~~Confidential~~

Helsinki, 06 November 2023

**Addressee**
Registrant of JS_109236-76-2 as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
22 July 2020

**Registered substance subject to this decision ("the Substance")**
Substance name: docosanyl 4-hydroxybenzoate
EC/List number: 920-338-0

**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 ***13 November 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. 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).

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

4. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310)

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

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

## Appendix 1: Reasons for the request(s)

**Contents**

**Reasons common to several requests**

**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 adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following data:

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

(ii) a review article (2008) discussing "*Several tests with different Parabens*". The following source substances were tested: methylparaben (EC 202-785-7), ethylparaben (EC 204-399-4), propylparaben (EC 202-307-7), isopropylparaben, butylparaben (EC 202-318-7), isobutylparaben, and benzylparaben. ECHA understands that within the context of the review article, you also state that "...*by QSAR-calculations according to relevant models (QSAR-Toolbox 3.3) no alert for sensitization can be found*".

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

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

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

4 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

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

##### *1.2.1.1. Critical deficiencies affecting the weight of evidence adaptation.*

###### *1.2.1.1.1. Only one source of information provided (i.e., point (ii) above)*

6 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information based on which a conclusion on the information requirement can be drawn.

7 You have only provided one source of information.

*1.2.1.1.2. Lack of documentation justifying the weight of evidence adaptation*

8 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

9 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

*1.2.1.2. Reliability of the contribution of the sources of information: read-across rejected*

10 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.

11 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).

12 You have not provided a read-across justification document.

13 You predict the properties of the Substance from information obtained from the following source substances:

- Methylparaben, EC 202-785-7,
- Ethylparaben, EC 204-399-4,
- Propylparaben, EC 202-307-7,
- Isopropylparaben,
- Butylparaben, EC 202-318-7,
- Isobutylparaben,
- Benzylparaben.

14 You provide the following reasoning for the prediction of toxicological properties: "The structural similarity between the substance described in section 1 and the substance group in this review is obvious and significant. [...] The substance defined in section 1 has exactly the same structural components and functional groups (p-hydroxybenzoate, aliphatic chain) as the tested Parabens".

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

*1.2.1.2.1. Inadequate read-across hypothesis*

16 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from other substances

in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

17 Your read-across hypothesis is only based on the structural similarity between the source substances, which you consider a sufficient basis for predicting the properties of the Substance. However, your hypothesis does not explain why the structural differences between the substances do not influence the toxicological properties or do so in a regular pattern.

18 While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar toxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for toxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substances.

*1.2.1.2.2. Missing supporting information to compare the properties of the substances*

19 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 substances (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

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

21 For the source substances, you provide the review article (ii) used in the prediction in the registration dossier. Apart from that article, your registration dossier does not include any read-across justification, robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

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

*1.2.1.2.3. Missing robust study summaries*

23 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include robust study summary for each source study used in the adaptation.

24 Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

25 For the source of information (ii), you have provided only the name of the study, but you have not provided detailed information on the methods, results and conclusions of the studies referenced in the review article (ii). As such, you have failed to provide robust study summaries for each study covered by source of information (ii).

26 You have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of the studies. Therefore, you have failed to provide a robust study summary for each source study used in the adaptation as required by Annex XI, Section 1.5.

*1.2.1.3. Conclusion on the weight of evidence adaptation*

27 In summary, you provide one source of information (ii), which is a review article referencing several read-across studies with multiple source substances. For the reasons explained above, ECHA cannot determine whether these studies can reliably contribute to your weight-of-evidence adaptation.

28 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for 'skin sensitisation'.

29 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

*1.2.2. No assessment of potency*

30 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).

31 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.

*1.2.3. Comments to the draft decision and conclusion of the assessment*

32 In the comments to the draft decision, you agree to perform the requested OECD TG 442C, OECD TG 442D, and OECD TG 442E studies. You do not agree to perform the conditionally requested in vivo study (OECD TG 429) due to "*animal welfare and exposure considerations*". Animal welfare is not on its own a legal ground for adaptation under Annex VII Section 8.3 column 2 or the general rules of Annex XI. Regarding your reference to "*exposure considerations*", Annex XI Section 3 defines the criteria for adaptation based on the exposure scenario(s) developed in the Chemical Safety Report. Annex XI subsection 3.1 specifies that this adaptation possibility is only applicable for omitting testing in accordance with Annex VIII Section 8.6.1, Annex VIII Section 8.7 and in accordance with Annex IX and Annex X. As such, exposure based considerations under Annex XI Section 3 do not constitute an adaptation possibility for the information requirement under Annex VII Section 8.3.

33 Further, ECHA understands from your comments that if the criteria for an in vivo study are met (see 'Information required from all the Registrants subject to Annex VII of REACH' point 1.b), you intend to adapt this information requirement on the basis of Annex XI, Section 1.5. (read-across) of the REACH Regulation. As this strategy relies on a read-across approach that has not yet been fully described and justified (including bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

*1.3. Study design*

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

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

## 2. Long-term toxicity testing on aquatic invertebrates

36 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

### *2.1. Triggering of the information requirement*

37 In the provided OECD TG 105 (2020), the saturation concentration of the Substance in water was determined to be < 4 µg/L.

38 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

### *2.2. Information provided*

39 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance. Instead, you have provided the following justification for omitting the information on long-term toxicity on aquatic invertebrates for the Substance: "The substance is extremely insoluble (< 4 µg/l), so no adverse effects are expected. Furthermore, the substance was found to be biodegradable, although it failed the 10 d Window, probably due to the poor solubility".

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

#### *2.3.1. Your justification to omit the study has no legal basis*

40 A registrant may only adapt the information requirement on long-term toxicity on aquatic invertebrates based on the general rules set out in Annex XI.

41 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

42 Therefore, you have not demonstrated that this information can be omitted.

43 Therefore the information requirement is not fulfilled.

44 In the comments to the draft decision, you state that "*a long-term test can only be designed as a limit test with a saturated solution*". You then state that you "*agree to perform the chronic daphnia test as a limit test if necessary*". ECHA acknowledges your agreement to perform the requested study and notes that while a limit test are within the scope of the OECD TG 211 a justification for performing such a test must be provided.

45 ECHA also understands that you may intend to adapt this information requirement on the basis of Annex XI, section 2 or Annex XI, subsection 3(2)(b) or (c), of the REACH

Regulation. As this strategy relies on a adaptation that has not yet been fully described and justified (taking into the criteria described under Annex XI, subsection 3(2)(b) or (c)), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

### 2.4. Study design

46 The Substance is difficult to test due to the low water solubility (< 4 µg/L). OECD TG 211 specifies 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 211. 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.

## 3. Growth inhibition study aquatic plants

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

### *3.1. Information provided*

48 You have adapted this information requirement by using Column 2 of Annex VII, Section 9.1.2. To support the adaptation, you have provided following justification: "the substance is extremely insoluble in water".

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

#### *3.2.1. The provided adaptation does not meet the criteria of Annex VII, Section 9.1.2., Column 2*

49 Under Annex VII, Section 9.1.2., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. 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).

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

51 Your registration dossier provides information on the solubility of the Substance in water (< 4 µg/L based on an OECD TG 105 (2020) study).

52 Even though the water solubility of the Substance is low, you do not provide any 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).

53 Therefore, you have not demonstrated that toxicity is unlikely to occur and your adaptation is rejected and the Substance must be considered as poorly water soluble.

54 Therefore the information requirement is not fulfilled.

55 In the comments to the draft decision, you do not agree to perform the requested study. You consider that "*due to the very low solubility of the substance* […] *it is difficult to investigate the algae toxicity*". Furthermore, you state that "[a]*n analytical determination of real concentration is not possible*".

56 ECHA understands that you consider the studyas being not technically feasible. According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 201, more specifically on the technical limitations of a specific method, shall always be respected. As this strategy relies on a adaptation that has not yet been fully described and justified (including experimental evidence to justify the study cannot be conducted), no conclusion on the compliance of the proposed adaptation can be made.

57 In your comments, you also refer to an OECD TG 222 study conducted on an analogue substance with a 56d-NOEC you consider "*another indication of the very eco-toxicity of such compounds*".

58 However, ECHA notes that the use of this information to omit this information does not refers to any legal ground for adaptation under Annex XI to REACH or Annex VII, Section 9.1.2., Column 2 and the legal basis you are relying on is not apparent to ECHA.

59 Finally, ECHA also understands that you may intend to adapt this information requirement on the basis of Annex XI, section 2 or Annex XI, subsection 3(2)(b) or (c), of the REACH Regulation.

60 Annex XI Section 3 defines the criteria for adaptation based on the exposure scenario(s) developed in the Chemical Safety Report. Annex XI subsection 3.1 specifies that this adaptation possibility is only applicable for omitting testing in accordance with Annex VIII Section 8.6.1, Annex VIII Section 8.7 and in accordance with Annex IX and Annex X. As such, exposure based considerations under Annex XI Section 3 do not constitute an adaptation possibility for the information requirement under Annex VII Section 9.1.2.

### 3.3. Study design

61 OECD TG 201 specify 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" under request 3.

## 4. Ready biodegradability

62 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

### *4.1. Information provided*

63 You have provided an OECD 301B study (2009) with the Substance.

### *4.2. Assessment of information provided*

#### *4.2.1. The provided study does not meet the specifications of the test guideline*

64 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following specification(s) must be met:

*Reporting of the methodology and results*

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
b) the test temperature is reported;
c) the results of measurements at each sampling point in each replicate is reported in a tabular form;
d) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported.

65 In the provided study:

*Reporting of the methodology and results*

a) the concentration of the inoculum in the test and any pre-conditioning treatment is not reported;
b) the test temperature is not reported;
c) the results of measurements at each sampling point in each replicate is not reported;
d) the inorganic carbon content (IC) of the material suspension in the mineral medium at the beginning of the test is not reported.

66 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of their reliability. More specifically, as you have not provided the information listed under point a) to d), ECHA is not in a position to assess whether the validity criteria of the test guideline were met, whether the test conducted under conditions that are consistent with the requirement of the OECD TG 301B, and to assess the interpretation of the study results.

67 On this basis, the specification(s) of OECD TG 301B are not met.

68 Therefore, the information requirement is not fulfilled.

69 In the comments to the draft decision, you do not agree to perform the requested study. You indicate your intention to provide the missing information in a future update of your registration dossier. As the information in your comments is not sufficient for ECHA to make any assessment, no conclusion on the compliance can currently be made.You remain responsible for complying with this decision by the set deadline.

### *4.3. Study design and test specification*

70 To fulfil the information requirement, the test method(s) according to OECD TG 301B/C/D/F or OECD TG 310 are in general appropriate. You can choose any of these methods, but you must ensure that the Substance is within the applicability domain of the test method chosen.

**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 07 October 2022.

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 took into account your comments and did not amend the requests.

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] |

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).