~~Confidential~~

Helsinki, 11 January 2023

Addressees
Registrant(s) of JS_Reactive_Black_31_B as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23/03/2018

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of Cuprate(4-), [4,5-dihydro-4-[[8-hydroxy-7-[[2-hydroxy-5-methoxy-4-[[2-(sulfooxy)Vinyl]phenyl]azo]-6-sulfo-2-naphthalenyl]azo]-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylato(6-)], trisodium salt and Cuprate(4-), [4,5-dihydro-4-[[8-hydroxy-7-[[2-hydroxy-5-methoxy-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-6-sulfo-2-naphthalenyl]azo]-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylato(6-)]-, sodium and Cuprate(4-), [4,5-dihydro-4-[[8-hydroxy-7-[[2-hydroxy-5-methoxy-4-[2-(sulfooxy)Ethanol]phenyl]azo]-6-sulfo-2-naphthalenyl]azo]-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylato(6-)], trisodium salt
EC/list number: 941-883-0

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 ***17 April 2024***.

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

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

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

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

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 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.

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 requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

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

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

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

0.1.1. Predictions for (eco)toxicological properties

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

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

1) Reactive Blue 220, EC No. 291-103-1, CAS: 90341-71-2, [RA substance 01];
2) Acid Yellow 023, EC No. 217-699-5, CAS: 1934-21-0, [RA substance 02].

7 You provide the following reasoning for the prediction of (eco)toxicological properties: *"(…) the use of read across substances with structural similarity and comparable physicochemical/(eco)toxicological profile is considered as valid. (…) a precautionary approach should be followed, namely read across substances should be at least as hazardous as target substance."*

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 substances.

9 We have identified the following issues with the prediction of (eco)toxicological properties:

0.1.1.1. Unreliable source studies

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

- have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

11 Specific reasons why the studies on the source substances do not meet this criterion are explained further below under the applicable information requirement sections 1 and 2. Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion on the read-across approach

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

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

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

1.1. Information provided

14 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:

- Reactive Blue 220, EC No. 291-103-1, CAS: 90341-71-2, [RA substance 01];
- Acid Yellow 023, EC No. 217-699-5, CAS: 1934-21-0, [RA substance 02].

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

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

1.2.1.1. Source study not adequate for the information requirement

16 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 OECD TG 471. Therefore, the following specifications must be met:

a. if the Substance is an azo-dye or a diazo-compound, the test in presence of metabolic activation is performed following the Prival modification;
b. the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

17 Your registration dossier provides:

i. a study on RA substance 01 (in vitro gene mutation study in bacteria, 1983) described as similar or equivalent to OECD Guideline 471;

ii. a study on RA substance 01 (in vitro gene mutation study in bacteria, 1989) described as OECD Guideline 471;

iii. a supporting study on RA substance 02 (in vitro gene mutation study in bacteria, 2005) described as OECD Guideline 471.

18 However, for the above studies the following specifications are not according to the requirements of OECD TG 471:

19 In the studies (i) and (iii) described as an in vitro gene mutation studies on bacteria:

a) although the tested substance is an azo-dye, the test in presence of metabolic activation was not performed following the Prival modification;

20 In the study (ii) described as an in vitro gene mutation study on bacteria:

b) the test was performed with the strains S. typhimurium TA 1535, TA 1537, TA 1538, TA 98 and TA 100 (i.e., the strain(s) *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing);

21 Based on the above, the studies do not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 471 and these studies are not an adequate basis for your read-across predictions.

22 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

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

24 Your Substance is an azo dye for which the standard procedure may not detect all mutations. Therefore, you are required to use the Prival modification (see Paragraph 10 of OECD TG 471).

2. Short-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

26 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 source substances:

- Reactive Blue 220, EC No. 291-103-1, CAS: 90341-71-2, [RA substance 01];
- Acid Yellow 023, EC No. 217-699-5, CAS: 1934-21-0, [RA substance 02].

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

27 As explained in Section 0.1. and below, 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 issues addressed below.

2.2.1.1. Source studies not adequate for the information requirement

28 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 OECD TG 202. Therefore, the following specifications must be met:

29 Characterisation of exposure

a) 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.

30 Your registration dossier provides:

i. a key study on RA substance 01 (48-hour acute toxicity to Daphnia magna screening test, 2009) described as OECD Guideline 202/EU Method C.2., and

ii. a supporting study on RA substance 02 (48h-Toxizität von „FAT 55064" gegen Daphnia magna durchführung als Limittest, 2001) described as OECD Guideline 202.

31 However, for both of the above studies the following specifications are not according to the requirements of OECD TG 202:

32 Characterisation of exposure

a) no analytical monitoring of exposure was conducted.

33 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically, the concentrations of the test material throughout the test duration were not analytically verified (monitored), which may result in an underestimation of toxicity.

34 Based on the above, the studies do not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 202 and these studies are not an adequate basis for your read-across predictions.

35 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

36 The Substance is difficult to test due to the colouring properties which are mentioned under additional information in section 6.1.5 of IUCLID dossier (Toxicity to aquatic algae and cyanobacteria). OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. 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 202. 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.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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.

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

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

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

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

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

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

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

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

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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.

[3] https://echa.europa.eu/manuals