EUROPEAN CHEMICALS AGENCY

Helsinki, 29 May 2020

Addressee
Registrant of JS_73507-17-2[redacted] as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
15/03/2018

Registered substance subject to this decision ("the Substance")
Substance name: Hydrogen tetrasodium bis[2-[[6-[[4-chloro-6-[3-sulphoanilino]-1,3,5-triazin-2-yl]amino]-1-hydroxy-3-sulpho-2-naphthyl]azo]benzoato(4-)]chromate(5-)
EC number: 277-492-0
CAS number: 73507-17-2

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

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 ***7 December 2020***.

A. 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: EU B.13/14. / OECD TG 471) with the Substance

Reasons for the request are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annex VII of REACH".

Information required depends on your tonnage band

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa.

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, where relevant, include any changes to the classification and labelling, based on the newly generated information.

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

Appeal

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

Failure to comply

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

Authorised[1] by **Catherine Cornu**, Scientific Officer, Data Availability.

[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 A: Reasons to request information required under Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. *In vitro* gene mutation study in bacteria

An '*in vitro* gene mutation study in bacteria' is a standard information requirement specified in section 8.4.1 of Annex VII of REACH.

In your dossier, you have adapted the standard testing regime by using a read-across approach, as foreseen in Annex XI, Section 1.5 of REACH, by providing information on '*in vitro* gene mutation study in bacteria' with source substances as follows:

Source substance	EC number: 228-819-0	EC number: 217-699-5
Source substance name	Disodium 2,5-dichloro-4-(5-hydroxy-3-methyl-4-(sulphophenylazo)pyrazol-1-yl)benzenesulphonate	trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo) pyrazole-3-carboxylate
Name of the study	[redacted] 1979)	[redacted] 1984)
Reported outcome	Negative	Negative

You reported your read-across approach in the record named 'WoE-1' in section 7.6.1 of your IUCLID dossier.

We have assessed this adaptation and identified the following issues:

Issue 1: The applicability of the read-across approach is not established

According to Annex XI, Section 1.5, when a read-across approach is used, adequate and reliable documentation of the applied method must be provided.

Such documentation must include a read-across hypothesis, substantiated by evidence, establishing why a prediction for the property is reliable. This hypothesis has to recognise the structural similarities and differences between the substances[2], and explain why the differences in chemical structure should not influence the property or should do so in a regular pattern.

You have provided studies conducted with other substances than your Substance and you have not provided documentation as to why this information is relevant for your Substance, other than a mere statement that the 'Data for the target chemical is summarized based on the structurally similar read across chemicals'.

A mere statement does not constitute adequate and reliable documentation of the applied method. In the absence of such documentation, ECHA cannot verify that the '*in vitro* gene mutation study in bacteria' of your Substance can be predicted from the data for the

[2] ECHA Guidance R.6

source substances you have chosen. Therefore, your approach does not satisfy the requirements for a read-across approach according to Annex XI, Section 1.5 of REACH.

Issue 2: The data provided for the source substances is not adequate

According to Annex XI, Section 1.5, results predicted with a read-across approach need to have adequate and reliable coverage of the key parameters addressed in the recognised test method. The recognised test method for this information is the OECD TG 471 (1997), which requires that test results are obtained with five specific bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one other strain; either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101), and that the test in the presence of metabolic activation is performed following the Prival modification for azo-dyes or diazo-compounds.

You have reported that test results were obtained as follows:

Source substance	EC number: 228-819-0	EC number: 217-699-5
Strain 1	TA98 tested	TA98 tested
Strain 2	TA100 tested	TA100 tested
Strain 3	TA1535 tested	TA1535 tested
Strain 4	Not tested	TA1537 tested
Strain 5	Not tested	Not tested
Use of the Prival modification	The Prival modification is not used, despite the substance being an azo-dye	The Prival modification is not used, despite the substance being an azo-dye

The data you have provided shows that the source substances you have chosen to read-across from to predict results for your Substance were not tested with all of the five required strains.

You have not provided data obtained with the Prival modification for the source substances you have chosen to read-across from to predict results for your Substance, despite the source substance being azo-dyes.

As the data you have provided on the source substances does not cover all of the five required strains and does not include data obtained with the Prival modification for the source substances requiring it, your predicted results for the Substance do not provide adequate and reliable coverage of the key parameters to be investigated. Therefore, it does not satisfy the requirements for a read-across approach according to Annex XI, Section 1.5 of REACH.

Issue 3: The data provided for the source substances is not reliable

According to Annex XI, Section 1.5, results predicted with a read-across approach need to have adequate and reliable coverage of the key parameters addressed in the recognised test method. The recognised test method for this information is the OECD TG 471 (1997), which requires certain test conditions:

- Maximum dose tested: the maximum dose tested must induce a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitation or limiting cytotoxicity is observed, the maximum dose tested must be 5 mg/plate or 5 ml/plate.
- Number of doses tested: at least 5 doses must be tested in each test condition.

The mean number of revertant colonies per plate for each dose must be reported.

- Positive control: a positive control must be included in the test. The positive control must produce a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control.
- Negative control: a negative control must be included in the test. The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.

You have provided data as follows:

Source substance	EC number: 228-819-0	EC number: 217-699-5
Maximum dose tested	No data or justifications are provided from performing the test with a maximum dose of 5 mg/plate or 5 ml/plate or a maximum dose that induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance.	No data or justifications are provided from performing the test with a maximum dose of 5 mg/plate or 5 ml/plate or a maximum dose that induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance.
Number of doses tested	No data on the mean number of revertant colonies per plate is provided from performing the test with at least five doses in each of the test conditions.	No data on the mean number of revertant colonies per plate is provided from performing the test with at least five doses in each of the test conditions.
Positive control	No data is provided that the positive control produced a statistically significant increase in the number of revertant colonies per plate compared with the negative control.	No data is provided that the positive control produced a statistically significant increase in the number of revertant colonies per plate compared with the negative control.
Negative control	No data is provided that the number of revertant colonies per plate for the negative control is inside the historical control range of the laboratory.	No data is provided that the number of revertant colonies per plate for the negative control is inside the historical control range of the laboratory.

You have not provided all of the required data on the test conditions, for the source substances you have chosen to read-across from to predict results for your Substance.

As the data you have provided on the source substances did not include all of the required data on the test conditions, your predicted results for the Substance do not provide adequate and reliable coverage of the key parameters to be investigated. Therefore, it does not satisfy the requirements for a read-across approach according to Annex XI, Section 1.5 of REACH.

In your comments, you have provided a new read-across approach for the '*in vitro* gene mutation study in bacteria', adapting the standard testing regime as foreseen in Annex XI, Section 1.5 of REACH, this time with source substances as follows:

Source substance	EC number: 219-746-5	EC number: 240-245-2	EC number: 220-491-7	EC number: 275-031-8
Source substance name	Tetrasodium 1-acetamido-2-hydroxy-3-(4-((4-sulphonatophenylazo)-7-sulphonato-1-naphthylazo))naphthalene-4,6-disulphonate	Disodium 2,2'-ethene-1,2-diylbis{5-[(4-anilino-6-morpholin-4-yl-1,3,5-triazin-2-yl)amino]benzenesulfonate}	Disodium 6-hydroxy-5-[(4-sulfonatophenyl)diazenyl]naphthalene-2-sulfonate	Potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate
Name of the study	[redacted] 2006)	[redacted] 2006)	[redacted] 2018	OECD SIDS (2005)
Reported outcome	Negative	Negative	Negative	Negative

We have assessed this adaptation and identified the following issues:

Issue 1: The applicability of the read-across approach is not established

According to Annex XI, Section 1.5, when a read-across approach is used, adequate and reliable documentation of the applied method must be provided.

Such documentation must include a read-across hypothesis, substantiated by evidence, establishing why a prediction for the property is reliable. This hypothesis has to recognise the structural similarities and differences between the substances, and explain why the differences in chemical structure should not influence the property or should do so in a regular pattern.

You have provided structural information on the new source substances, reported structural similarity (40-50%, 50-60%, 30-40% and 50-60%), and provided data on some physico–chemical properties and some alerts found. You have not provided a read-across hypothesis, substantiated by evidence, establishing why a prediction for the property is reliable and explaining why the differences in chemical structure should not influence the property or should do so in a regular pattern.

Therefore the provided information does not constitute adequate and reliable documentation of the applied method.

In the absence of such documentation, ECHA cannot verify that the '*in vitro* gene mutation study in bacteria' of your Substance can be predicted from the data for the source substances you have chosen. Therefore, your new approach also does not satisfy the requirements for a read-across approach according to Annex XI, Section 1.5 of REACH.

Issue 2: The data provided for the source substances with EC number 219-746-5, 240-245-2 and 220-491-7 is not adequate

According to Annex XI, Section 1.5, results predicted with a read-across approach need to have adequate and reliable coverage of the key parameters addressed in the recognised test method. The recognised test method for this information is the OECD TG 471 (1997),

which requires that test results are obtained with five specific bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one other strain; either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101), and that the test in the presence of metabolic activation is performed following the Prival modification for azo-dyes or diazo-compounds.

You have reported that test results were obtained as follows:

Source substance	EC number: 219-746-5	EC number: 240-245-2	EC number: 220-491-7
Strain 1	TA98 tested	TA98 tested	TA98 tested
Strain 2	TA100 tested	TA100 tested	TA100 tested
Strain 3	Not tested	Not tested	TA1535 tested
Strain 4	Not tested	Not tested	TA1537 tested
Strain 5	Not tested	Not tested	TA102 tested
Use of the Prival modification	Yes	Yes	The Prival modification is not used, despite the substance being an azo-dye

The data you have provided shows that two of the source substances (EC number: 219-746-5 and EC number: 240-245-2) you have chosen to read-across from to predict results for your Substance were not tested with all of the five required strains, and another source substance (EC number: 220-491-7) was not tested using the Prival modification, despite it being an azo-dye.

As the data you have provided on these source substances does not cover both all of the five required strains and the use of the Prival modification, the predicted results for the Substance do not provide adequate and reliable coverage of the key parameters to be investigated. Therefore, a read across adaptation based on these studies does not satisfy the requirements of Annex XI, Section 1.5 of REACH.

Issue 3: The data provided for the source substance is not reliable

According to Annex XI, Section 1.5, results predicted with a read-across approach need to have adequate and reliable coverage of the key parameters addressed in the recognised test method. The recognised test method for this information is the OECD TG 471 (1997), which requires certain test conditions:

- Maximum dose tested: the maximum dose tested must induce a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitation or limiting cytotoxicity is observed, the maximum dose tested must be 5 mg/plate or 5 ml/plate.
- Number of doses tested: at least 5 doses must be tested in each test condition. The mean number of revertant colonies per plate for each dose must be reported.
- Positive control: a positive control must be included in the test. The positive control must produce a statistically significant increase in the number of revertant colonies per plate compared with the concurrent negative control.
- Negative control: a negative control must be included in the test. The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.

You have not provided the required data on the test conditions, for the source substances you have chosen to read-across from to predict results for your Substance.

As the data you have provided on the source substances does not include the required data on the test conditions, your predicted results for the Substance do not provide adequate and reliable coverage of the key parameters to be investigated. Therefore, it does not satisfy the requirements for a read-across approach according to Annex XI, Section 1.5 of REACH.

In conclusion, the read across adaptations you provided both in the dossier and in your comments do not comply with the general rules for adaptation set out in Annex XI, Section 1.5 of REACH. Your adaptation is therefore rejected and the information requirement is not fulfilled.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) must be performed. As the substance is a diazo-compound, the test in the presence of metabolic activation must be performed following the Prival modification.

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

A. Test methods, GLP requirements and reporting

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

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

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

B. Test material

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

1. Selection of the Test material(s)

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

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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

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

Appendix C: Procedure

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

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

The compliance check was initiated on 07/08/2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the request.

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

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

Appendix D: List of references - ECHA Guidance[5] and other supporting documents

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

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

Read-across assessment framework (RAAF, March 2017)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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

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

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

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

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

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

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

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

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.
OECD Guidance documents[7]

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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

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

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

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

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

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

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