~~Confidential~~

Helsinki, 13 October 2023

Addressee
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
24/06/2022

Registered substance subject to this decision ("the Substance")
Substance name: 4-amino-5-hydroxy-6-(5-{4-chloro-6-[4-(2-sulfonatooxyethanesulfonyl)phenylamino]-1,3,5-triazin-2-ylamino}-2-sulfonatophenylazo)-3-(2-sulfonato-4-(2-sulfonatooxyethanesulfonyl)phenylazo)naphthalene-2,7-disulfonate potassium/sodium; reaction mass of: 4-amino-3-(4-ethenesulfonyl-2-sulfonatophenylazo)-5-hydroxy-6-(5-{4-chloro-6-[4-(2-sulfonatooxyethanesulfonyl)phenylamino]-1,3,5-triazin-2-ylamino}-2-sulfonatophenylazo)naphthalene-2,7-disulfonate potassium/sodium
EC/List number: 451-440-9

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 ***20 April 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. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201 or EU C.26./OECD TG 221)

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

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

3. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106)

4. 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.

5. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: EU C.25/OECD TG 309)

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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 request(s)
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.

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Appendix 1: Reasons for the request(s)

Contents

0. Reasons common to several requests

0.1. Assessment of the read-across approach

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

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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 toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance (also referred to as [redacted] or [redacted]) from information obtained from the following source substance(s):

[redacted] or [redacted] (EC No. [redacted]).

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

8 "[…] it is concluded that the target chemical and the source chemical have comparable physical-chemical properties and are therefore supposed to behave similar in biological systems, hence supporting the read-across from the source chemical, [redacted], to the target chemical, [redacted]."

9 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.

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

0.1.1.1. Missing supporting information

11 Annex XI, Section 1.5 of the REACH Regulation states that "physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)". For this purpose "it is important to provide supporting information to strengthen the rationale for the read-across" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify

the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

12 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).

13 For the source substance, you provide the reproductive/developmental toxicity screening test used in the prediction, and a prenatal developmental toxicity study (not discussed in this decision). You did not provide any mammalian toxicity study with the Substance that investigates reproductive/developmental toxicity.

14 In your comments to the draft decision you disagreed with the ECHA assessment and asked ECHA to re-evaluate the read-across approach. You claim the read-across justification document is "demonstrating a strong chemical analogy between the source and the target substance." More specifically, you note the similar physico-chemical properties, such as water solubility, partitioning coefficient and surface activity. You also note the comparable acute toxicity, irritation and sensitisation data. On this basis you state that "since the physical-chemical properties are also determining the physiological and toxicological behaviour of a substance both substances are also expected to behave identical regarding absorption distribution, metabolism, and excretion in mammals (toxicokinetics)" and that "no difference between both substances regarding reproduction and developmental toxicity is expected." However, as explained above, the available acute toxicity, irritation and sensitisation data does not allow comparison of the source substance and the Substance for their effects relating to reproductive/developmental or systemic toxicity.

15 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.

0.1.2. Conclusion on the read-across approach

16 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.

0.2. Comments to the draft decision - Substance-tailored exposure-driven testing adaptation rejected

17 ECHA understands that you may have sought adaptation of the following standard information requirement(s) under Annex XI, Section 3.2 (a) or (c) substance-tailored exposure-driven testing:

- Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.),
- Identification of degradation products (Annex IX, Section 9.2.3.).

This is because in the comments to the draft decision, you provide arguments regarding the lack of environmental release of the Substance. You have not specified an adaptation and you have not set out a legal basis for the adaptation.

18 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c).

0.2.1. Lack of appropriate PNEC

19 Under Annex XI, Section 3.2(a)(ii) and (iii), a relevant and appropriate predicted no effect concentration (PNEC) must be derived and the results of the exposure assessment must show that exposures are always well below the PNEC, i.e. risk characterisation ratios RCRs must always be well below 1.

20 For substances satisfying the PBT and vPvB criteria of Annex XIII long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As a result, for such substances, PNECs and PECs cannot be derived with sufficient reliability to demonstrate that the ratio between PECs and the PNEC are always well below 1.

21 As explained in request 4, the information from your dossier does not allow excluding that the Substance is PBT/vPvB.

22 Therefore, you have neither demonstrated that an appropriate PNEC can be derived nor that RCRs are well below 1.

0.2.2. Substance is not handled under strictly controlled conditions

23 Under Annex XI, Section 3(2)(c), it must be demonstrated and documentated for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply (see further Guidance on Intermediates and Practical Guide 16).

24 You have not claimed that the Substance is used under strictly controlled conditions and you have not provided any documentation.

25 Therefore, the use of the Substance under strictly controlled conditions is not demonstrated.

0.2.3. Conclusion on the substance-tailored exposure driven testing adaptation

26 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

28 You have provided:

(i) a study on algal growth inhibition (2003) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline

29 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

30 Reporting of the methodology and results

a) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

b) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

31 Additional specifications used for testing colouring test materials according to OECD GD 23

c) the following adjustments to the OECD TG 201 test method are applied for colouring test materials:

- the irradiation (light intensity) is above 120 µE/m^2sec
- the light path is shortened by reduction of the volume of the test solutions
- sufficient agitation (for example by moderate shaking) is performed in order to obtain a high frequency of exposure of the algae to high irradiation at the surface of the test solution.

32 Results

d) The results must be based on direct effects (Guidance on IRs and CSA, Section R.7.b, Table R.7.8-3: "Since the amount of light absorbed will vary with solution concentration, effects seen at high concentration are not necessarily environmentally relevant. The endpoint for regulatory use should therefore be based on direct toxic effects. If the test has not been designed to indicate whether any observed effects are caused by light limitation, then the results cannot be used.").

33 In study (i) described as growth inhibition study on aquatic plants/algae:

34 Reporting of the methodology and results

a) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

b) on the analytical method adequate information, i.e. the performance parameters of the HPLC method used, including the recovery efficiency of the method and the limit of quantification in the test matrix are not provided;

35 Additional specifications used for testing colouring test materials according to OECD GD 23 and results

c) and d) You report that the OECD TG 201 test was modified in order to "quantify the algicidal effect of the test item, but also the growth inhibition effect caused by reduced light intensities in the colored test solutions". In addition to this, you conclude that the test modified by the ETAD method demonstrated that the observed growth inhibition effect of the Substance was caused by the indirect effect (i.e., the light absorption in the colored test solutions) and the direct effect (i.e., the toxic effect of the dissolved test material) on the growth can be excluded in all tested concentrations.

36 Based on the above,

- the Substance is difficult to test because of its colouring properties (technical function reported in section 3 of your IUCLID dossier: dye) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the results of the test are not be based on direct effects. ECHA understands you used the so-called ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) method instead of applying the adjustments listed in OECD GD 23. The ETAD method attempted to compare direct and indirect contact of the test substance with algae, with the indirect contact used to evaluate light inhibition only. The ETAD method is not designed to indicate whether any observed effects are caused by light limitation and thus it is not a reliable basis for evaluation of aquatic toxicity to algae.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, you have not reported the performance parameters of the analytical monitoring method used, and the biological observations for each treatment group that would allow ECHA to assess the reliability of the effect concentrations reported in the Robust Study Summary.

37 Therefore, the requirements of OECD TG 201 are not met.

38 Therefore, the information requirement is not fulfilled.

39 In the comments to the draft decision, you agree to perform an OECD TG 221 test.

1.3. Study design and test specifications

40 The Substance has colouring properties. While OECD TG 201 is the preferred method to fulfil the information requirement, OECD TG 221 can be an acceptable alternative for coloured substances.

41 The Substance is difficult to test due to the colouring properties. OECD TG 201 and OECD TG 221 specify that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used

to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

Reasons related to the information under Annex VIII of REACH

2. Screening for reproductive/developmental toxicity

42 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

2.1. Information provided

43 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a screening for reproductive/developmental toxicity study (2011) with the source substance [redacted];
(ii) a prenatal developmental toxicity study (2011) with the source substance [redacted].

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

44 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.

2.3. Specification of the study design

45 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

46 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

47 Therefore, the study must be conducted in rats with oral administration of the Substance.

3. Adsorption/ desorption screening

48 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

3.1. Information provided

49 You have provided a study conducted with the Substance, using the Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) test method (EU C.19 / OECD TG 121).

3.2. Assessment of the information provided

50 To fulfil the information requirement, a study must comply with the OECD TG 121 (Article 13(3) of REACH). Therefore, the following specifications must be met:

51 Applicability domain

a) The method is applicable to substances having a log K_{oc} between 1.5 and 5.

52 Technical specifications impacting the sensitivity/reliability of the test

b) The reference substances have log K_{oc} values which encompass the log K_{oc} of the test material.

53 Your registration dossier provides an OECD TG 121 showing the following:

54 Applicability domain

a) The Substance has a log K_{oc} < 1.32, therefore it is out of the applicability domain of the test method.

55 Technical specifications impacting the sensitivity/reliability of the test

b) The reference substances have log K_{oc} values (range of log K_{oc} values: 1.32-5.63) which do not encompass the log K_{oc} of the test material.

56 Based on the above,

- the Substance is outside of the applicability domain of the coreesponding test guideline, and
- there are critical methodological deficiencies resulting in the rejection of the study results since the Substance is outside the applicability domain of the OECD TG 121.

57 Therefore, the specifications of OECD TG 121 are not met.

58 In the comments to the draft decision, you agree to perform the requested test.

3.3. Specification of the test selection and study design

59 The OECD TG 106 Batch Equilibrium Method is the appropriate method to study the adsorption of the Substance. This method uses a range of actual soils and so represents a more realistic scenario than the HPLC (OECD TG 121) method. The ionisable properties of the Substance should be considered when selecting the appropriate test design. For ionisable substances, soil types should cover a wide range of pH.

4. Simulation testing on ultimate degradation in surface water

60 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).

4.1. Triggering of the information requirement

61 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 (*i.e.* <60% degradation in an OECD TG 301A), and
- it shows <70% degradation within 14 days in an inherent biodegradation test OECD 302B and/or lag phase > 3 days;

- 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.

62 Your registration dossier provides the following:

- the Substance is not readily biodegradable (3% degradation after 28 days in OECD TG 301A);
- the Substance is not inherently biodegradable (7% degradation after 28 days in OECD TG 302B;
- the Substance is an ionisable substance and therefore high potential for bioaccumulation cannot be excluded based on available information. The Substance is ionisable on the basis of the following pieces of information:
  - the Substance is permanently ionised at environmental pH (i.e. in the pH range 4-9), on the basis of an ACD/Percepta estimation of the dissociation behaviour;
  - in section 1.2 of your IUCLID dossier, you report that the Substance is a sodium, potassium salt and you provide a structural formula that indicates that the structure includes multiple sulphate groups and is charged;
  - in section 4.8 of your IUCLID dossier, you report that the Substance is very soluble (water solubility: > 413 g/L at 20°C), which is also in line with the dissociation behaviour mentioned above.

63 Under section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that the Substance is P, but does not fulfil the vP or the B/vB criteria. In support of your conclusion you provide the following additional information:

- With regards to Persistence: You conclude that the Substance fulfils the P criterion because it is not readily biodegradable and it is not inherently biodegradable on the basis of the available studies. In addition to this, you claim that the Substance does not fulfil the vP criterion because it is hydrolytically unstable. With regards to hydrolysis, in section 5.1.2. of your IUCLID dossier, you report that the Substance has a DT50 value of 94 hours or 3.9 days (at pH 7, 50°C) and < 24 hours (at pH 9, 25°C).
- With regards to Bioaccumulation: You conclude that the Substance does not fulfil the B/vB criteria because it has a low octanol-water partition coefficient (log K_{ow}: < -5.5).

64 However,

- Ready biodegradability, inherent degradability and hydrolytic stability are not assessment elements for persistence (Annex XIII, Section 3.2.1) and you have not explained how they would be relevant and suitable. Your IUCLID dossier does not include a simulation study which would allow you to conclude whether the Substance fulfils the vP criteria.
- Because the Substance is ionisable, the potential for bioaccumulation of the Substance may not be solely driven by lipophilicity. Therefore, the octanol-water partition coefficient may not be a reliable predictor of bioaccumulation potential for this type of substances. Your IUCLID dossier does not include data for the bioaccumulation information requirement, that would allow you to conclude on the bioaccumulation potential of the Substance.

65 Therefore, the additional information from your PBT assessment is not adequate to conclude that the Substance is not a potential PBT/vPvB substance.

66 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.

4.2. Information provided in the comments to the draft decision relevant to the potential PBT properties of the Substance and assessment of the provided information

67 In the comments to the draft decision, you have provided the following:

i. a justification related to the toxicokinetic behaviour of the Substance. You base these toxicokinetic considerations on physico-chemical properties of the Substance, and on observations from mammalian studies (OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents) conducted with the Substance. On this basis, you claim that the Substance has a low potential for bioaccumulation.

68 ECHA understands that you have provided the above information relevant to the B/vB assessment of the Substance, in order to show that the Substance is not a potentially PBT/vPvB substance.

69 However, the provided information does not change the above conclusion. This is because the provided information is insufficient to conclude on the B/vB assessment of the Substance.

70 Under Annex XIII, Section 3.2., available information on the toxicokinetic behaviour of the substance has to be considered for the assessment of B/vB properties, provided that its suitability and reliability can be reasonably demonstrated.

71 In the comments to the draft decision, you have provided a justification related to the toxicokinetic behaviour of the Substance, arguing that the Substance has low potential for bioaccumulation. You based this justification on physico-chemical properties of the Substance (e.g. log Pow, vapour pressure, molecular weight of the Substance), and on observations from a mammalian study conducted with the Substance. You argue that the substance is expected to be taken up mainly via the oral route; will likely be distributed among organs; it will be metabolized; and finally, it will be excreted via bile and through urine.

72 However, you have not provided any new scientific information (e.g. experimental data on toxicokinetic behaviour, and in particular, on elimination processes) that could support your claims.

73 On this basis, your justification related to the low bioaccumulation potential of the Substance is rejected.

4.3. Information provided to meet the simulation testing on ultimate degradation in surface water information requirement in your comments to the draft decision

74 In the comments to the draft decision, you have provided the following information:

i. You argue that the environmental releases of the Substance are negligible.

ii. You indicate your intention to submit QSAR data to identify the potential degradation products of the Substance and provide screening information on their PBT/vPvB properties.

iii. You claim that radiolabelling of dyes is technically challenging.

iv. You claim that the Substance does not pose any hazard to the environment, based on available data from aquatic tests. In relation to this, you propose to conduct sediment toxicity and terrestrial toxicity testing to be able to conclude on the lack of ecotoxicity of the Substance.

75 ECHA understands that in points i. ii., and iii., you may have sought adaptation of the information requirement under Annex XI, Section 3, Annex XI, Section 1.3, and Annex XI, Section 2, respectively.

4.4. Assessment of the information provided

4.4.1. Issues identified with information provided to meet the simulation testing on ultimate degradation in surface water information requirement

4.4.1.1. Substance-tailored exposure-driven testing adaptation rejected

76 ECHA understands that in point i., you may have sought adaptation of the the information requirement by means of substance-tailored exposure-driven testing, under Section 3 of Annex XI.

77 As explained above in Section 0.2 of this decision, your adaptation under Annex XI, Section 3 is rejected.

4.4.1.2. The QSAR result is not equivalent to results obtained from the required experimental test

78 In point ii., you propose to follow a tiered approach, in which you identify the potential biodegradation products of the substance using an appropriate QSAR model (you mention the EAWAG-BBD Pathway Prediction System as an example) and then screen the PBT properties of the potential biodegradation products using appropriate QSAR models.

79 ECHA understands that in point ii., you may have sought adaptation of the the information requirement by means of qualitative or quantitative structure-activity relationship models ((Q)SARs), under Section 1.3 of Annex XI.

80 ECHA acknowledges your intention to submit a new adaptation as part of a future dossier update. However, as indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

81 Further, ECHA notes that results from (Q)SAR models are adequate for risk assessment or classification and labelling when they are equivalent to results obtained from the required experimental test. The corresponding study that must normally be performed for this particular information requirement is test method OECD TG 309, which measures the following key parameters:

i. the rate of aerobic transformation of the test material in natural surface water;

ii. the identity and rates of formation and decline of transformation/degradation products are determined if those are detected at ≥ 10% of the applied radioactivity (AR) in the total water-sediment system at any sampling time, or are continuously increasing during the study even if their concentrations are < 10% AR (unless appropriate justification is provided).

82 You have indicated your intention to provide predictions from the (Q)SAR model EAWAG-BBD Pathway Prediction System, which predicts plausible pathways for microbial degradation of chemical compounds by using biotransformation rules, which based on reactions found in the EAWAG-BBD database or in the scientific literature.

83 The model predicts potential biodegradation products but does not measure the rate of aerobic transformation of the test material in natural surface water and the rates of formation and decline of transformation/degradation products. Therefore, the prediction you have indicated to submit would not be adequate to meet the information requirement for soil simulation testing for the purpose of classification and labelling and/or risk assessment.

4.4.1.3. No technical impossibility demonstrated

84 In the provided information in point iii., you claim that radiolabelling of dyes is technically challenging. ECHA understands that you may have sought adaptation of the the information requirement by claiming that testing is technically not possible, under Section 2 of Annex XI.

85 However, you have not provided any substance-specific information about the testing of the Substance.

86 On this basis, your justification is rejected.

4.4.1.4. Your justification to omit the study has no legal basis

87 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.2., Column 2.

88 Your justification to omit this information under point iv. does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.2., Column 2.

89 Therefore, you have not demonstrated that this information can be omitted.

90 Further, ECHA acknowledges your intention to submit a testing proposal for sediment toxicity testing as part of a future dossier update. However, as indicated in your comments, this strategy relies on a testing proposal which is yet to be submitted. Therefore, no conclusion on the proposal can be made.

91 Based on the above, the information requirement is not fulfilled.

4.5. Study design and test specifications

92 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.

93 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.).

94 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.

95 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. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

a) For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, 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 (NER - summary 2019 (europa.eu)).

96 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.).

5. Identification of degradation products

97 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. Triggering of the information requirement

98 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.).

99 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

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

101 Your registration dossier does not include any information on degradation products identity.Therefore, the information requirement is not fulfilled.

5.2. Information provided to meet the identification of degradation products information requirement – comments to the draft decision

102 In the comments to the draft decision, you have provided the following information:

i. You argue that the environmental releases of the Substance are negligible.

ii. You indicate your intention to adapt the information requirement by submitting

QSAR. You propose to follow a tiered approach, in which you first identify the potential biodegradation products of the substance using an appropriate QSAR model (you mention the EAWAG-BBD Pathway Prediction System as an example) and then screen the PBT properties of the potential biodegradation products using appropriate QSAR models.

5.3. Assessment of the information provided

103 ECHA understands that in point i., you may have sought adaptation of the the information requirement by means of substance-tailored exposure-driven testing, under Section 3 of Annex XI.

104 As explained above in Section 0.2 of this decision, your adaptation under Annex XI, Section 3 is rejected.

105 ECHA understands that in point ii., you may have sought adaptation of the the information requirement by means of qualitative or quantitative structure-activity relationship models ((Q)SARs), under Section 1.3 of Annex XI.

106 ECHA acknowledges your intention to submit such a new adaptation as part of a future dossier update. However, as indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

5.4. Study design and test specifications

107 Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Request 4 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

108 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 4) 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).

109 You may also use other appropriate and suitable test method(s) to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated.

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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are 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 06 April 2022.

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

ECHA took into account your comments and amended the request(s). The request for skin sensitisation was removed, as in your comments you provided scientific rationale for the use of the vehicle.

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.

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

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

Appendix 3: Addressee 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 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.

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. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.