~~Confidential~~

Helsinki, 16 January 2024

Addressee(s)
Registrants of Reactive Red 198:1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/08/2020

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of tetrasodium 5-{[4-chloro-6-(4-{[2-(sulfonatooxy)ethyl]sulfonyl}anilino)-1,3,5-triazin-2-yl]amino}-4-hydroxy-3-[(4-{[2-(sulfonatooxy)ethyl]sulfonyl}phenyl) diazenyl]naphthalene-2,7-disulfonate and trisodium 5-({4-chloro-6-[4-(vinylsulfonyl) anilino]-1,3,5-triazin-2-yl}amino)-4-hydroxy-3-[(4-{[2-(sulfonatooxy)ethyl]sulfonyl}phenyl)diazenyl]naphthalene-2,7-disulfonate
EC number/List number: 701-360-8

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 ***23 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. Skin sensitisation (Annex VII, Section 8.3.)

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

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

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

2. Screening study 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. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111) – test under slightly alkaline conditions (i.e., covering only pH values between 7 and 8.5 and at least pH values of 8 and 8.5).

The reasons for the request(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

Reasons common to several requests

0.1. Read-across adaptation rejected

1 You have adapted the following standard information requirements 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 from information obtained from the following source substance(s):

- Reactive Red F03-0318 [redacted];
- Reactive Black 5 / tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate (EC 241-164-5, CAS 17095-24-8)
- Reactive Blue 225 / Lithium sodium hydrogen 4-amino-6-(5-(5-chloro-2,6-difluoropyrimidin-4-ylamino)-2-sulfonatophenylazo)-5-hydroxy-3-(4-(2-(sulfonatooxy)ethylsulfonyl)phenylazo)naphthalene-2,7-disulfonate (EC 401-560-2, CAS not available);

7 You provide the following reasoning for the prediction of toxicological properties: " Given that the metabolism of dyestuffs is understood and due to the similarities in the physicochemical properties between the molecules and the common "skeleton" and cleavage products of the structure, it is considered a viable conclusion to state that the expected (eco)toxicological effects for Reactive Red F66813 and the structural analogues selected are likely to be similar."

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

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

0.1.1.1. Missing supporting information to compare properties of the substances(s)

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

11 Supporting information must include bridging studies to compare properties of the Substance and the source substance(s).

12 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the substance(s) is necessary to confirm that the 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 You have provided a one generation reproductive toxicity study, two prenatal developmental toxicity studies and a screening for reproductive/ developmental toxicity study with the source substances.

14 You did not provide data investigating reproductive toxicity with the Substance.

15 In your comments to the draft decision you state that "from the subacute oral toxicity study in rats as bridging study, it can be seen, that all these substances do not cause severe adverse effects." ECHA acknowledges the available subacute oral toxicity study with the Substance reported no adverse effects on investigated target organs. However, the study does not investigate sexual function and fertility, nor development, and does therefore not inform on the adapted information requirement (i.e. screening for reproductive/ developmental toxicity study). Furthernore, the investigations of reproductive organs in the study were incomplete in comparison to the requirements of the corresponding OECD TG 407, as for example female reproductive organs were not investigated at all in the study. ECHA notes that supporting bridging data with the Substance is required to decrease the uncertainty that the Substance will (not) have the same hazard as the source substance.

16 The available studies do not allow comparison of the toxic properties of the Substance and the source substances. This is because only source study(ies) are available and no (bridging) studies with the Substance that are relevant to the information requirement are available.

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

0.1.2. Comments to the draft decision

18 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and

bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

19 You included in the updated read-across justification document provided with your comments a wide array of QSAR Toolbox structural similarity parameters and profiler alerts, and ADME profiling, claiming they "confirm that both source and target substances cause the same type of effects." You further state that "characteristic of both substances is that they do not become biologically available at a relevant amount as a consequence of their physico-chemical properties, and mainly due to the sizes of the molecules" and "this assumption is supported by the available bridging studies, the estimations of the Swiss ADME Program and the QSAR Toolbox." You assume that only the parabase cleave product ([redacted]) will likely account for the systemic toxicological properties of the target and source substances because you assume mainly this cleavage product is absorbed orally to some degree.

20 You have not provided any explanation to demonstrate the robustness of profilers for a complex endpoint (development / fertility) despite that profilers are mainly meant for searching for analogues, or for screening or prioritisation: "The outcome of the profiling determines the most appropriate way to search for analogues, but they are also useful for preliminary screening or prioritization of substances." (https://qsartoolbox.org/features/profiling/)

21 You have not provided hazard information with the Substance relevant to the adapted endpoint that would support your claims of same type of effects.

22 Physico-chemical similarity, structural similarity and similar profiling results alone do not necessarily lead to predictable or similar toxicological properties. You have not provided a well-founded hypothesis with supporting data to establish a reliable prediction for a toxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substance(s).

0.1.3. Conclusion on the read-across approach

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

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

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

1.1. Information provided

25 You have adapted this information requirement by using Annex VII, Section 8.3., Column 2. To support the adaptation, you have provided the following information:

(i) justification: "*an in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available*";

(ii) guinea pig maximisation test (1989) with the Substance.

1.2. Assessment of the information provided

1.2.1. Assessment whether the Substance causes skin sensitisation

1.2.1.1. The provided study does not meet the specifications of the test guideline(s)

26 To fulfil the information requirement, and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the EU Method B.6/OECD TG 406 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the induction concentration is the highest causing mild-to-moderate irritation to the skin;

b) the challenge dose is the highest non-irritation concentration.

27 In study (ii):

a) according to the study record in the dossier, the concentration used for induction did not cause mild-to-moderate irritation in the dose-range finder experiment or in the main experiment (no concentrations above 5% and 25% tested in intradermal and epicutaneous dose-range finder experiments, respectively);

b) the challenge concentration was not demonstrated to be the highest non-irritating concentration because the concentration used for challenge did not cause mild-to-moderate irritation in the dose-range finder study and was the highest concentration tested in the main experiment and in the dose-range finder experiment (25%).

28 The information provided in the dossier does not cover the specification(s) required by the EU Method B.6/OECD TG 406.

29 In your comments to the draft decision you provide the missing details of the pre-test. You state that "injection of 5% preparation caused oedema of the administration sites" and that "no irritation was seen after administration of the 1% and 0.2% preparation." You also state

that for topical pre-test "evaluation of erythema after treatment with the 25% substance preparation was impossible due to an intensive red discoloration of the surface of the skin" and that "the 5% and 1% substance preparation did not cause irritations."

30 On the basis of the information included in your current registration dossier, it cannot be concluded whether the Substance causes skin sensitisation. However, the information regarding the pre-test provided in your comments to the draft decision justifies the dose-selection in the main study, and needs to be included in the dossier by the deadline of this decision.

1.2.2. No assessment of potency

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

32 As the currently available data in your registration dossier does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1. above), this condition cannot be assessed. This is, however, remedied by the information in your comments.

33 Therefore, the information requirement is not fulfilled in your registration dossier. The information regarding the pre-test provided in your comments to the draft decision needs to be included in the dossier by the deadline of this decision.

1.3. Specification of the study design

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

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

Reasons related to the information under Annex VIII of REACH

2. Screening study for reproductive/developmental toxicity

36 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

2.1. Information provided

37 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 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (2011) with the source substance Reactive Red F03-0318, [redacted];

(ii) a generation reproductive toxicity study (2002) with the source substance Reactive Blue 225 EC 401-560-2;

(iii) a prenatal developmental toxicity study (2002) with the source substance Reactive Blue 225 EC 401-560-2;

(iv) a prenatal developmental toxicity study (1994) with the source substance Reactive Black 5 EC 241-164-5.

38 You indicate the adequacy of these studies as weight of evidence in the IUCLID dossier.

39 Your comments to the draft decision and the updated read-across justification document have been addressed in Section 0.1 of this decision.

2.2. Assessment of the information provided

2.2.1. Weight of Evidence

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

41 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement (in this case, OECD TGs 421/422 require to investigate as key elements: 1) sexual function and fertility, 2) toxicity to offspring, and 3) systemic toxicity).

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

43 However, you have not submitted any explanation why the sources of information provide sufficient weight of evidence, and including adequate and reliable (concise) documentation

as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

44 Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the a weight of evidence adaptation, ECHA has assessed the available information according to the requirements of Annex XI 1.5 (grouping of substances and read-across) under Section 3.2.2, because you have provided experimental data with read-across source substances.

2.2.2. Read-across adaptation rejected

45 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.

46 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

47 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.

48 As the Substance is a solid the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1).

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

3. Hydrolysis as a function of pH

50 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

3.1. Information provided

51 You have provided two key studies:

(i) a hydrolysis study (1990) according to 84/449/EWG, EU Method C.10, with the Substance;

(ii) a hydrolysis study (2007) according to EU Method C.7/OECD TG 111 with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided studies do not meet the specifications of the test guideline

52 To fulfil the information requirement, a study must comply with OECD TG 111 (Article 13(3) of REACH). This TG is designed as a tiered approach and each tier is triggered by the results of the previous tier. Therefore, the following specifications must be met:

53 Preliminary test (Tier 1)

a) the test must be conducted at least in duplicate at 50± 0.5°C for 5 days;

54 Hydrolysis testing (Tier 2)

b) the test is required if more than 10 % hydrolysis occurs after 5 days in the preliminary test (Tier 1);

c) the test must be performed at the pH value(s) at which the test material was found unstable in the preliminary test (i.e. > 10 % hydrolysis in Tier 1 test);

55 Testing at pH values other than 4, 7, 9

d) additional tests at pH values other than 4, 7 and 9 may be required for a hydrolytically unstable test substance.

56 In studies (i) and (ii):

57 Preliminary test (Tier 1)

a) The test was not conducted in duplicates in study (i) and there is no information if the test was performed in duplicates in study (ii);

58 Tier 2

b) the preliminary test (Tier 1) indicates that > 10 % hydrolysis occurs after 5 days at pH 9;

c) hydrolysing testing (Tier 2) was not performed at pH 9 while the test material was found unstable in the preliminary test (Tier 1) at pH 9 (the Substance reached > 99% decomposition after 5 days at 50°C in study (i) and > 50% decomposition in 2.4 hours at 50°C in study (ii));

59 Testing at pH values other than 4, 7, 9

d) The studies provided indicate substantial hydrolytical degradation of the Substance in alkaline pH. At pH 7 the determined half-life is 6 days at 25°C in study (i) and 161 hours at 25°C in study (ii). However, based on Tier 1 test results at pH 9 the half-life is estimated to be only < 1 day at 25°C in both studies. This indicates significant depletion of the Substance between pH 7 and 9 and implies hydrolytical instability of the Substance in alkaline pH. However, you have not considered testing hydrolysis at pH values other than 4, 7 and 9.

60 In your comments to the draft decision you explain the mechanism of the dyeing reaction according to the literature and knowledge of "common industrial dyeing process". You mention that the Substance is fully hydrolysed in this process and as such is released in the environment. Based on that, you mention that carrying out further testing of the hydrolysis behaviour of the Substance would not lead to the new knowledge of the environmental hazard.

61 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results, specifically:

- The hydrolysis was not investigated at pH 9 (Tier 2 test was not performed for pH 9 in any of the studies);
- You have further not investigated the hydrolysis behaviour of the Substance between pH 7 and 9. An abrupt change of the hydrolytical behaviour is expected for the Substance between pH 7 and 9. This pH range is relevant both for the environmental assessment and for the interpretation of ecotoxicological tests. The pH of wastewater or sewage water is typically between 6–8 but can reach 8.5, implying that the Substance may be hydrolysed in the wastewater or sewage water before it reaches the environment[2]. Test guidelines for aquatic toxicity tests

[2] The pH of domestic wastewater is typically between 6–8 but is largely related to the alkalinity of the carriage water. In areas having soft water (alkalinity between 50 and 100 mg/L as $CaCO_3$), the pH of domestic wastewater is around 6.0 to 6.5. In areas having moderately hard water (alkalinity between 100 and 300 mg/L

tolerate pH of up to 8.5 and even beyond for some of them. Therefore, investigating further the hydrolysis behaviour of the Substance between pH 7 and 8.5 is necessary for the environmental risk assessment of the Substance and for interpreting the results of the ecotoxicity tests.

- Regarding your claim in the comments on the draft decision that testing at such pH would not result in new knowledge, the OECD TG does not provide for any exception. Further, you refer to information on use, which is irrelevant for the investigation of intrinsic properties, as is the case here, except in the case of exposure-based adaptation under Annex XI, Section 3, which you have not submitted. In any case, your claim is based on generic considerations (literature and knowledge), rather than being substantiated on the basis of your registration dossier, in particular on the basis of a rigorous exposure assessment.
- The objective of this test is to investigate an intrinsic property, hydrolysis, in pH that may be relevant for the environment, including in waste treatment. It is in light of this objective that this decision discusses pH in sewage water, i.e. in light of the objective of the OECD TG for hydrolysis. However, your claim in the comments on the draft decision that testing at such pH would not result in new knowledge is a use consideration specific to your Substance which must be assessed on the basis of and rejected on the basis of the considerations set above.

62 On this basis, the specifications of OECD TG 111 are not met.

63 Therefore, the information requirement is not fulfilled.

3.3. Study design

64 As explained above, the hydrolysis test must be performed under slightly alkaline conditions at pH values between 7 and 8.5 and at least at pH values of 8 and 8.5.

as $CaCO_3$) it is between 7.0 and 8.0. In areas having hard water (alkalinity higher than 300 mg/L as $CaCO_3$) it is between 7.5 and 9.0. Some industrial wastewaters can be quite acidic or alkaline. The optimum pH range for aerobic biodegradation lies between 6.5 and 8.5. Any wastewater beyond that range would need to be neutralised by the operator of the wastewater treatment system.

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 08 August 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 information on *in vitro* gene mutation in mammalian cells included in your registration dossier is considered compliant. The request for a study on *in vitro* gene mutation in mammalian cells was included in the initial draft decision due to an administrative mistake. This request has now been removed.

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(s) 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[3].

(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.

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

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).