~~Confidential~~

Helsinki, 19 October 2022

**Addressees**
Registrant(s) of Salibact_EC_813-944-0 as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
21/02/2021

**Registered substance subject to this decision ("the Substance")**
Substance name: N,N'-bis{N-[N-(4-chlorophenyl)carbamimidoyl]carbamimidoyl}hexane-1,6-bis(aminium) diundec-10-enoate
EC number: 813-944-0

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

## DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***28 October 2024***.

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

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

1. Surface tension (Annex VII, Section 7.6.; test method: EU A.5./OECD TG 115)

2. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29)

3. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method)

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

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

6. If the substance is not poorly water soluble according to request 2., Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202) OR

7. If the substance is poorly water soluble according to request 2., Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

The reasons for the decision(s) are explained in Appendix 1.

**Information required depends on your tonnage band**

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

You are only required to share the costs of information that you must submit to fulfil your information requirements.

**How to comply with your information requirements**

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

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

**Appeal**

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

**Failure to comply**

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

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
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 decision

### Contents

## 0. Reasons common to several requests

### *0.1. Assessment of information for short-term toxicity testing on invertebrates, and for toxicity testing on aquatic plants*

1 This section addresses information provided for the following standard information requirements:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

2 Under Sections 9.1.1 and 9.1.2., Column 2, Annex VII to REACH, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water or the substance is unlikely to cross biological membranes. Guidance on IRs and CSA, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely. Therefore, the justification must demonstrate very low water solubility and low likelihood to cross biological membranes. For the latter, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* $D_{max}$ > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log $K_{ow}$ > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

3 Unless it can reliably be demonstrated that aquatic toxicity is unlikely to occur, the Substance must be considered as poorly water soluble.

4 Your registration dossier provides:

- an adaptation based on Sections 9.1.1 and 9.1.2., Column 2, first indent, Annex VII to REACH with the following justifications under 6.1.3 "*Salibact is highly insoluble in water, therefore toxicitty is unlikely to occur*" and under 6.1.5 "*The solubility of Salt of chlorhexidine and undec-10-enoic acid (1:2) commercially known as salibact is quite low, therefore the aquatic toxicity is unlikely to occur*"

5 The following contradicts your justification:

- As explained under sections 2 and 3 below, there is no adequate information provided on solubility in water and octanol-water partitioning coefficient (Kow) of the Substance in the registration dossier;
- there is no supporting experimental evidence (e.g. from chronic ecotoxicity studies etc.) of hindered uptake.

6 Therefore, you have not demonstrated that aquatic toxicity is unlikely to occur and your adaptation is rejected.

### *0.2. Assessment of the read-across approach*

7 In the registration dossier you have provided information derived from experimental data from a group of substances using the OECD QSAR Toolbox and flagged the information as QSAR. As the group of substances are used as source substances to predict the property of the Substance, we understand that you have adapted the standard information

requirements under Annex XI, Section 1.5 of REACH (grouping and read-across) for the following standard information requirements:

- Surface tension
- Partitioning coefficient

8 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.

9 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. 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).

*0.2.1. Scope of the grouping of substances (category)*

10 You predict the surface tension of the Substance from information obtained from the following source substance(s):

1) Chlorhexidine (CAS No 55-56-1);
2) Caprylic acid (CAS No 124-07-2);
3) Nonanoic acid (CAS No 112-05-0);
4) Decanoic acid (CAS No 334-48-5);
5) Hexadecanoic acid (CAS No 57-10-3).

11 You predict octanol-water partitioning coefficient (Kow) of the Substance from information obtained from the following source substance(s):

1) Docosanoic acid (CAS No 112-85-6);
2) Arachidic acid (CAS No 506-30-9);
3) Undecanoic acid (CAS No 112-37-8);
4) Hexadecanoic acid (CAS No 57-10-3);
5) Myristic acid (CAS 544-63-8).

12 There is no justification for the grouping of the substances provided.

13 You define the applicability domain as:

14 - for the surface tension: the group of substances by molecular weight which is from 144 to 505 Da;

15 - for the Kow: the group of substances by molecular weight which is from 186 to 341 Da.

16 We have identified the following issue(s) with the proposed scope of the grouping:

*0.2.2. Applicability domain of the category*

17 A category (grouping) hypothesis should address "the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint" (Guidance on IRs and CSA, Section R.6.2.4.1.). Particularly, "the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the

(sub)category members" (Guidance on IRs and CSA, Section R.6.2.1.2.). Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

18 Furthermore, ECHA Guidance, R.7a, Section R.7.1.6 explains that "For the determination of the surface tension read-across is usually not possible. However interpolation may still be possible within homologous series.". Similarly, Section R.7.1.8 explains that "For the determination of the partition coefficient n-octanol/water read-across is usually not possible. However interpolation may still be possible within homologous series."

*0.2.2.1. Surface tension*

19 The predicted value of surface tension of the Substance is 66.4 mN/m while surface tension values of source substances are from 28.2 to 50 mN/m.

20 The Substance is the organic salt which is derivative of chlorhexidine (base) and of undec-10-enoic acid. None of the source substances is an organic salt, so cannot be a member of the homologous series, i.e. a sequence of substances with the same functional group and similar chemical properties in which the members of the series can differ by some specific structural feature, e.g. one carbon atom in the carbon chain, to which the Substance would belong to.

21 The value of the surface tension of the Substance predicted by you is outside of the range of values of surface tension of the source substances, i.e. you predict the surface tension of the Substance by extrapolation and not by interpolation from values of the source substances. Furthermore, you report molecular weight of the Substance to be 874 Da and note that the Substance "is out of domain" defined for the group of substances from which you read-across to the Substance. ECHA agrees with your assessment and conclusion that the substance is outside of the applicability domain of the group (category) as defined by you.

22 Therefore, the predicted value of the surface tension is not reliable.

*0.2.2.2. Octanol-water partitioning coefficient*

23 The Substance is the organic salt which is derivative of chlorhexidine (base) and of undec-10-enoic acid. None of the source substances is an organic salt, so cannot be a member of the homologous series, i.e. a sequence of substances with the same functional group and similar chemical properties in which the members of the series can differ by some specific structural feature, e.g. one carbon atom in the carbon chain, to which the Substance would belong to.

24 You report molecular weight of the Substance to be 874 Da and note that the Substance "is out of domain" defined for the group of substances from which you read-across to the Substance. ECHA agrees with your assessment and conclusion that the substance is outside of the applicability domain of the group (category) as defined by you.

25 Therefore, predicted value of Kow is not reliable.

*0.2.3. Conclusion on read-across*

26 For the reasons above, you have not established that relevant properties of the Substance, i.e. surface tension and Kow, 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. Surface tension

27 Surface tension of an aqueous solution is a standard information requirement in Annex VII to REACH (Section 7.6.).

### *1.1. Information provided*

28 You have provided the following information:

29 - an adaptation under Section 7.6., Column 2 of Annex VII with the following justification: 'the study does not need to be conducted because surface activity is not a desired property of the material with the justification that "The determination of surface tension is much more difficult for solids than for liquids. Based on the structure of Salt of chlorhexidine and undec-10-enoic acid (1:2) commercially known as salibact, the substance is a solid, thus the determination of surface tension is not a desired property of the substance.". In this regard, you have submitted supporting publication, i.e. 'scientific paper about the surface tension on solids'.

30 - information derived from experimental data from a group of substances using the OECD QSAR Toolbox. As the group of substances are used as source substances to predict the property of the Substance, we understand that you have adapted the standard information requirements under Annex XI, Section 1.5 of REACH (grouping and read-across).

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

31 We have assessed this information and identified the following issues:

#### *1.2.1. Assessment of adaptation under Section 7.6., Column 2 of Annex VII*

32 Under Section 7.6., Column 2, first indent, Annexes VII to REACH, the study needs only to be conducted if based on structure, surface activity is expected or can be predicted.

33 ECHA Guidance, R.7a, Section R.7.1.6 explains that "The surface tension of an aqueous solution of a substance can be used to determine whether the substance is surface active. Surface active substance (surfactant):"Surfactant' means any organic substance and/or preparation [mixture]used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces'(see Article 2(6) of Council Regulation (EC) No 648/2004)."

34 Based on the information provided in the registration dossier the Substance is an organic salt which contains potentially hydrophobic chlorinated aromatic rings and unsaturated relatively long carbon chains and potentially hydrophilic ionised amine and/or carboxyl groups. Thus, the chemical structure of the Substance indicates the potential to reduce the surface tension of the water, i.e. has the potential of a surface-active property, and you have not explained in your justification of the adaptation why presence of potentially hydrophobic and hydrophylic groups in the structure of the Substance would not result in the reduction of the surface tension of the water.

35 Furthermore, the supporting publication discusses the surface tension of the solids in their

natural state while the standard information requirement is for the surface tension of an aqueous solution of a substance (this is explained in ECHA Guidance, R.7a, Section R.7.1.6). Therefore, the provided supporting publication is not relevant to this information requirement and cannot support your adaptation.

36 Therefore, your adaptation is rejected.

*1.2.2. Assessment of adaptation under Annex XI, Section 1.5*

37 As explained under section 0.2. above, your adaptation is rejected.

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

39 To fulfil the information requirement, a study must comply with OECD TG 115 (Article 13(3) of REACH).

## 2. Water solubility

40 Water solubility is a standard information requirement in Annex VII to REACH (Section 7.7.).

*2.1. Information provided*

41 You have provided the following information:

42 - Non-standard guideline key study (study period: 2018) for which you note that ”The guideline was followed as the solubility practice at "[redacted]". The solubility study is conducted by using over 20 different solvent media.”

43 - Supporting study (study period: 2016), you claim the study to be ‘equivalent or similar’ to OECD TG 105 and in the attached document you refer to the water solubility measurements by reverse osmosis during preparatory stage of ‘Bacterial Reverse Mutation Assay’

*2.2. Assessment of the information provided*

44 We have assessed this information and identified the following issue:

45 To fulfil the information requirement, a study must comply with OECD TG 105 (Article 13(3) of REACH). Therefore, the following specifications must be met:

The following must be reported:
- the results of the preliminary test,
- precise specification of the substance (identity and impurities),
- the individual analytical determinations and the average where more than one value was determined for each flask,
- the pH of each sample,
- the average of the value for the different flasks which were in agreement,
- the test temperature,
- the analytical method employed,
- all information relevant for the interpretation of the results, especially with regard to impurities and physical state of the substance.

46 The provided studies do not meet the information requirement:

- Key study: the method used did not follow an accepted guideline and none of the

above listed reporting requirements of the standard TG 105 have been met.

- Supporting study: the study report lacks details on test conditions, the procedure, design as well as the detailed results but only provides the following summary: *'As mentioned in the above table, solubility of test item was checked in reverse osmosis water and found insoluble.'*

47 Based on the above, it is not sufficient to conduct an independent assessment of the reliability of the provided studies.

48 Therefore, the requirements of OECD TG 105 are not met.

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

## 3. Partition coefficient n-octanol/water

50 Partition coefficient n-octanol/water is a standard information requirement in Annex VII to REACH (Section 7.8)

### *3.1. Information provided*

51 You have provided following information:

- information derived from experimental data from a group of substances using the OECD QSAR Toolbox and flagged the information as QSAR. As the group of substances are used as source substances to predict the property of the Substance, we understand that you have adapted the standard information requirements under Annex XI, Section 1.5 of REACH (grouping and read-across).

#### *3.1.1. Assessment of adaptation under Annex XI, Section 1.5*

52 As explained under section 0.2. above, your adaptation is rejected.

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

## 4. In vitro gene mutation study in bacteria

54 In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020).

### *4.1. Information provided*

55 You have provided:

i. An *in vitro* gene mutation study in bacteria (2016) with the Substance

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

56 We have assessed this information and identified the following issue(s):

#### *4.2.1. The provided study does not meet the information requirement*

57 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 maximum dose tested induces a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test dose corresponds to 5 mg/plate or 5 µl/plate

58 The study (i) is described as an in vitro gene mutation study on bacteria.

59 However, the following specifications are not according to the requirements of the OECD TG 471:

a) the maximum dose tested did not induce a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance and it was less than 5 mg/plate or 5 ml/plate.

60 The information provided does not cover the key parameter(s) required by the OECD TG 471

61 Therefore, the information requirement is not fulfilled.

On this basis, the information requirement is not fulfilled.

*4.3. Specification of the study design*

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

## 5. Growth inhibition study aquatic plants

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

*5.1. Information provided*

64 You have provided an adaptation under Annex VII, Section 9.1.2., Column 2 with the following justification: "The solubility of Salt of chlorhexidine and undec-10-enoic acid (1:2) commercially known as salibact is quite low, therefore the aquatic toxicity is unlikely to occur. This is also verified by the aquatic toxicity of Chlorhexidine, values indicated below: EC50 for freshwater algae:0.046 mg/L. EC10 or NOEC for freshwater algae: 0.017 mg/L".

*5.2. Assessment of the information provided*

65 We have assessed this information and identified the following issues:

*5.2.1. Rejection of an adaptation*

66 As explained under section 0.1 above, your adaptation is rejected.

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

*5.3. Study design and test specifications*

68 Water solubility, surface tension and octanol-water partitioning coefficient (Kow) determine if a substance is difficult to test or not. As explained under sections 1, 2 and 3 above no adequate information is provided on surface tension, solubility in water and octanol-water

partitioning coefficient (Kow) and new studies are requested for these endpoints. If the substance appears to be difficult to test after the information on the physico-chemical properties requested under sections 1-3 is provided then OECD TG 23 must be followed 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.

## 6. If the Substance is not poorly soluble according to 2. then Short-term toxicity testing on aquatic invertebrates

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

### *6.1. Information provided*

70 You have provided the following information:

- an adaptation under Annex VII, Section 9.1.2., Column 2 with the following justification: "The solubility of Salt of chlorhexidine and undec-10-enoic acid (1:2) commercially known as salibact is quite low, therefore the aquatic toxicity is unlikely to occur.";

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

71 We have assessed this information and identified the following issues:

#### *6.2.1. Rejection of an adaptation*

72 As explained under section 0.1 above, your adaptation under Annex VII, Section 9.1.2., Column 2 is rejected.

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

### *6.3. Study design and test specifications*

74 OECD TG 202 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance might be difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under section 5.3 above.

## 7. If the Substance is poorly soluble according to 2. then Long-term toxicity testing on aquatic invertebrates

75 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

76 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5). As explained under section 2 above, there is no adequate information on solubility of the Substance in water provided in the registration dossier. Therefore, if the Substance is poorly water soluble according to the study requested under request 2 the information on long-term toxicity on aquatic invertebrates must be provided at Annex VII.

7.1. *Information provided*

77 You have provided the following information:

- no information on the long-term toxicity to aquatic invertebrates.

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

7.2. *Study design and test specifications*

79 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As explained above, the Substance might be difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under section 5.3 above.

## 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).

All Guidance on REACH is 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 16 November 2021.

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.

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.

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

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

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

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

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

## 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

(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 and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance.

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

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