~~Confidential~~

Helsinki, 25 April 2022

Addressees
Registrant(s) of Joint_Submission_EC_429-070-4 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: reaction mass of: 7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4- hydroxynaphthalene-2-sulfonic acid, Na/K salt; 7-amino-3-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxy-8-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; 7-amino-8-[4-(2-sulfoxyethylsulfonyl)-phenylazo]-4-hydroxy-3-[4-(2-sulfoxyethylsulfonyl)- 2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; 7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]-4-hydroxynaphthalene-2- sulfonic acid, Na/K salt
EC number: 429-070-4
CAS number: 214362-06-8

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***2 May 2024***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211) – test on an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives.

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210) – test on an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives.

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method).

Reasons for the requests are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

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

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

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

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

Appendix on Reasons common to several requests

i. Assessment of the Grouping of substances and read-across approach under 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:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)
- Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)
- Identification of degradation products (Annex IX, Section 9.2.3.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) 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(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. Predictions for ecotoxicological properties

You have provided an updated read-across justification document together with your comments to the initial draft decision. You read-across between the structurally similar substances, Reactive Black 5, EC No. 241-164-5 as source substance and the Substance as target substance.

Your reasoning for the prediction of ecotoxicological properties is that *"the source substance and the target substance consist of high molecular weight compounds with a similar structural formula and manufacturing process. (…) The types of effects observed for the source substance predict the type of effects to be expected for the target substance."*

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 shortcomings with regards to predictions of ecotoxicological properties:

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

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

(1) be adequate for the purpose of classification and labelling and/or risk assessment;
(2) have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3);
(3) cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement sections A.1, A.2, A.3, and A.4. Therefore, no reliable predictions can be made for these information requirements.

B. Conclusions on the read-across approach

For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

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

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1.5, Column 2. In support of your adaptation, you provided the following justification:

  "According to REACH REGULATION No 1907/2006 (EC), Official Journal of the European Union L 396/354, the study does not need to be conducted. The chemical safety assessment does not indicate the need to investigate further the effects on aquatic organisms. Reactive Brown 49 [i.e. the registered Substance] *has shown no signs of toxicity when tested in acute tests at three trophic levels (fish, algae and daphnia) at limit concentrations of 100 mg/l. Furthermore, it is known that Reactive Brown 49 hydrolyses considerably under environmental conditions (pH 7) in the aquatic environment with a half-life of only 2.7 days. Therefore, the substance is not expected to be present in the aquatic system for a longer time".*

We have assessed this information and identified the following issues:

Annex IX, Section 9.1.5, Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

As part of your justification, you also indicate that the Substance hydrolyses under pH 7 with a half-life of only 2.7 days. However, you have not provided any information about the major hydrolysis products observed during testing at this pH. In addition, the hydrolysis was not further investigated at pH 9, despite the Substance was found to be unstable at this pH in a preliminary test (the half-life was estimated to be < 1 day).

The half-life < 3 days may result in the possible formation of hydrolysis products in pH range 7-9, which is relevant both for the environmental assessment and the interpretation of the aquatic toxicity tests. However, you have not justified why testing of the hydrolysis products (in addition or instead of the parent substance) was not considered in aquatic toxicity studies.

In your comments to the draft decision, you state: *"The chemical safety assessment (…) showed no indication for further testing. This is supported by the results of OECD TG 211 for the read-across substance Reactive Black 5 (…), which is reported with a NOEC of 1.25 mg/L."* You further explain that the study was conducted as a semi-static test with refreshment of the test substance every 24 hours, and that the source substance shows a DT_{50} of ca. 45 hours at pH 7, which ensures the availability of the degradation product(s) in the test medium. On that basis you do not agree that the requested test is necessary.

We have assessed this information and identified the following issues:

Adequacy and reliability of the study on the source substance

As explained in the Appendix on Reasons common to several requests, the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the

corresponding test method referred to in Article 13(3), in this case OECD TG 211, and meet the requirements of OECD GD 23 if the substance is difficult to test.

As clarified under the "Study design" section below, your Substance is difficult to test and OECD TG 211 specifies that for difficult to test substances, you must consider the approach described in OECD GD 23, which in case of your Substance, i.e. a hydrolytically unstable substance, is testing of an aged aqueous solution, i.e. generally six degradation half-lives, to promote the formation of hydrolysis product(s).

Reactive Black 5 has a degradation half-life of approximately 45 hours.

The study was conducted in a semi-static system with a daily renewal.

A daily renewal frequency is much shorter than six degradation half-lives and also shorter than a single degradation half-life. For that reason, you have not demonstrated that testing would promote the formation of hydrolysis product(s) and thus that the study reliably investigated the properties of the tested substance.

Therefore, the study submitted in your adaptation does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG 211 for a hydrolytically unstable substance.

Your adaptation is therefore rejected.

Study design

The Substance is difficult to test due to the hydrolysable properties. OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your Substance. In all cases, the approach selected must be justified and documented.

The Substance hydrolyses in pH range 7-9 (the estimated half-lives at 25°C range between < 2.7 days for pH 7 and < 1 day for pH 9). The hydrolytical stability of the Substance further decreases towards more alkaline pH. As specified in OECD GD 23, section 7.3, "*if the test chemical is likely to be unstable, a decision to test the parent test chemical and/or its degradation products, if identified, should be based on a consideration of its half-life under test and real-world conditions*".

OECD GD 23, section 7.3 further indicates that "*testing of degradation products will normally be required where the results of a preliminary range-finding experiment or a (Q)SAR analysis indicates that the degradants have significant toxicities or other relevant properties (e.g. low or no degradability).*" The available hydrolysis test, ready biodegradability and inherent biodegradability studies show no mineralisation of the Substance which indicates the potential for building-up of recalcitrant hydrolysis products.

Therefore, to promote the formation of hydrolysis products in the test medium, testing of an aged aqueous solution must be considered, as specified by OECD TG 23, section 7.3, point 86: "*The aquatic toxicity of degradation products may be determined by allowing the parent compound to degrade and then exposing the test organisms to the resulting test solution. Leaving a stock or test solution of the parent test chemical for a period equal to 6 degradation half-lives of the test chemical will generally be sufficient to ensure that the test solution contains only degradation products. The pH of the test solution after allowing for degradation should be neutralised to that of the control test medium prior to testing.*

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1.6, Column 2. In support of your adaptation, you provided the following justification:

> *"According to REACH REGULATION No 1907/2006 (EC), Official Journal of the European Union L 396/354, the study does not need to be conducted. The chemical safety assessment does not indicate the need to investigate further the effects on aquatic organisms. Reactive Brown 49* [i.e. the registered Substance] *has shown no signs of toxicity when tested in acute tests at three trophic levels (fish, algae and daphnia) at limit concentrations of 100 mg/l. Furthermore, it is known that Reactive Brown 49 hydrolyses considerably under environmental conditions (pH 7) in the aquatic environment with a half-life of only 2.7 days. Therefore, the substance is not expected to be present in the aquatic system for a longer time".*

We have assessed this information and identified the following issues:

Your adaptation is rejected for the same reasons as those provided in Section A.1 above.

In your comments to the draft decision, you provide an OECD 204 study performed on source substance Reactive Black 5 and conclude: *"Without conducting an additional test, the results of the TG 204 for Reactive Black 5 (NOEC > 10 mg/l) should be considered, with nominal test concentrations of 12.5, 25, 50 and 100 mg/L in a flow-through system, and no further testing is required."*

We have assessed this information and identified the following issues:

Adequacy and reliability of study on the source substance

As explained in the Appendix on Reasons common to several requests, the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding OECD TG, in this case OECD TG 210, and meet the requirements of OECD GD 23 if the substance is difficult to test. These includes:

- Key parameters to be measured:
  - parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage following exposure to the test substance are measured, including:
    1) the stage of embryonic development at the start of the test, and
    2) hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
    3) the appearance and behaviour of larvae and juvenile fish, and
    4) the weight and length of fish at the end of the test.

The registration dossier of a source substance provides an OECD TG 204 study in which only adults were exposed to the test material.

This study does not provide information on the toxicity of the test material to relevant sensitive life-stages (i.e., juveniles, eggs and larvae). OECD TG 204 only provides information

on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test.

Therefore, the study submitted in your adaptation, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG 210 and does not cover an exposure duration comparable to or longer than the one required for OECD TG 210.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must consider the approach described in 'Study design' under point 1 (Long-term toxicity testing on aquatic invertebrates) of Appendix A, namely testing of an aqueous solution of the Substance aged for a period equal to at least 6 degradation half-lives.

3. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have provided the following information:

- an adaptation under Annex IX, Section 9.2, Column 2 with the following justification:

  "Due to their design and nature of use, dyes are not intended to be readily biodegradable, which is also shown in a study by Pagga & Brown (1986), where the testing results of 87 dyes have been described. As a result of the substance design the substance was found poorly biodegradable in three different screening tests OECD 301 DOC Die-Away, OECD 302B Zahn/Wellens Test, EU C.5 BOD/COD ratio, but is found good soluble in water (277 mg/l), not bioaccumulative (calculated with log POW <- 4,5) and stability (Hydrolysis) is given with DT50 = 64.5h. Chemical Safety report shows no evidence for PBT/vPvB properties of the substance. Substance is applied in processes with high temperature and high pH, which is leading to a fast degradation of the substance via Hydrolysis during the process. Based on the poor results of the biodegradation screening tests and the substance design and nature of use, simulation studies on surface water are also expecting poor results. Therefore, simulation studies in surface water are not conducted, even if requested by REACH Annex VIII – X, column 2."

We have assessed this information and identified the following issue:

Annex IX, Section 9.2, Column 2 does not allow omitting the need to submit information on ultimate degradation in surface water under Column 1. It must be understood as a trigger for providing further information on ultimate degradation in surface water if the chemical safety assessment according to Annex I indicates the need.

In your comments to the draft decision, you provide a biodegradation study performed on source substance Reactive Black 5 and conclude: *"(…) the test substances degrade fast in the environment and the metabolites bind to the sediment as non-extractable residues. However, after a lag-phase of one month the bound metabolites started to get mineralized. The available information from the read-across substance, the demonstrated comparability of the target substance and its read-across make it clear that this type of substance (reactive dye)*

does not remain in the system in the form of non-extractable residues. Even if dyes are designed to be not readily/inherently biodegradable, the abiotic degradation way is fast and the degradation of NER starts after a lag-phase of about one month." On that basis you do not agree that the requested test is necessary.

We have assessed this information and identified the following issues:

As explained in the Appendix on Reasons common to several requests, the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 309. Therefore, the following specifications must be met:

Key parameters

a) the rate of aerobic transformation of the test material in natural surface water is determined;

Technical specifications impacting the sensitivity/reliability of the test

b) the measurement of degradation and the determination of mass balances are done in at least in duplicate for each concentration and at each sampling time;
c) to determine the transformation rates, the test material concentrations must reflect environmentally realistic concentrations and be ≤ 100 µg/L;
d) at least two different concentrations of test material are used, which must differ from each other by a factor of 5 to 10;
e) the lowest test material concentration is ≤ 10 µg/L;
f) if water is amended with sediment, the concentration of suspended solids is between 0.01 and 1 g/L;
g) the test duration is ≤ 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied.

The study available in the registration dossier of source substance Reactive Black 5 shows the following:

Key parameters

a) aerobic transformation of the test material was determined in a water-sediment system (composition of the test medium: 20 g sediment + 180 g surface water);

Technical specifications impacting the sensitivity/reliability of the test

b) the measurement of degradation and the determination of mass balances was not performed in duplicate for each concentration and at each sampling time;
c) to determine the transformation rates, the test material concentration was 0.201 mg/200 $g_{test\ medium}$ (equivalent to 1117 µg/L_{water});
d) a single test material concentration was used to conduct the test
e) the lowest test material concentration was >> 10 µg/L;
f) the water was amended with sediment at a concentration of solids > 100 g/L;
g) the test duration was 112 days. No semi-continuous procedure with periodical renewal of the test suspension was applied.

Based on the above, the key parameters of OECD TG 309 are not covered and there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically the study with the source substance seems to have been performed in a water-sediment system, instead of in water. The concentration tested is far higher those required for an OECD 309 test and the degradation rates reported for that study are therefore not reliable. Furthermore, that study does not provide the breakdown of the mass balances during and at the end of the study. The executive summary of the study concludes that "*the majority*

of the metabolites of the TS [test substance] *was deposited in form of non-extractable residues* (NER) *in sediment during test phase*" and also that "*after about 1 month, mineralization of the metabolites started*". However, neither the evolution of the amount of radioactivity in NER nor in CO_2 is provided to support those statements. Furthermore, it is not clear how it could be concluded that metabolites were deposited as NER, since radiolabelled substances were not, by definition, extracted from NER and, as such, could not be analysed and identified.

Therefore, the study with source substance Reactive Black 5 does not provide an adequate and reliable coverage of the key parameters of OECD TG 309.

On this basis, the information requirement is not fulfilled.

Study design

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.7.9.4.1).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1.).

4. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

In your registration dossier, you have provided no information on the identity of transformation/degradation products for the Substance.

In your comments to the draft decision, you provide information on the assumed abiotic degradation of the Substance and abiotic degradation (hydrolysis study) of source substance Reactive Black 5. In the biodegradation study performed on the same source substance, 7 metabolites have been quantified, 2 of them have been identified. You further compare

potential metabolites of the Substance and of the source substance predicted by a metabolism simulator ("Rat liver S9") to claim that both substances are metabolised through the same pathways to similar or even identical metabolites.

We have assessed this information and identified the following issues:

As explained in the Appendix on Reasons common to several requests, the results to be read across must have an adequate and reliable coverage of the key parameters for this information requirement. To fulfil the information requirement:

- information on the identity of environmentally relevant biotic (i.e. microbial) and abiotic degradation products must be provided.
- For a study conducted according to OECD TG 309, the concentration of the transformation/degradation products needs to be measured and reported at every sampling time. Transformation/degradation products for which concentrations are continuously increasing during the study needs to be identified.

In your comments to the draft decision, you refer to potential abiotic hydrolysis products of the Substance and of the source substance. However, information on abiotic hydrolysis does not provide information on potential further (biotic) degradation products.

You also compare potential metabolites of the Substance and of the source substance predicted by metabolism simulator "Rat liver S9". However, this metabolism simulator is only applicable to liver metabolism in mammals and is not relevant to predict microbial metabolism in the environment.

In the biodegradation study performed on the source substance, the concentration of the transformation/degradation products was not reported at every sampling time. Some degradation products seem to have their concentration increasing during the test, but they were not identified (e.g. metabolite "M7"). You claim that most of the degradation products formed during this study were in NER, but they could not be identified, and your claim is not substantiated by actual analytical data. Furthermore, as explained above in Appendix A.3, that study does not provide an adequate and reliable coverage of the key parameters of OECD TG 309.

Therefore, the information provided in your comments does not provide an adequate and reliable coverage of the key parameters for this information requirement.

Therefore, this information requirement is not met.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Section 3: Simulation testing on ultimate degradation in surface water (Appendix A) or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Appendix A.3) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification

of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

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

A. Test methods, GLP requirements and reporting

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

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

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

B. Test material

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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

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

Appendix C: Procedure

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

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

The compliance check was initiated on 21 April 2021.

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

ECHA took into account your comments, amended the request(s) by removing the pre-natal developmental toxicity study request and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 24 months from the date of adoption of the decision. You justified your request by providing time estimations from testing laboratories. Due to compromised substance batch, you require additional time to acquire new samples of the Substance.

On this basis, ECHA has extended the deadline to 24 months.

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

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

Appendix D: List of references - ECHA Guidance[6] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

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

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

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

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

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

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

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

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

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

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]

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

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

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

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

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.