~~Confidential~~

Helsinki, 17 November 2022

Addressees
Registrants of JS_Direct_Black_19 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08/09/2021

Registered substance subject to this decision ("the Substance")
Substance name: Disodium 4-amino-3,6-bis[[4-[(2,4-diaminophenyl)azo]phenyl]azo]-5-hydroxynaphthalene-2,7-disulphonate
EC number: 229-208-1

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 ***26 May 2026***.

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

Information required from all the Registrants subject to Annex VII of REACH

1. Skin sensitisation (Annex VII, Section 8.3.)

   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

   ii. Only if the *in vitro/in chemico* test methods specified under point 1.i are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020)

Information required from all the Registrants subject to Annex VIII of REACH

3. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

4. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: in vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490)

5. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; 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.

6. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: OECD TG 309)

7. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: EU C.13./OECD TG 305, aqueous exposure)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Read-across adaptation rejected

1 In your comments to the draft decision you have proposed to adapt the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

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

3 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.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Predictions for toxicological properties

5 You provide a read-across justification document in Annex X of your comments to ECHA decision.

6 You predict the properties of the Substance from information obtained from the following source substance:

DBlk RBK [Direct Black RBK], EC 824-263-3.

7 You provide the following reasoning for the prediction of toxicological properties:

- "*the typical compositions of DBlk19 and similar substances are comparable and they are expected to be not significant responsible of an eventual different toxicological and eco toxicological characterization*";
- "*this two dyes could give the same metabolites in case of azo-cleavage*";
- "*The only difference between the two dyes is the presence of aniline in Direct Black RBK. The presence of this metabolites is considered to support the conservative approach in term of read across*";
- "*It is clear from the structural study that the two substance have the same alerts, generated by the same functional groups. It is therefore expected that they will have the same results in the genotoxicity tests and read across from Direct Black RBK is justified for Direct Black 19*";
- "*The chemical structure, the type of metabolites and the toxicological properties for Direct Black 19 and Direct Black RBK are considered to be similar*"

8 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

We have assessed this information and identified the following issues:

0.1.1.1. *Missing robust study summaries*

9 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include robust study summary for each source study used in the adaptation.

10 A robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

11 In your comments to the draft decision, you referred to:

i. a study according to the OECD TG 471 (study number [redacted]);
ii. a study according to the OECD TG 476 (study number [redacted]).
iii. a toxicological profile for genotoxicity endpoints estimated with the OECD Toolbox.

12 You have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of the studies (i, ii, and iii). Therefore, you have failed to provide a robust study summary for each source study used in the adaptation as required by Annex XI, Section 1.5.

0.1.1. Conclusion on the read-across approach

13 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

14 Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Under Section 8.3., Column 1, the registrants must submit information allowing (1) A) a conclusion whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and (2) risk assessment, where required.

1.1. Information provided

15 In the registration dossier you have provided:

(i) *In vivo* Guinea Pig Maximization Test (1994) with the Substance.

16 In addition, in you comments to the draft decision, you refer to:

(ii) Another *In vivo* Guinea Pig Maximization Test (1995) with the Substance

1.2. Assessment of the information provided

1.2.1. Non-compliant study in your dossier

17 To be considered compliant and enable concluding whether the Substance causes skin sensitisation, a study has to meet the requirements of the EU Method B.6/OECD TG 406. The following key parameter(s) of this test guideline include:

a) Dose level selection rationale.
b) The induction concentration should be the highest causing mild-to-moderate irritation to the skin and the challenge dose should be the highest non-irritation concentration (OECD TG 406, paragraph 14).
c) Positive controls to establish the sensitivity and reliability of the experimental technique (OECD TG 406, paragraph 11).

18 In the study provided in the registration dossier:

a) No dose level selection rationale was provided.
b) The concentration used for induction did not cause mild-to-moderate irritation
c) No information on positive control group were provided.

19 Therefore, study (i) does not fulfil the key parameter(s) set in the EU method B.6/OECD TG 406 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

20 In the comments to the draft decision, you specify that:

a) the dose level selection rationale was available in the original report of study (i) and that it had been omitted during translation. You further describe the dose level selection rationale. However, the information is currently not available in your registration dossier.
b) in study (i) the concentration used for induction caused mild-to-moderate irritation. You further provide an overview of the evaluation of the primary dermal irritation results at different concentrations. However, it appears that at [redacted]% (concentration used for intradermal induction), none of the animals exposed had erythema or edema. Therefore, the concentration used for intradermal induction did not cause mild-to-moderate irritation, as required by the OECD TG 406. Moreover, it is unclear whether the concentration used for challenge ([redacted]% solution in water) is the highest non-irritating concentration as:

- no dose-response was seen in the dose range finding test ([redacted]% solution showed grade 2 ertyhema and [redacted]% solution did not show any effects), and
- the Substance is not considered to be irritating.

ECHA further notes that according to study (ii), a [redacted]% solution in water was stated to be the highest non-irritating concentration. This suggests that a [redacted]% solution in water cannot be regarded as the highest non-irritating concentration.

c) the OECD TG 406 on skin sensitisation had no requirement for positive control in the existing version in 1994. ECHA notes, that the OECD TG 406 version adopted in 1992 i.e. applicable at the time the study was performed, contained a requirement that the results of a reliability check (performed every 6 months) must be included in the study report (including the substance, concentration, and vehicle). You did not include the results of the reliability check for study (i).

21 Therefore, the information provided in your comments does not change the outcome of the assessment of study (i).

1.2.2. Missing robust study summary for study (ii) provided as part of your comments to the draft decision.

22 A robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

23 In your comments to the draft decision, you referred to:

iv. a study according to the OECD TG 471 (study number [redacted]);
v. a study according to the OECD TG 476 (study number [redacted]).
vi. a toxicological profile for genotoxicity endpoints estimated with the OECD Toolbox.

24 You have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of study (ii). For example, you have provided no information on induction concentrations. Therefore study (ii) does not meet the information requirement.

25 Therefore, the information requirement is not fulfilled and you remain responsible for complying with this decision by the set deadline.

1.2.3. No assessment of potency

26 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

27 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section A above), this condition cannot be assessed.

28 On this basis, the information requirement is not fulfilled.

1.3. Specification of the study design

29 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and/or inflammatory response in keratinocytes and/or activation of dendritic cells (OECD TG 442C and/or OECD TG 442D and/or EU B.71/OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required as a result of the classification of the Substance as a skin sensitiser (Cat 1A or 1B).

30 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. In vitro gene mutation study in bacteria

31 In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020).

2.1. Information provided

32 You have provided in your registration dossier:

(i) *In vitro* gene mutation study in bacteria (1994) with the Substance.

2.2. Assessment of the information provided

2.2.1. Study not adequate for the information requirement

33 To fulfil the information requirement, the study must meet the requirements of OECD TG 471 (2020). Therefore, the following specifications must be met:

a) If Substance is an azo-dye or a diazo-compound, the test in presence of metabolic activation must be performed following the Prival modification.
b) The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)
c) Triplicate plating must be used at each dose level.
d) The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.
e) The mean number of revertant colonies per plate must be reported for the treated doses and the controls.

34 The study (i.) is described as in vitro gene mutation study in bacteria. However, the following specifications are not according to the requirements of OECD TG 471 (2020):

a) The Prival modification, in spite of the fact that the tested substance is an azo-dye/a diazo-compound.

b) Results for the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

c) Triplicate plating at each dose level.
d) A negative control with a number of revertant colonies per plate and the historical control range of the laboratory.
e) Data on the number of revertant colonies per plate for the treated doses and the controls.

35 The information provided does not cover several of the key parameters required by OECD TG 471. Therefore, the information requirement is not fulfilled.

36 In your comments to the draft decision, you state that "*the indicated positivity is quite reliable and consistent with the same frameshift positivity on strain T97 and T98 with and without metabolic activation found in several similar azo dyes, therefore no further information is needed in order to trigger the proposed in-vivo test*".

37 However, your claim does not relate to any legal ground for adaptation under Annex XI of the REACH Regulation and your comments do not specifically address the deficiencies

identified above. Therefore, the information provided in your comments does not change the assessment outcome.

38 In addition, you propose to predict the mutagenicity properties of the Substance from a study on [redacted] (EC 824-263-3, CAS 2196165-14-5) by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

39 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

40 Therefore, you remain responsible for complying with this decision by the set deadline.

2.3. Specification of the study design

41 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

Reasons related to the information under Annex VIII of REACH

3. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

42 An in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

3.1. Information provided

43 You have provided:

(i) *In vivo* micronucleus assay (1993) with the Substance.

44 We understand that, by submitting this study, you intended to rely on an adaptation under Section 8.4.2., column 2 of Annex VIII to REACH.

3.2. Assessment of the information provided

3.2.1. Column 2 adaptation criteria not met

45 Under Section 8.4.2., column 2 of Annex VIII to REACH, the study usually does not need to be conducted "if adequate data from an in vivo cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the in vivo somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively.

46 For the data from an in vivo somatic cell cytogenicity test to be considered adequate, the in vivo study you submitted has to meet the requirements of OECD TG 474, and the specifications/conditions of this test guideline include:

a) The proportion of immature among total (immature + mature) erythrocytes must be determined for each animal (by counting a total of at least 500 erythrocytes for bone marrow and 2000 erythrocytes for peripheral blood).
b) At least 4000 immature erythrocytes per animal must be scored for the incidence of micronucleated immature erythrocytes.
c) The proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes must be reported for each group of animals.

47 The study (i.) is described as in vivo micronucleus assay. However, based on the information in the registration dossier the following specifications are not according to the requirements of OECD TG 474:

a) The proportion of immature among total (immature + mature) erythrocytes for each animal is not provided.
b) Only 2000 immature erythrocytes per animal were scored.
c) Data on the proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes for each group of animals is not provided.

48 The information provided in the registration dossier does not cover specifications/conditions required by OECD TG 474. The column 2 criteria are not met.

49 Therefore, your adaptation is rejected.

50 In your comments to the draft decision, you have attached a copy of the original study report. This study reports includes:

- the proportion of immature among total erythrocytes for each animal.
- data on the proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes for each group of animals.

51 In your comments to the draft decision, you also indicate that the number of immature erythrocytes per animal scored is in accordance with the OECD Test Guideline available at the time of the study. ECHA agrees with your comment.

52 The information provided as part of your comments addresses the deficiencies identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

3.3. Specification of the study design

53 To fulfil the information requirement for the Substance, either in vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

4. In vitro gene mutation study in mammalian cells

54 An in vitro gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the in vitro gene mutation test in bacteria and the in vitro cytogenicity test.

4.1. Triggering for in vitro gene mutation study in mammalian cells

55 Your dossier contains data for an in vitro gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study.

56 The information for the in vitro gene mutation study in bacteria and for the in vitro micronucleus study provided in the dossier are rejected for the reasons provided in requests 2 and 3.

57 The result of the requests for an in vitro gene mutation study in bacteria and for an in vitro micronucleus study will determine whether the present requirement for an in vitro mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

~~58~~ Consequently, you are required to provide information for this endpoint, if the in vitro gene mutation study in bacteria and the in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study provide a negative result.

4.2. Information provided on in vitro gene mutation study in mammalian cells

59 You have provided:

(i) *In vitro* gene mutation study in mammalian cells (1994) with the Substance.

4.3. Assessment of information provided

4.3.1. Study not adequate for the information requirement

60 To fulfil the information requirement, the study must meet the requirements of OECD TG 476 or OECD TG 490 (Guidance on IRs and CSA, Table.7.7-2). Therefore, the following specifications must be met:

a) One positive control must be included in the study. The positive control substance

must produce a statistically significant increase in the response compared with the concurrent negative control.
b) The response for the concurrent negative control must be inside the historical control range of the laboratory.
c) Data on the cytotoxicity and the mutation frequency for the treated and control cultures must be reported.

61 The study (i) is described as in vitro gene mutation study in mammalian cells. However, the following specifications are not according to the requirements of OECD TG 476:

a) one positive control.
b) a negative control with a response inside the historical control range of the laboratory.
c) data on the cytotoxicity and the mutation frequency for the treated and control cultures.

62 Therefore, the information requirement is not fulfilled.

63 In your comments to the draft decision, you:

a) state that the study summary contains the following sentence: "*the positive controls induced a clear increase in mutant frequency*".
b) claim that it is reasonable to think that this detail has been respected, but you do not provide specific information addressing the issues identified.
c) refer to data tables but you do not provide them.

64 Therefore, the information provided in your comments does not change the assessment outcome. The information provided does not cover key parameters required by OECD TG 476.

65 In addition, you propose to predict the mutagenicity properties of the Substance from a study on [redacted] (EC 824-263-3, CAS 2196165-14-5) by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

66 As explained in Section 0.1, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

67 You remain responsible for complying with this decision by the set deadline.

68 Consequently, you are required to provide information for this endpoint, if the in vitro gene mutation study in bacteria and the in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study provide a negative result.

4.4. Specification of the study design

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

5. Simulation testing on ultimate degradation in surface water

70 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

5.1. Trigering of further degradation testing

71 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII,

Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable, and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid.

72 Your registration dossier provides the following:

- The Substance is not readily biodegradable;
- The Substance is an ionisable substance and therefore high potential for bioaccumulation cannot be excluded based on available information.

73 Furthermore,

- for the reasons explained in request 7 of this decision, it is not possible to conclude on the bioaccumulation potential of the Substance, and
- for the reasons explained in requests 2-5 of this decision, it is not possible to conclude on the toxicity of the Substance.

74 In addition, under section 5.3.1 of your IUCLID dossier and section 8 of your CSR ('PBT assessment'), you conclude that the Substance is not B/vB. In support of your conclusion you provide the following additional information:

- The log Kow of the substance is below the B/vB screening critierion of log Kow ≤ 4.5;
- A QSAR prediction of BCF of 3.162 for the substance.

75 However,

- Log Kow is not a valid descriptor of the bioaccumulation potential because the substance is ionised under environmentally relevant pH.
- The QSAR prediction of BCF cannot be assessed because you provide no documentation.

76 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the additional information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

77 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

5.2. Information provided on further degradation

78 Your dossier contains no information on further degradation.

79 Therefore, the requirements for further degradation are not met and the information requirement is not fulfilled.

80 In the comments to the draft decision, you state that "*the substance is not toxic and not bioaccumulative, and therefore not considered either PBT or vPvB*". As explained under Request 7, it is not possible to conclude on the bioaccumulation potential of the Substance in aquatic species. Therefore, the information in your comments does not allow excluding that the Substance may be PBT/vPvB.

5.3. Study design and test specifications

81 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section 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.

82 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) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

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

84 As specified in Guidance on IRs and CSA, Section 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 material 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. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

85 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; Guidance on IRs and CSA, Section R.11.4.1.).

6. Identification of degradation products

86 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

6.1. Triggering of identification of degradation products

87 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

88 As already explained in request 5, the Substance is a potential PBT/vPvB substance.

89 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

6.2. Information provided on identification of degradation products

90 Your dossier contains no information on identification of degradation products.

91 Therefore, the requirements for identification of degradation products are not met and the information requirement is not fulfilled.

92 In the comments to the draft decision, you state that "*the substance is not toxic and not bioaccumulative, and therefore not considered either PBT or vPvB*". As explained under Request 7, it is not possible to conclude on the bioaccumulation potential of the Substance in aquatic species. Therefore, the information in your comments does not allow excluding that the Substance may be PBT/vPvB.

6.3. Study design and test specifications

93 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 K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You must obtain this information from the degradation study requested in request 5.

94 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 5) 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).

7. Bioaccumulation in aquatic species

95 Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

7.1. Triggering of bioaccumulation in aquatic species

96 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

97 As already explained in request 5, the Substance is a potential PBT/vPvB substance.

98 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

7.2. Information provided on bioaccumulation in aquatic species

99 Your dossier contains no information on bioaccumulation in aquatic species.

100 In the comments to the draft decision, you provide a justification to adapt this information requirement by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2:

i. LogBCF values on analogue substances derived from studies performed under the Japanese Regularoty framework;
ii. a scientific publication entitled [redacted] (1981);
iii. a survey report entitled "Survey of azo-colorants in Denmark: Consumption, use, health and environmental aspects" by Danish Environmental Protection Agency (1998);
iv. the test guideline for "Bioconcentration test of substances in fish or shellfish" by the National Institute of Technology and Evaluation (MITI), Japan Chemical

Management Center (2021);
v. QSAR predictions of BCF with BCF model (Meylan) 1.0.3 for the Substance;
vi. QSAR predictions of BCF with BCFBAF v.3.01 model of the potential main degradation products for the Substance;
vii. a presentation entitled "Use of read-across for the assessment of biodegradation and bioaccumulation potential of chemicals under Japan Chemical Substances Control Law" by National Institute of Technology and Evaluation, Japan Chemical Management Center (2016);
viii. LogD predictions with ChemAxon's Chemicalize model for the Substance;
ix. Information on the topological general characteristics of the Substance.

7.3. Assessment of the information provided in the comments to the draft decision

7.3.1. Assessment of the weight of evidence approach

101 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

102 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

103 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

104 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex IX, Section 9.3.2 includes similar information that is produced by the OECD TG 305. OECD TG 305 requires the study to investigate the following key elements:

1. the uptake rate constant (k1) and loss rate constants including the depuration rate constant (k2), and/or
2. the steady-state bioconcentration factor (BCFSS), and/or
3. the kinetic bioconcentration factor (BCFK), and/or
4. the biomagnification factor (BMF).

105 The source of information (iv) and (vii) do not provide relevant information on any of the key elements listed above. Source of information (iv) is consisting of the testing guideline text used for performing a test. As such, no reporting (e.g. methodology, conditions, results) on an actual test is provided in this source of information. The source of information (vii) is consisting of a general presentation on the use of read-across for the assessment of biodegradation and bioaccumulation potential of chemicals and does not provide any specific information on the Substance.

106 The sources of information (viii) and (ix) that do not provide similar information that is produced by the OECD TG 305 and therefore they are considered as not relevant information within the context of the Weight of Evidence approach. However, these sources of information include relevant indicators for assessing low potential for bioaccumulation and low potential to cross biological membranes within the context of Annex IX, Section 9.3.2., column 2. Therefore, ECHA considers this information as relevant under Annex IX, Section 9.3.2., column 2 and this information is assessed below.

107 The sources of information (i), (ii), (iii), (v) and (vi) provide relevant information on the key parameters 1 to 3 as listed above. However, the reliability of these sources of information is significantly affected by the following deficiencies:

7.3.1.1. *Read-across adaptation rejected for the sources of information (i), (ii) and (iii)*

108 ECHA understands that the sources of information (i), (ii) and (iii) included in your weight of evidence approach rely on grouping and read-across approach under Annex XI, Section 1.5. As you rely on a trend analysis to predict the properties of the Substance, ECHA understands that the selected substances follow a regular pattern as result of structural similarity and that you consider those as a group or 'category' of substances.

109 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.

110 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

111 You do not provide a read-across justification document in your comments.

112 You define the the structural basis for the grouping as "azo-dyes" and "ionic dyestuffs". ECHA understands that this is the applicability domain of the grouping and will assess your predictions on this basis.

113 You predict the properties of the Substance from information obtained from the source substances listed in the respective information source (ii) and (iii). ECHA further noted that the source substances in the information source (i) are not reported.

114 You provide the following reasoning for the prediction of bioaccumulation in aquatic species: "*the applicability of logKow as a predictor of bioaccumulation* […] *in the case of ionic dyestuffs*" is justified .

115 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance based on an identified trend within the group.

116 We have identified the following issues with the proposed scope of the grouping:.

7.3.1.1.1. Incomplete description of the applicability domain of the category

117 A category (grouping) hypothesis should address "the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint" (Guidance on IRs and CSA, Section R.6.2.4.1.). Particularly, "the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members" (Guidance on IRs and CSA, Section R.6.2.1.2.). Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

118 You describe the applicability domain of the substances covered by the grouping as: "azo-dyes" and "ionic dyestuffs".

119 This applicability domain does not introduce unambiguous inclusion/exclusion criteria which would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members.

7.3.1.1.2. Absence of read-across documentation

120 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

121 You have not provided a read across justification and robust study summaries for the studies conducted with the other substances than the Substance in order to comply with the REACH information requirements.

122 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substances.

7.3.1.1.3. Conclusion on the read-across approach

123 As explained above, the sources of information (i), (ii) and (iii) cannot be considered as reliable sources of information that could contribute to the conclusion on the key parameter investigated by the required study.

7.3.1.2. *The provided (Q)SAR adaptation is rejected for sources of information (v) and (vi).*

124 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

i. the prediction needs to be derived from a scientifically valid model,
ii. the substance must fall within the applicability domain of the model,
iii. results need to be adequate for the purpose of risk assessment or classification and labelling, and
iv. adequate and reliable documentation of the method must be provided.

125 With regard to these conditions, we have identified the following issues which are common to both sources of information (v) and (vi):

7.3.1.2.1. Selection of the representative structure.

126 Under ECHA Guidance R.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following condition is met:

- representative structures for the assessment are selected.

127 Your registration dossier provides the following information:

- In Section 1.1 of your technical dossier, you define the Substance as mono-constituent substance.
- In Section 1.2, you indicate the following impurities in the composition of your Substance:
  i. sodium 4-amino-6-((E)-(4-aminophenyl)diazenyl)-3-((E)-(4-((E)-(2,4-diaminophenyl)diazenyl)phenyl)diazenyl)-5-hydroxynaphthalene-2,7-disulfonate
  ii. sodium 5-amino-3,6-bis((E)-(4-aminophenyl)diazenyl)-4-hydroxy-7-sulfonaphthalene-2-sulfonate
- For the assessment, you provided predictions for the following constituent:

iii. disodium 4-amino-3,6-bis({4-[(2,4-diaminophenyl)diazenyl]phenyl}diazenyl)-5-hydroxynaphthalene-2,7-disulfonate

128 You have considered the constituent (iii) as representative structure for the whole Substance. While (iii) is the main constituent of the Substance the impurities present in the composition, as reported in the section 1.2 of the registration dossier, are not addressed.

129 Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

7.3.1.2.2. The selected structure is outside the applicability domain of the models.

130 Under ECHA Guidance R.6.1.5.3., a prediction is within the applicability domain of the model, when, among others, the substance and the structures selected for the prediction falls within descriptor, structural, mechanistic and metabolic domain.

131 However, the selected structures used as input for the QSAR predictions you have provided are outside the mechanistic domain of the model as the model uses log Kow as an input parameter. However, as already explained above, the Substance is surface active and ionisable at environmentally relevant pH. Hence logKow is not a suitable descriptor to predict bioaccumulation because it does not take into account other potential mechanisms of bioaccumulation than lipid storage.

7.3.1.2.3. The predictions are not adequate due to low reliability.

132 Under ECHA Guidance R.6.1.3.4 a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. ECHA Guidance R.6.1.5.3. specifies that, among others, the following condition must be met:

- the model predicts well substances that are similar to the substance of interest

133 The predictions for the selected structure used as input are not reliable because no similar substances to the Substance are included in training set of the model in study.

134 Therefore, you have not demonstrated that the prediction for the Substance is adequate for the purpose of classification and labelling and/or risk assessment.

7.3.1.2.4. Conclucion on the Q(SAR) adaptation

135 In conclusion, the provided predictions cannot be considered as reliable source of information that could contribute to the conclusion on the key parameter investigated by the required study.

7.3.1.3. *Conclusion on the Weight of Evidence*

136 In summary, the sources of information (i), (ii), (iii), (v) and (vi) provide relevant information on the key elements of this information requirement. However, these sources of information have significant reliability issues as described above and cannot contribute to the conclusion on the information requirement for bioaccumulation in aquatic species.

137 As it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for bioaccumulation in aquatic species. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

7.3.2. Assessment of the adaptation under Annex IX, Section 9.3.2., Column 2

7.3.2.1. *The log Dow is not a valid descriptor of the bioaccumulation potential of the Substance (source of information viii.)*

138 Under Section 9.3.2., Column 2, first indent of Annex IX to REACH, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes. A low log Kow (i.e., log Kow < 3) may only be used to support low potential for bioaccumulation if the partitioning to lipids is the sole mechanism driving the bioaccumulation potential of a substance. For some groups of substances (e.g., organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g., binding to protein/cell membranes). For this reason, log Kow is not considered a valid descriptor of the bioaccumulation potential for such substances (Guidance on IRs and CSA, Appendix R.7.10-3). Similarly, the log Dow would only address the potential for bioaccumulation for substances for which the bioaccumulation is solely driven by lipophilicity. This excludes, for example, situations where the substance is surface active or ionisable at environmental pH (pH 4 – 9).

139 In your comments to the draft decision you provided the source of information (viii) based on which you conclude that the Substances has low potential for bioaccumulation based on a calculated Log Dow with ChemAxon's Chemicalize platform and a comparison with BCF data from National Institute of Technology and Evaluation (Japan). You report the log Dow ranging from 5.99 to 1.72 at pH values of 1.7 and 8 respectively. You then conclude that "as the logD is < 2.5 at pH (7), therefore no Bioaccumulation is expected."

140 The Substance is ionisable and it may interact with cell membranes based on chemical structure. Therefore, log Dow is not a valid descriptor of the bioaccumulation potential of the Substance.

7.3.2.2. *Low likelihood to cross biological membranes is not demonstrated (source of information ix.)*

141 Under Section 9.3.2., Column 2, first indent, Annex IX to REACH, the study may be omitted if the Substance is unlikely to cross biological membranes. Guidance on IRs and CSA, Section R.7.8.5. explains that there is no scientific basis to define molecular characteristics that would render a substance unlikely to cross biological membranes. In this context, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Section R.11, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

142 In your comments to the draft decision you provided the source of information (ix) on which you based your conclusion of low likelihood to cross biological membranes based on hindered uptake of the Substance and substantiated with the following physico-chemical indicators:

- the molecular weight of the substance, 793.9 g/mol
- the $D_{maximum}$ of 18 Å as calculated by ChemAxon's Chemicalize platform.

143 The predicted $D_{maximum}$ alone is not sufficient to demonstrate low likelihood to cross biological membranes. The available information on the Substance do not support that the Substance is unlikely to cross biological membranes. In particular in the registration dossier you report a NOAEL = 80 mg/kg/day in males and females in an OECD TG 422 study. This

information is indicative of systemic exposure to the substance. Therefore, you have not demonstrated that the Substance has low likelihood to cross biological membranes. Therefore, the adaptation is rejected.

144 Therefore, the requirements on bioaccumulation in aquatic species are not met and the information requirement is not fulfilled.

7.4. Study design and test specification

145 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

146 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

147 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: 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 23 April 2021.

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.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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[2].

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(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[3].

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

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.