~~Confidential~~

Helsinki, 09 June 2023

Addressee(s)
Registrants of SAS-Registration as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08/01/2019

Registered substance subject to this decision ("the Substance")
Substance name: Sulfonic acids, C14-17-sec-alkane, sodium salts
EC/List number: 307-055-2

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 ***14 September 2026***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.)

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

ii. only if the in *vitro/in chemico* test methods specified under point i.) 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);

2. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test OECD TG 471 (2020)) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102

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

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

4. *In vitro* micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional control group for aneugenicity on top of the control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei

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

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

6. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

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

7. Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit or rat)

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 related to the information under Annex VII of REACH

1. Skin sensitisation

1 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

2 You have provided:

(i) an *in vivo* skin sensitisation study (1974) with the Substance;

(ii) an *in vivo* skin sensitisation study (1986) 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 studies do not meet the specifications of the test guideline(s)

3 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;
c) positive controls is included to establish the sensitivity and reliability of the experimental technique;
d) a justification for the concentration selected, including the results of a dose-range finding study.

4 In studies (i and ii):

a) for study (i) it was not reported whether intradermal induction caused mild-to-moderate irritation and what was the actual concentration used for induction. For study (ii) you have not provided information on the dose range findings studies to substantiate your claim that the concentrations used for induction (intradermal and topical) cause mild-to-moderate irritation;
b) and d) in the studies (i and ii) you have not provided any information from the results of the dose range finding studies to substantiate your claim that the concentrations used in the challenge was the highest non-irritant dose in topical application;
c) no information on positive control group were provided.

5 The information provided does not cover the specifications(s) required by OECD TG 406 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

1.2.2. No assessment of potency

6 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).

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

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

1.3. Specification of the study design

9 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.

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

2. *In vitro* gene mutation study in bacteria

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

2.1. Information provided

12 You have provided:

(i) an *in vitro* gene mutation study in bacteria (1977) with the Substance;

2.2. Assessment of the information provided

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

13 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) 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).

14 In study (i):

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

15 The information provided does not cover the specification(s) required by the OECD TG 471.

16 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

17 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

19 You have provided:

(i) Growth inhibition study on algae (1995) with the Substance;

(ii) Growth inhibition study on algae (1992) 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(s)

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

21 Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;
b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
c) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata / Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%;

22 Technical specifications impacting the sensitivity/reliability of the test

e) for *Desmodesmus subspicatus* the initial cell density is 2-5 x10^3 cells/mL;
f) the pH of the control medium does not increase by > 1.5 units;

23 Characterisation of exposure

g) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
h) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test;
i) if the concentration of the test material has not been maintained within ±20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations

during exposure or on a model describing the decline of the concentration of the test material over the exposure period.

24 In study (i):

Validity criteria

a) exponential growth in the control cultures was not provided nor raw data in the registration dossier;
b) the biomass at the start of the test was 10^4 cells/mL but no information on the biomass at the end of the test is reported;
c) the mean coefficient of variation for section-by-section specific growth in the control was not provided nor raw data in the registration dossier;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was not provided nor raw data in the registration dossier.

25 Technical specifications impacting the sensitivity/reliability of the test

e) the test was conducted on *Desmodesmus subspicatus* and the initial cell density was 10^4 cells/mL;
f) the pH increase in the controls was 2.4 units.

26 Based on the above,

- the validity criteria of OECD TG 201 are not met;
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the initial cell density is higher than that required in the OECD TG 201, this can affect the exponential growth throught the incubation period due to the risk of nutrient depletion; the pH during the study increased more than the acceptable value reported in the OECD TG 201 in the control medium, this can impact on the growth in the control and therefore on the obtained toxicity values.

27 In study (ii):

28 Validity criteria

a) exponential growth in the control cultures was not proved over the entire duration of the test as only mean cells density at the start and the end of the test was reported;
b) the biomass at the start and end of the test was 2 $x10^4$ cells/mL and 6.4 $x10^5$ cells/mL, respectively. This correspond to a 32-fold increase;
c) the mean coefficient of variation for section-by-section specific growth in the control was not provided nor raw data in the registration dossier;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was not provided nor raw data in the registration dossier.

29 Technical specifications impacting the sensitivity/reliability of the test

e) the test was conducted on *Desmodesmus subspicatus* and the initial cell density was 2 $x10^4$ cells/mL.

30 Characterisation of exposure

g) no analytical monitoring of exposure was conducted;
h) and i) You have expressed the effect values based on nominal concentrations. The concentrations of the test material were not proved to be within ± 20 % of nominal concentrations throughout the test.

31 Based on the above,

- the validity criteria of OECD TG 201 are not met
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no analytical measurements have been conducted, therefore it is not possible to verify that the exposure of tested organisms to the Substance has been maintained through the study; the initial cell density is higher than that required in the OECD TG 201, this can affect the exponential growth through the incubation period due to the risk of nutrient depletion.

32 On this basis, the specifications of OECD TG 201 are not met.

33 Therefore, the information requirement is not fulfilled.

3.3. Study design and test specifications

34 The Substance is difficult to test due to the surface tension lower than 60 mN/m. OECD TG 201 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.

35 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

36 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (*i.e.* loading rate) and in a consistent manner.

Reasons related to the information under Annex VIII of REACH

4. *In vitro* micronucleus study

37 An in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

4.1. Information provided

38 You have adapted this information requirement by using Annex VIII, Section 8.4., Column 2. To support the adaptation, you have provided the following information:

(i) In vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus with the Substance (1978)

(ii) In vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus with the Substance (1975)

4.2. Assessment of the information provided

4.2.1. The provided adaptation does not meet the criteria of Annex VIII, Section 8.4., Column 2

39 Under Annex VIII, Section 8.4., Column 2, the study usually does not need to be conducted "if adequate data from an in vivo cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the in vivo somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to the OECD TG 474 or 475, respectively.

40 For the data from an in vivo somatic cell cytogenicity test to be considered adequate, the in vivo study you submitted has to meet the requirements of the OECD TG 474. Therefore, the following specifications must be met:

a) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes are reported for each group of animals;

b) a clear negative outcome is concluded when the data available shows that bone marrow exposure to the Substance or its metabolite(s) occurred;

41 In studies (i) and (ii):

a) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes were not reported for each group of animals;

b) you did not demonstrate that bone marrow exposure to the Substance, or its metabolite(s), occurred.

42 The information provided does not cover the specification(s) required by the OECD TG 474.

43 Based on the above, your adaptation is rejected.

44 Therefore, the information requirement is not fulfilled.

4.3. Specification of the study design

45 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the in vitro mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the in vitro mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations in vitro. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2).Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential in vitro.Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

4.3.1. Assessment of aneugenicity potential

46 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

47 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

Reasons related to the information under Annex IX of REACH

5. Pre-natal developmental toxicity study in one species

48 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

5.1. Information provided

49 You have provided:

(i) a developmental toxicity study in rats (1978) with the Substance.

5.2. Assessment of the information provided

To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

- pregnancy is terminated one day prior to the expected day of delivery and the foetuses removed by caesarian section.

50 The study (i) has been conducted as a non-guideline developmental toxicity study.

51 In study (i) it has not been reported when and how pregnancies were terminated.

52 The information provided does not cover the specification(s) required by the OECD TG 414.

53 On this basis, the study is not adequate for the information requirement.

54 Therefore, the data provided do not have adequate and reliable coverage of the key parameters of the OECD TG 414.

55 Based on the above, the adaptation is rejected.

56 Therefore, the information requirement is not fulfilled.

5.3. Specification of the study design

57 A PNDT study according to the test method OECD TG 414 should be performed in rats or rabbits as preferred species.

58 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex IX, Section 8.7.2., Column 1).

59 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

6. Long-term toxicity testing on fish

60 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

6.1. Information provided

61 You have provided:

(i) a long-term toxicity study on fish (1995) with the Substance;

6.2. Assessment of the information provided

6.2.1. The OECD TG 204 is not a valid test guideline to meet this information requirement

62 To fulfil the information requirement, a study must be a long-term fish test. Guidance on IRs and CSA, Section R.7.8.4.1. specifies that only studies in which sensitive life-stages (juveniles, eggs and larvae) are exposed can be regarded as long-term fish tests.

63 Your registration dossier provides an OECD TG 204 study in which only juveniles were exposed to the test material.

64 This study does not provide information on the toxicity of the test material to all relevant sensitive life-stages (i.e. juveniles, eggs and larvae). OECD TG 204 only provides information on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test. Therefore, this information is rejected.

65 Therefore, the information requirement is not fulfilled.

6.3. Study design and test specifications

66 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under request 3.3.

Reasons related to the information under Annex X of REACH

7. Pre-natal developmental toxicity study in a second species

67 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X, Section 8.7.2.

7.1. Information provided

68 ECHA understands that you have adapted this information requirement by using Annex X, Section 8.7., Column 2. To support the adaptation, you have provided the following information:

(i) *"based on the available data from reproductive /developmental and repeated dose toxicity studies and from the available data presented in the IUCLID 6 section toxickinetics, metabolism and distribution, the test for developmental toxicity in second species is scientifically not warranted"*;

(ii) a developmental toxicity study in rats (1978) with the Substance.

7.2. Assessment of the information provided

7.2.1. Criteria for the application of the adaptation for Annex X, Section 8.7., Column 2 not met

69 Under Annex X, Section 8.7., Column 2, the study does not need to be conducted if the following criteria are met:

- the substance is of low toxicological activity, demonstrated by a comprehensive and informative dataset showing no toxicity in any of the tests available; and
- that there is no or no significant human exposure.

70 The study (ii) is a non-guideline, non-GLP study with severe deficiencies related to pre-natal developmental effects as described above in request 5. Furthermore, results from the study indicate lower body weight gain and a slight depression of viability index in pups exposed to the Substance.

71 The uses of the Substance include widespread professional uses (including PROCS 10, 11) and consumer uses.

72 The study (ii) shows evidence of toxicity.

73 The uses of the Substance indicate that here is human exposure which you have not addressed. For several exposure scenarios RCRs are above 0.5.

74 On this basis, you have not demonstrated that the criteria for this adaptation are fulfilled.

75 Based on the above, your adaptation is rejected.

76 Therefore, the information requirement is not fulfilled.

7.3. Specification of the study design

77 A PNDT study according to the test method OECD TG 414 should be performed in rabbit or rat as preferred second species, depending on the species tested in the first PNDT study (request 5 in this decision).

78 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex X, Section 8.7.2., Column 1).

79 Based on the above, the study must be conducted in rabbits or rats with oral administration of the Substance.

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 03 August 2022.

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

ECHA did not receive any comments within the commenting period.

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[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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification

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

and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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).