD TG 414 is not fulfilled in your proposed study design.

Therefore, key parameters of the OECD TG 414 study are not fulfilled if a test is performed according to your proposed study design. Your proposed study design is thus not accepted.

Read-across

Additionally you have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 REACH by providing an OECD 421 study (2009), [2] with the analogue substance Diaminotoluene, propoxylated EC no. 500-158-5. As explained in the Appendix on general considerations i) your adaptation is rejected and the information requirement is not fulfilled.

Information on study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[7] administration of the Substance.

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

3. 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 an OECD TG 211 study (2010) as a key study with the Substance.

We have assessed this information and identified the following issue:

Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. For a study conducted according to OECD 211, it includes:

- a clear description of the test material, including purity and impurities;
- a description of the test organism, including the age of the parents;
- a description of test conditions including the number of organism used per concentration, dissolved oxygen concentration, pH etc.;
- a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used) and justification for using it for water soluble test substance;
- a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
- the results of the analytical determination of exposure concentrations and (if necessary) the calculation of effect levels as measured concentrations;
- adequate raw data (e.g. mortality of the parent, number of living offsprings produces) to allow a verification that the validity criteria of the method were fulfilled.

However, in the study summary of your key study (2010), you have not provided the above listed critical elements.

Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

In your comments to the draft decision, you agree that key information is missing in the Robust Study Summary. However you have now provided it. You consider that the information provided is sufficient to fulfill the information requirement and hence you do not agree to perform a test. In addition, you indicate that you intend to update the technical dossier to include this data. ECHA notes that you have now addressed this request with your newly submitted information, however you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process.

4. 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 adapted this information requirement by stating that long-term toxicity studies with fish do not need to be conducted as "based on available toxicity data the Substance is not classified as hazardous. A further refinement of the PNECs for the aquatic compartment with long-term toxicity data on fish is therefore not required".

In order to adapt the information requirement for long-term toxicity to fish 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 Chemical Safety Assessment (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:

a. all relevant hazard information from your registration dossier,
b. the outcome of the exposure assessment in relation to the uses of the Substance,
c. 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).

You did not submit in your dossier any specific justification as to why the risks of the substance are controlled. However, to reach the conclusion that the risks are controlled, we understand that you rely on: the availability of studies on short-term daphnia and fish, algae and long-term daphnia as well as PNEC derived from these studies.

As specified in requests A.2.- 3.; B.2., C.3., the data on short-term daphnia and fish, algae and long-term daphnia is not compliant. Hence your dossier currently does not include adequate information to characterise the hazard property of the Substance.

Therefore your Chemical Safety Assessment 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.

In your comments to the draft deicision, you consider that the long-term fish toxicity study is not required as your Chemical Safety Assessment demonstrated that the risks of the Substance are adequately controlled. You propose to update the technical dossier taking into account the following available information:

- All available aquatic toxicity studies with missing information specified in the draft decision, as well as with other hazard information,
- The outcome of the exposure assessment,
- The outcome of the PBT/vPvB assessment including information on relevant degradation products.

Furthermore, you are of opinion that the information provided in your comments to the draft decision is adequate to characterise the harzard properties of the Substance and to demonstrate that the risk of the Substance is adequately controlled.

In addition, you believe that the Substance is not considered to be PBT/vPvB based on the physico-chemical properties and available experimental data for which you provide additional information in your comments to the draft decision.

ECHA notes that you have now addressed this request with your adaptation based on newly available information, however you must provide this information in your updated dossier by the deadline of this decision. ECHA will assess the latest dossier update during our Follow up process.

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

In accordance with Articles 10(a) and 12(1) of REACH, a technical dossier at tonnage above 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII-X to REACH.

1. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species;**

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

You have adapted this information requirement by:

A. Using a weight of evidence approach by providing an OECD 421 study (2009) with the analogue substance Diaminotoluene, propoxylated EC no. 500-158-5.
B. Claiming that the Substance has a low toxicological activity, no systemic absorption and there is no or no significant human exposure.

We have assessed this information and identified the following issues:

A. Regarding your weight of evidence approach, as explained above under section C.2. (Pre-natal developmental toxicity study in a first species) and under General considerations section i) your adaptation is rejected.

B. According to Annex IX, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria:

- that there is no evidence of toxicity seen in any of the tests available and
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure and
- that there is no or no significant human exposure.

You justify the adaptation by stating that:

a) the Substance is of low toxicological activity based on the test available,
b) there is no systemic toxicity/absorption (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and
c) no significant human exposure.

You further state that: "*Diaminotoluene, propoxylated and ethoxylated is not classifiable as hazardous in respect to its reproductive toxicity. There is sufficient information from a qualitative and quantitative understanding of the toxicological properties of the core substance, the repeating unit, and screening studies on the most bioavailable members of the category* ...]"

However, you have not substantiated your claims. There is no information with the Substance from 28- or 90-day studies available to support your claim on no toxicity. You have not provided reliable data to support your claim on no systemic absorption, e.g. from a toxicokinetic study. Furthermore, the uses ([redacted] indicate exposure of workers and consumers.

Therefore, your adaptation is rejected.

In your comments on the draft decision, you acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study.

Information on study design

A PNDT study according to the OECD TG 414 study should be performed in rabbit or rat as the preferred second species, depending on the choice of species in the PNDT study in the first species (request C.2. in this decision).

The study shall be performed with oral[8] administration of the Substance.

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

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 the REACH Regulation.

The compliance check was initiated on 14 January 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 requests and the deadline.

With reference to your comments, the timeline indicated in the draft decision to provide the information in the requests A.1. - A.3.; B.1. – B.3.; and C.1 is 12 months from the date of adoption of the decision.

In your comments on the draft decision, you propose to perform a combined OECD TG 408 and OECD TG 421 study and you request an extension of the timeline to 18 months. You justify your request stating that "Due to the more complex nature of this combined OECD 408/421 study design, the registrants also request that ECHA allows 18 months for the completion of this study."

As explained above, the proposed study design is not accepted as a substitute for the PNDT study. Therefore the deadline to submit the study results of the OECD TG 408 study is not extended. Therefore, ECHA has not modified the deadline of the decision.

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 information requirement under Section 8.7.3. of Annex X to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

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'[9].

5. Test material

Selection of the test material(s) for UVCB substances

The registrant of the Substance is 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 is known to have or could have 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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods. The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU)

[9] https://echa.europa.eu/practical-guides

440/2008, as amended by Regulation (EU) 2016/266, requires that "if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents". In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

Technical Reporting of the test material for UVCB substances. The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The description of the composition must include all constituents/group of constituents of the test material and their concentration values. For this substance, the test material should be selected in such way to include the following group of constituents: [redacted] in line with the composition as reported in IUCLID section 1.2. The propoxylation degrees of these groups of constituents and their concentrations in the test material used to perform the requested test(s) should also be specified in the description of the test material. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[10]

6. List of references of the ECHA Guidance and other guidance/ reference documents[11]

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)[12]

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

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

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[13]

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.

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

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

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