~~Confidential~~

Helsinki, 17 November 2022

Addressee
Registrant of JS_Direct_Black_19 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
01/06/2018

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 1.3) 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)

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

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

5. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F)

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.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

2 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 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 aquatic toxicity properties*

5 You provide read-across justification documents in IUCLID Section 6.1.3 regarding Short-term toxicity testing on invertebrates and in Section 6.1.5. regarding Growth inhibition study on aquatic plants.

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

Direct Blue 301	lithium;sodium;5-amino-3-[[4-[[4-[(8-amino-1-hydroxy-6-sulfo-3-sulfonatonaphthalen-2-yl)diazenyl]-2-methylphenyl]diazenyl]phenyl]diazenyl]-4-hydroxy-7-sulfonaphthalene-2-sulfonate, EC No. 408-210-8.
Acid Black 1	disodium;4-amino-5-hydroxy-3-[(4-nitrophenyl)diazenyl]-6-phenyldiazenylnaphthalene-2,7-disulfonate, EC No. EC 213-903-1.
Acid Black 94	trisodium;4-amino-5-hydroxy-3-[[4-[4-[[4-hydroxy-2-(2-methylanilino)phenyl]diazenyl]phenyl]phenyl]diazenyl]-6-[(4-sulfonatophenyl)diazenyl]naphthalene-2,7-disulfonate, EC No. 228-784-1.
Acid Green 68	4-amino-6-[[4-[[[4-[(2,4-dihydroxyphenyl)azo]phenyl]amino]sulphonyl]phenyl]azo]-5-hydroxy-3-[(4-nitrophenyl)azo]naphthalene-2,7-disulphonic acid, potassium salt, EC No. 284-407-0
Reactive Black 2506-MS	2,7-Naphthalenedisulfonic acid, 4-substituted-6-[[5-[(substituted-chloroheteromonocyclyl)substituted]-2-substituted-phenyl]azo]-3-[(2,5-disubstituted-phenyl)-azo]-

5-hydroxy-, lithium sodium salt, EC No. 415-420-3

7 You provide the following reasoning for the prediction of ecotoxicological properties: the sources substances share some similarities in chemical structure with the target substances.

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.

9 We have identified the following issues with the predictions of aquatic toxicity:

0.1.1.1. Characterisation of the source substances

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

11 According to the Guidance on IRs and CSA, Section R.6, "the purity and impurity profiles of the substance and the structural analogue need to be assessed", and "the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s)(Guidance on IRs and CSA, Section R.6.2.3.1). Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) must be provided to allow assessing whether the attempted predictions are compromised by the composition and/or impurities.

12 For the source substances Acid Black 1, Acid Black 94 and Acid Green 68 you only specify that the dye content in the formulation used was higher than 70% and no further information are provided. For the other source substances Direct Blue 301 and Reactive Black 2506-MS, you have not provided any information on the composition, including their purity profile and the presence of impurities.

13 Without this information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substance(s) can be completed. Therefore, it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance(s).

0.1.1.2. Missing supporting information

14 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

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

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

17 For the source substances, you provide the studies used in the prediction in the registration dossier. Apart from the studies on the selected source substances, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that the target and selected source substances cause the same type of effects.

18 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

0.1.1.3. Adequacy and reliability of source studies

19 According to 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).

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

0.1.2. *Conclusion on the read-across approach*

21 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

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

1.1. Information provided

23 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

(i) a justification for an Annex VII, Section 8.3.1., Column 2 adaptation: "an *in vitro* skin sensitisation study does not need to be conducted because adequate data from an *in vivo* skin sensitisation study are available";
(ii) an *in vivo* skin sensitisation (1994) with the analogue substance Reactive black 2506-MS (EC No. 415-420-3, CAS 155522-15-9).

1.2. Assessment of the information provided

1.2.1. *Assessment whether the Substance causes skin sensitisation*

1.2.1.1. Read-across adaptation rejected

24 You provide a read-across justification document in IUCLID Section 7.4 for the prediction of the properties of Reactive Black 39 (EC No. 269-505-3) from information obtained from the source substance Reactive Black 2506-MS (EC No. 415-420-3).

25 You provide the following reasoning for the prediction of toxicological properties: "*Reactive Black 39 and the source substance Reactive Black 2506 are structurally identical dyes since the similarity of the source molecule with the target is 1. Reactive Black 2506 only differs to the target for the presence of two lithium counter ions instead of two sodium ions. It is possible to expect that the target Reactive Black 39 is not a skin sensitizer as well as Reactive Black 2506*".

26 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.

27 We have identified the following issue(s) with the prediction of toxicological properties:

1.2.1.1.1. Read-across hypothesis unrelated to the Substance

28 The hypothesis should be based on recognition of the structural similarities and differences between the substance registered and an analogue substance (Guidance on IRs and CSA, Section R.6.).

29 Your read-across hypothesis is based on the structural similarity between Reactive Black 2506-MS (EC No. 415-420-3) and Reactive Black 39 (EC No. 269-505-3).

30 However, none of these substances is the registered Substance.

1.2.1.1.2. Characterisation of the source substance

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

32 Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) must be provided to allow assessing whether the attempted predictions are compromised by the composition and/or impurities.

33 You have provided no information on the composition, including the purity profile and the presence of impurities of the source substance.

34 Without quantitative information on the compositions of the Substance and of the source substance, it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance(s).

1.2.1.1.3. Missing supporting information

35 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

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

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

38 You only provided the prediction results of the QSAR Toolbox 4.4.1 "protein binding profilers" in your read-across justification. Apart from that information, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

39 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

1.2.1.1.4. The provided study does not meet the information requirement

40 Under Annex XI, Section 1.5., the study 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 EU Method B.6/OECD TG 406. Therefore, the following specifications must be met:

a) a dose level selection rationale is provided;
b) the induction concentration is the highest causing mild-to-moderate irritation to the skin;
c) a positive control is included to establish the sensitivity and reliability of the experimental technique.

41 The study (i) is described as a Guinea Pig Maximisation Test.

42 However, the following specifications are not according to the requirements of OECD TG 406:

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 a positive control group was provided.

43 The information provided does not cover the key parameter(s) required by OECD TG 406.

44 Based on the above, the information provided does not allow to make a conclusion whether the Substance causes skin sensitisation.

1.2.1.1.5. Conclusion on the read-across approach

45 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.

1.2.2. *No assessment of potency*

46 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).

47 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1 above), this condition cannot be assessed.

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

1.3. Specification of the study design

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

50 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated 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

51 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2.1. Information provided

52 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided following information:

(i) A prediction from an expert system (knowledge-based) SAR model implemented in the software KNIME for predicting mutagenicity of aromatic amines and azo-compounds

2.2. Assessment of the information provided

2.2.1. *Assessment of (Q)SAR information*

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

(1) the prediction needs to be derived from a scientifically valid model,
(2) the substance must fall within the applicability domain of the model,
(3) results need to be adequate for the purpose of risk assessment or classification and labelling, and
(4) adequate and reliable documentation of the method must be provided.

54 With regard to these conditions, we have identified the following issue(s):

2.2.1.1. Inadequate documentation of the prediction (QPRF)

55 ECHA Guidance R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the model prediction(s), including the endpoint,
- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

56 You provided the following information about the model and the prediction in the (Q)SAR reporting template:

a) (Q)SAR predicted results: mutagen (5 generated amines; 4 mutagenic amine ; 1 not mutagenic);
b) Information about a compound (Direct Blue 301) with high degree of similarity to the Substance: "*Direct Blue 301 has the same main chemical substituents and aromatic groups characteristics of Direct Black 19 but they are placed in different order in the molecule*".

57 However, the following information is missing:

a) you do not specify the structure of the 5 generated amines and which path of the rule system is applicable to the structure of the Substance and the generated amines (e.g. to which sub-class the structures are assigned);
b) you do not include a comparison of the amines generated by the Substance and by the structurally similar substance Direct Blue 301. Without this information, the relevance of Direct Blue 301 as a structurally similar substance to the Substance cannot be assessed.

58 Without having this information and a justification on how it supports the prediction in light of the reported specificity of the model, the prediction cannot be accepted.

59 In absence of such information, ECHA cannot establish that the prediction can be used to meet this information requirement.

60 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

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

3. Short-term toxicity testing on aquatic invertebrates

62 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

3.1. Information provided

63 You have adapted this information requirement by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2. In support of your adaptation, you provided the following sources of information:

(i) a study according to EU Method C.2 (Acute Toxicity for Daphnia) on the analogue substance Direct Blue 301 with EC No. 408-210-8. (CAS RN 124605-82-9)
(ii) a non guideline study similar to OECD TG 202 (Daphnia sp. Acute Immobilisation Test) on the analogue substance Acid Black 94 with EC No. 228-784-1. (CAS RN 6358-80-1)
(iii) a non guideline study similar to OECD TG 202 (Daphnia sp. Acute Immobilisation Test) on the analogue substance Acid Black 1 with EC No. 213-903-1. (CAS RN 1064-48-8)
(iv) alert profiles of the target and the source substances. In support of your Annex XI, Section 1.5. adaptation, you have assessed the impact of potential structural differences using structural characteristics and mechanistic alerts obtained from the QSAR model CORAL-2020

64 To relation to your adaptation, you have also provided the following statements: "[…] *there are also differences in some functional group and some physicochemical properties are unknow* […] *the reasoning is based on a weight of evidence approach, which is supported by a QSAR analysis of the target for the endpoint 6.1.3*".

65 ECHA understands that your weight of evidence approach relies on grouping and read-across approach under Annex XI, Section 1.5. ECHA understands that you consider that the selected source substances follows a regular pattern as result of structural similarity and that you consider those as a group or 'category' of substances.

3.2. Assessment of the information provided

66 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.

67 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.

68 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.

69 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 9.1.1 includes similar information that is produced by the OECD TG 202. OECD TG 202 requires the study to investigate the following key elements:

- the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test is estimated;

70 In the source of information (iv), you provide ecotoxicity alerts obtained from the CORAL-2020 QSAR model, a model that predicts whether a substance is expected to be "toxic" or "non-toxic". These structural alerts reported in the justification document do not represent relevant information with regard the above key parameter as they are not provide information on EC50 and as the basis of the effect used for the conclusion is not specified. Also the experimental data used as input data for the prediction are not described. Therefore, this source of information cannot be regarded as providing relevant information to conclude on the information requirement.

71 For the sources of information (i) to (iii), you report an EC50 values which is relevant to the key parameter as defined in OECD TG 202. However, the reliability of these sources of information is significantly affected by the following deficiencies:

3.2.1. *Read-across adaptation rejected for all the sources of information*

72 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. In addition, ECHA identified endpoint specific issue addressed below.

3.2.2. *Adequacy and reliability of studies i to iii.*

73 Under Annex XI, Section 1.5., 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 202. Therefore, the following specifications must be met:

74 Technical specifications impacting the sensitivity/reliability of the test

a) test animals are derived from a healthy stock (i.e. showing no signs of stress such as high mortality, presence of males and ephippia, delay in the production of the first brood, discoloured animals) and should not be first brood progeny;

75 Characterisation of exposure

b) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

76 Reporting of the methodology and results

c) the test design is reported (e.g. static or semi-static test, number of replicates);
d) the test procedure is reported (e.g. composition of the test medium, loading in number of Daphnia per test vessel);
e) the methods used to prepare stock and test solutions is reported;
f) the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;
g) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported.

77 Your registration dossier provides a studies showing the following:

78 Technical specifications impacting the sensitivity/reliability of the test

a) in the studies (ii) and (iii), the test was conducted on neonates derived from ephippia. Therefore, the test animals did not originate from a stock culture as defined

by the test guideline. The life-stage of test animals was not reported in study (i).

79 Characterisation of exposure

b) no analytical monitoring of exposure was conducted for studies (i) to (iii).

80 Reporting of the methodology and results

c) the test design is not reported in study (i).
d) the test procedure is not reported in study (i). .
e) the methods used to prepare stock and test solutions are not reported in study (i);
f) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported is not reported in studies (i) to (iii);
g) the dissolved oxygen and pH measured at least at the beginning and end of the test is not reported in study (i).

81 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results in studies (i) to (iii). More, specifically,
  - exposure has not been verified analytically for studies (i) to (iii). Therefore, you have not demonstrated that exposure was satisfactorily maintained over the duration of these tests.
  - neonates derived from ephippia instead of juvenile from lab culture were used in studies (ii) and (iii) and no justification for this deviation is provided. Neonates derived from ephippia are likely to have different sensitivity to the substance. Therefore, this deficiency might impact the sensitivity and reliability of the test.
- the reporting of the studies (i) to (iii) is not sufficient to conduct an independent assessment of their reliability. For study (i) key elements of the test design and test procedure are missing. For studies (i) to (iii), in the absence of tabulated data on the number of immobilised daphnids, it is not possible to verify that the relevant validity criteria from the test guideline was met.

82 Therefore, the studies (i) to (iii) submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter of the corresponding OECD TG.

3.2.3. *Conclusion on the weight of evidence adaptation*

83 As indicated above, the sources of information (i) to (iii) supporting your weight of evidence provide information on the key parameter normally investigated for this information requirement. However, the reliability of these sources of information is so severely affected by the issues identified above that no conclusion on the key parameter investigated by the required study can be reached. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

4. Growth inhibition study aquatic plants

84 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

4.1. Information provided

85 You have provided the following information an adaptation under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you provide the following information:

(i) a study according to OECD TG 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test) on the analogue substance Acid Black 1 with EC No. 213-903-1. (CAS 1064-48-8)
(ii) a study according to OECD TG 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test) on the analogue substance Acid Black 94 with EC No. 228-784-1. (CAS 6358-80-1)
(iii) a study according to OECD TG 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test) on the analogue substance Acid Black 68 with EC No. 284-407-0. (CAS 84878-17-1)
(iv) a study according to EU Method C.3 (Algal Inhibition test) on the analogue substance Reactive Black 2506-MS with EC No. 415-420-3. (CAS 155522-15-9)

4.2. Assessment of the information provided

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

4.2.1. *Read-across adaptation rejected for all the sources of information*

87 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. In addition, ECHA identified endpoint specific issue(s) addressed below.

4.2.2. *Adequacy and reliability of studies on the source substances.*

88 Under Annex XI, Section 1.5., 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 201. Therefore, the following specifications must be met:

89 Key parameter to be measured

a) the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated. Growth must be expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period;

90 Characterisation of exposure

b) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

91 Reporting of the methodology and results

c) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);
d) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);
e) the methods used to prepare stock and test solutions are reported;
f) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported. Algal biomass is normally determined based on dry weight per volume, or alternatively as cell counts or biovolume using microscopy or an electric particle counter. If an alternative method is used (*e.g.* flow cytometry, *in vitro* or *in vivo* fluorescence, or optical density), a satisfactory correlation with biomass must be demonstrated over the range of

biomass occurring in the test;

g) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
h) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;

92 Your registration dossier provides studies showing the following:

93 Key parameter measured

a) the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are not reported for the study (v).

94 Characterisation of exposure

b) no analytical monitoring of exposure was conducted for any of the studies (i) to (iv);

95 Reporting of the methodology and results

c) the test design is not reported for study (iv).
d) the test conditions are not reported for study (iv).
e) the test procedure is not reported for study (iv).
f) the method used to determine algal biomass is not reported for study (iv).
g) tabulated data on the algal biomass determined daily for each treatment group and control are not reported for studies (i) to (iv);
h) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported for study (iv).;

96 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no analytical monitoring of exposure concentrations was reported in any of studies (i) to (iv). Therefore, you have not demonstrated that exposure was satisfactorily maintained over the duration of these tests.
- the reporting of studies (i) to (iv) is not sufficient to conduct an independent assessment of their reliability. In particular,
  - you have not provided adequate information (i.e., raw biomass data) to verify whether validity criteria equivalent to those specified in OECD TG 201 were met. Without this information, it is also not possible to verify the interpretation of the studies;
  - you have not provided adequate information on the study design and the test conditions in study (iv). Therefore, it is not possible to verify whether this study was conducted under conditions that are consistent with the specifications of the OECD TG 201;
  - you have not provided adequate information on the method used to determine algal biomass in study (iv). Therefore, the reliability of the reported effect values cannot be verified.

97 Therefore, the requirements of the OECD TG 201 are not met for any of the above studies.

98 Therefore, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG 201.

5. Ready biodegradability

99 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

5.1. Information provided

100 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided following information:

(i) ISIDA Consensus – Ready Biodegradability (RB) classification model, 2020.
(ii) VEGA Ready Biodegradation model, 1.2.8, 2014

5.2. Assessment of information provided

5.2.1. *(Q)SAR results only are not sufficient to fulfil the information requirement under Annex VII, Section 9.2.1.1.*

101 Guidance on IRs and CSA, Section R.7.9.5.1. specifies that (Q)SARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation. However, when no useful information on degradability is available (either experimentally derived or estimated), (Q)SAR predictions can be used as supporting evidence of that the substance is not rapidly degradable.

102 Your dossier only provides (Q)SARs predictions. You have used this information to conclude that the Substance is readily biodegradable. As explained above, (Q)SARs predictions alone is not adequate to conclude on the persistence of the Substance. Therefore, this information does not fulfil the information requirement and your adaptation is rejected.

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

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 09 December 2021.

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

ECHA did not receive any comments within the commenting period.

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 to be the same as the deadline of a decision sent to other registrants of the Substance requesting some of the same studies. The decision sent to the other registrants requests additional studies that require longer timelines.

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]

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].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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 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.

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