

Helsinki, 12 October 2023

**Addressee**

Registrant of LAPHS\_JS as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**

25 February 2021

**Registered substance subject to this decision ("the Substance")**

Substance name: (2-hydroxy-3-sulphopropyl)dimethyl[3-[(1-oxododecyl)amino]propyl]ammonium hydroxide

EC/List number: 242-893-1

**Decision number:** Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)**DECISION ON A COMPLIANCE CHECK**

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **20 October 2025**.

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).
  
2. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471).

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

3. *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.
  
4. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490).

5. Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below.
6. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats.

The reasons for the requests are explained in Appendix 1.

### **Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

### **How to comply with your information requirements**

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

### **Appeal**

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

### **Failure to comply**

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

Authorised<sup>1</sup> 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

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<sup>1</sup> 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)**

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## 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.:
- Skin sensitisation (Annex VII, Section 8.3.)
  - *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.)
  - *In vitro* micronucleus study (Annex VIII, Section 8.4.2.)
  - *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
  - Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.)
  - 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 13.2.
- 6 You predict the properties of the Substance from information obtained from the following source substance(s):
- 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8- 18(even numbered) acyl) derivs., hydroxides, inner salt, List 939-455-3 (source substance 1).
- 7 You provide the following reasoning for the prediction of toxicological properties:
- *"The read-across is based on the hypothesis that the source and target substances have toxicological [...] properties likely to be similar (i.e. analogue approach = different compounds having qualitatively similar properties) as a result of structural similarity due to common functional groups, common precursors, likelihood of common breakdown products, and a constant pattern in the changing of the potency of the properties between substances."*
  - *"Other constituents of the source substance, not represented in the target substance (short and long C chain sultaines, i.e. C8, C10, C14, C16 and C18 and corresponding breakdown products) are not expected to display significantly different toxicokinetic or toxicological properties than the main constituent (C12)."*
  - *"Should the short and long C-chain constituents be associated with a significant toxicity, this would be taken into account in the classification and labelling or the"*

*risk assessment, as a worst-case for the target substance resulting from the read-across based on the target substance data."*

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 based on a worst-case approach.

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

9 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.).

10 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source 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).

11 Regarding the prediction for the information requirements listed above, you have only provided studies with the source substance 1. Only exception is skin sensitisation as you have provided a GPMT study with the source substance 1 and also included as a supporting data a human repeated insult patch test (HRIPT) on the Substance as a supporting data.

12 Specific reasons why the provided HRIPT with the Substance cannot be considered reliable for the hazard identification are explained further below under the request 1.

13 Apart from the HRIPT with the Substance, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects in studies required for the information requirements listed above.

14 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.

*0.1.1.2. Missing supporting information to substantiate worst-case consideration*

15 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.).

16 As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the

source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the source substance(s).

- 17 For the source substance 1, in your registration dossier you have provided studies used in the prediction for the hazards examined in the studies required for the information requirements listed above. Apart from these studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm a conservative prediction of the properties of the Substance taking into account the differences in the alkyl chain lengths in the source substance 1 (C8, C10, C12, C14, C16 and C18) and in the Substance (only C12).
- 18 In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

*0.1.2. Conclusion*

- 19 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

20 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

21 You have provided:

(i) a human repeat insult patch test (HRIPT) (2009) with the Substance

22 In addition, 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:

(ii) a Guinea Pig Maximisation Test (1988) with the source substance 1, List 939-455-3.

#### 1.2. Assessment of the information provided

##### 1.2.1. Assessment whether the Substance causes skin sensitisation

###### 1.2.1.1. Adequacy of the provided study (i) for hazard identification

23 A study must be adequate for the corresponding information requirement. According to the Guidance on IRs and CSA, Section R.4. (page 1), "The evaluation of data quality includes assessment of adequacy of the information for hazard/risk assessment and C&L purposes". The Guidance on IRs and CSA, Section R.4. (page 1) defines adequacy as "the usefulness of data for hazard/risk assessment purposes". As a consequence, a study must be relevant for hazard assessment and for classification and labelling purposes.

24 You have provided a study (i) according to the Human Repeat Insult Patch Test (HRIPT) and you consider that the Substance is not a skin sensitiser. ECHA understands that the study has been performed for a safety assessment by testing a ■% aqueous solution of ■ (a commercial product containing the Substance used e.g. in personal care products) in healthy human volunteers.

25 The study (i) appears to have been designed to establish safe levels for specific intended uses in personal care products, rather than to investigate the intrinsic properties of the Substance as required for the purpose of hazard identification. In particular, the dose level used in this study is far lower (i.e. ■% concentration) than the doses expected to be used for hazard assessment purposes, as the method (HRIPT) is only intended to confirm the absence of irritation and sensitisation potential under specific uses.

26 Therefore, the study (i) is rejected.

###### 1.2.1.2. Read-across adaptation rejected

27 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.

28 On this basis, the information provided in study (ii) does not contribute to the assessment whether the Substance causes skin sensitisation.

###### 1.2.2. No assessment of potency

29 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).

30 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.

31 Therefore, the information requirement is not fulfilled.

### *1.3. Study design*

32 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 sensitizer (Cat 1A or 1B) is warranted.

33 In case no conclusion on the skin sensitisation potency can be made for the Substance based the 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**

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

### *2.1. Information provided*

35 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) an *in vitro* gene mutation study in bacteria (1997) with the source substance 1, List 939-455-3.

### *2.2. Assessment of the information provided*

#### *2.2.1. Read-across adaptation rejected*

36 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. In addition, ECHA identified endpoint-specific issue addressed below.

#### *2.2.1.1. Inadequate or unreliable study (i) on the source substance*

37 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 471. 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);
- b) at least 5 doses are evaluated, in each test condition;



- c) a concurrent negative control is included in each assay and the number of revertant colonies per plate for the concurrent negative control is inside the historical control range of the laboratory;
- d) negative results are confirmed in a repeat experiment with modification of study parameters to extend the range of conditions assessed, or a justification why confirmation of negative results is not considered necessary is provided.

38 In study (i):

- a) the test was performed with *S. typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 and TA 1538 (i.e., *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) strain is missing);
- b) Only 3 and 4 doses were evaluated in absence and in presence of metabolic activation (i.e., less than 5 doses) in experiments 1 and 2, respectively;
- c) you have not reported whether the number of revertant colonies per plate for the concurrent negative control was inside the historical control range of the laboratory;
- d) no repeat experiment was performed to confirm the negative results and no justification was provided.

39 Therefore, the study (i) submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) required by the OECD TG 471.

40 Therefore, the information requirement is not fulfilled.

## Reasons related to the information under Annex VIII of REACH

### 3. *In vitro* micronucleus study

41 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.

#### 3.1. *Information provided*

42 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) an *in vitro* cytogenicity study in mammalian cells (2012) with the source substance 1, List 939-455-3.

#### 3.2. *Assessment of the information provided*

##### 3.2.1. *Read-across adaptation rejected*

43 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.

44 Therefore, the information requirement is not fulfilled.

#### 3.3. *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).

##### 3.3.1. *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).

### 4. *In vitro* gene mutation study in mammalian cells

48 An in vitro gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the in vitro gene mutation test in bacteria and the in vitro cytogenicity test.

*4.1. Triggering of the information requirement*

49 Your dossier contains an adaptation for an in vitro gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study.

50 The information for the in vitro gene mutation study in bacteria and for the in vitro cytogenicity study in mammalian cells provided in the dossier are rejected for the reasons provided in requests 2 and 3.

51 The result of the requests for an in vitro gene mutation study in bacteria and for an in vitro micronucleus study will determine whether the present requirement for an in vitro mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3. is triggered.

52 Consequently, you are required to provide information for this information requirement, if the in vitro gene mutation study in bacteria and the in vitro micronucleus study provides a negative result.

*4.2. Information provided*

53 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) an *in vitro* gene mutation study in mammalian cells (2012) with the source substance 1, List 939-455-3.

*4.3. Assessment of the information provided*

*4.3.1. Read-across adaptation rejected*

54 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.

55 Therefore, the information requirement is not fulfilled.

*4.4. Study design*

56 To fulfil the information requirement for the Substance, either the in vitro mammalian cell gene mutation tests using the *hprt* and *xprt* genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

**5. Short-term repeated dose toxicity (28 days)**

57 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

*5.1. Information provided*

58 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 reproduction/developmental toxicity screening test (2012) with the source substance 1, List 939-455-3;
- (ii) a sub-chronic repeated dose toxicity study (2019) with the source substance 1, List 939-455-3.

### 5.2. *Assessment of the information provided*

#### 5.2.1. *Read-across adaptation rejected*

59 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.

60 Therefore, the information requirement is not fulfilled.

### 5.3. *Study design*

61 When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

62 The study design is addressed in request 6.

## **6. Screening study for reproductive/developmental toxicity**

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

### 6.1. *Information provided*

64 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 reproduction/developmental toxicity screening test (2012) with the source substance 1, List 939-455-3.

### 6.2. *Assessment of the information provided*

#### 6.2.1. *Read-across adaptation rejected*

65 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.

66 Therefore, the information requirement is not fulfilled.

### 6.1. *Study design*

67 When there is no information available neither for the 28-day repeated dose toxicity study (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

- 68 The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 5.
- 69 Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats.
- 70 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).
- 71 Therefore, the study must be conducted in 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 (2023).

**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 22 February 2023.

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

ECHA did not receive any comments within the commenting period.

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

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

**Appendix 3: Addressee of this decision and their corresponding information requirements**

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

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

<b>Registrant Name</b>	<b>Registration number</b>	<b>Highest REACH Annex applicable to you</b>

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 (<https://echa.europa.eu/practical-guides>).

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

#### **1.2 Test material**

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (<https://echa.europa.eu/manuals>).