~~Confidential~~

Helsinki, 09 August 2023

Addressees
Registrants of JS_2437-25-4_[redacted] as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
30 March 2018

Registered substance subject to this decision ("the Substance")
Substance name: dodecanenitrile
EC/List number: 219-440-1

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

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

3. Only if a negative result in Annex VII, Section 8.4.1. 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).

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

Information required depends on your tonnage band

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

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

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Reasons common to several requests

0.1. Weight of evidence adaptation rejected

1 You have adapted the following standard information requirements by using Annex XI, Section 1.2. (weight of evidence):

- Skin sensitisation (Annex VII, Section 8.3);
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.).

2 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.

3 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.

4 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.

0.1.1. Lack of documentation justifying the weight of evidence adaptation

5 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.

6 You have provided summaries, under the endpoint summary in IUCLID for skin sensitisation and genotoxicity. In those summaries you briefly present each of the sources of information, describe the results. However, you have not weighted the individual sources of information nor provided a clear and transparent assessment of to which extent the sources of information cover each of the key parameters foreseen by the study normally required for the information requirement.

7 You have not included a justification for your weight of evidence adaptation for each of the relevant information requirement, 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.

8 Beside this critical deficiency common to all information requirements under consideration, your weight of evidence approach has additional deficiencies.

9 Additional deficiencies that are specific for each of the information requirements individually are addressed under requests 1 and 2.

10 Additional common deficiency is identified below.

0.1.2. Reliability of the information (calculations) provided from the Danish QSAR database

11 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

(1) the prediction needs to be derived from a scientifically valid model,
(2) the substance must fall within the applicability domain of the model,
(3) results need to be adequate for the purpose of risk assessment or classification and labelling, and
(4) adequate and reliable documentation of the method must be provided.

12 Regarding these conditions, we have identified the following issue(s):

13 You have provided a reference to the Danish QSAR predictions database.

14 ECHA has assessed the provided information and noted the following deficiencies:

15 Guidance on IRs and CSA R.6.1.6.3. states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

16 You provided the following information about the prediction: negative predictions by the skin sensitisation models in the Danish QSAR Database. The information you provided about the prediction lacks the following elements: details to independently verify that the substance falls within the applicability domain of the models, information on analogues and how their predicted and experimental data supports the prediction. In absence of such information, the documentation of the model is neither adequate nor reliable.

17 Therefore, the information obtained from Danish QSAR database submitted under your weight of evidence adaptation is not considered reliable.

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

18 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

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

(i) Reference to the Danish QSAR database;

(ii) *In vivo* skin sensitisation study (1999), performed with the analogue substance 2,2'-Azobis(isobutyronitrile) (EC: 201-132-3);

(iii) *In vivo* skin sensitisation (2003), performed with the analogue substance 2,2'-Azobis(2-methylbutyronitrile (EC: 236-740-8).

20 Sources (ii) and (iii) are provided as part of a category read-across prediction using the QSAR Toolbox v. 3.4. (2017).

21 You conclude that "*The skin sensitization potential of test substance Dodecanenitrile (CAS No: 2437-25-4) and its closest read across substance using log Pow as the primary descriptor 2,2'-Azobis(isobutyronitrile) (CAS No: 78-67-1) and 2,2'-Azobis(2-methylbutyronitrile) (CAS No: 13472-08-7) were observed in various studies. From the results obtained from these studies it is concluded that the chemical Dodecanenitrile (CAS No: 2437-25-4) is not likely to cause skin sensitization and hence can be classified as non skin sensitizer*".

1.2 Assessment of the information provided

22 In addition to the deficiencies identified in Section 0.1. ECHA identified endpoint specific issue(s) addressed below.

1.2.1. Assessment whether the Substance causes skin sensitisation

23 Information that can be used to support a weight of evidence adaptation for the information requirements of Section 8.3 at Annex VII includes similar information to that investigated by the internationally recognised in vitro, in chemico and/or in vivo test methods on skin sensitisation. The key investigations of such test methods address each of the 3 key events of skin sensitisation, either individually or in an integrated approach as follows:

- investigation of cell proliferation in the draining lymph nodes (local lymph node assay), or
- investigation of local responses in animals or humans (guinea pig assays or human studies), or
- investigation of molecular interaction with proteins, inflammatory response in keratinocytes and activation of dendritic cells (*in vitro* and *in chemico* assays).

24 The sources of information (i) to (iii) provide relevant information on skin sensitisation. However, the reliability of the contribution of the source of information (i) is significantly affected by the deficiency identified and explained under Section 0.1.2. of the Reasons

common to several requests. The reliability of the contributions to the weight of evidence adaptation of the sources of information (ii-iii) have been affected by the following deficiencies, explained below.

1.2.1.1. Reliability of the provided information with analogue substances

25 In your registration dossier you have provided information derived from source substances identified using the OECD QSAR Toolbox and flagged the information as QSAR. As the substances are used as source substances to predict the property of skin sensitisation of the Substance, ECHA understands that you intend to predict the toxicological properties of the Substance for skin sensitisation from data obtained with analogue substances in a read-across category approach (under Annex XI, Section 1.5 to REACH) as part of your weight of evidence adaptation.

1.2.1.1.1. Grouping of substances and read-across approach

26 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 (addressed under 'Assessment of prediction(s)').

27 Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2].

Scope of the grouping of substances (category)

28 In IUCLID Section 7.4.1 you have provided a document entitled "[redacted]. In this document you claim that the "*Toxicity of the target chemical (not sensitising) is predicted from category members using read-across based on 8 values (not sensitising x7, not classified x1) from 8 nearest neighbours compared by prediction descriptors*".

29 You have formed the category through identification of analogues using the OECD QSAR Toolbox. The selection of category members listed in OECD QSAR Toolbox report and provided below, for the endpoint skin sensitisation was done on basis of general mechanistic and structural criteria and log Kow boundaries.

30 In the document you list the following substances as members of the category used for read-across:

- *Cat. member 1*: propanenitrile, 3-[[4-[2-(4-nitrophenyl)diazenyl]phenyl](phenylmethyl)amino]- (EC: 619-236-6; CAS: 96662-24-7)
- *Cat. member 2*: 2,2'-azobis[2-methylbutyronitrile] (EC:236-740-8; CAS: 13472-08-7) – *source substance 1*
- *Cat. member 3* 2,2,4-trimethyl-4-phenyl-butane-nitrile (EC : 422-580-8 ; CAS : 75490-39-0)
- *Cat. member 4*: 2-benzyl-2-methyl-3-butenitrile (EC: 407-870-4; CAS: 97384-48-0)
- *Cat. member 5*: 2,2'-Azobis(isobutyronitrile (EC: 201-132-3; CAS: 78-67-1) - *source substance 2*
- *Cat. member 6*: dichlobenil (EC : 214-787-5; CAS: 1194-65-6)

[2] ECHA Guidance R.6

- *Cat. member 7*: 2,2,4(or 2,4,4)-trimethylhexanedinitrile (EC: 283-810-9; CAS: 84713-17-7)
- *Cat. member 8*: 3-(triethoxysilyl)propionitrile (EC: 213-050-5; CAS: 919-31-3)

31 ECHA has assessed the provided information and noted the following deficiencies with regards to your grouping approach.

- *Grouping of substances*

32 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 identifies "the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made" (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. Such description must cover the borders of the category, define unambiguous inclusion- and exclusion criteria, and include a justification for these.

33 You describe the applicability domain of the substances by general mechanistic and structural criteria and log Kow boundaries.

34 These criteria document the selection of the source substances but do not constitute on their own descriptions of unambiguous inclusion/exclusion criteria defining boundaries of the categories, which 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.

- *Characterisation of the source substances*

35 Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group."

36 According to the Guidance on IRs and CSA, Section R.6., "in identifying a category, it is important that all potential category members are described as comprehensively as possible", because the purity profile and composition can influence the overall toxicity/properties of the potential category members (Guidance on IRs and CSA, Section R.6.2.4.1.). Therefore, qualitative and quantitative information on the compositions of the category members must be provided to confirm the category membership

37 The category members were identified by CAS number. You have not provided any information on the composition of the selected analogue substances, including their purity profile and the presence of impurities.

38 In the absence of qualitative and quantitative information on the compositions of the category members, the category membership of these substances cannot be confirmed.

39 Based on the above, your grouping is rejected.

1.2.1.1.2. Predictions for toxicological properties

40 In your document "*QSAR Toolbox prediction based on read-across*" you have provided a read-across prediction based on information on 8 category members. In IUCLID, under section 7.4.1. you have provided experimental data only for two of the category members:

- source substance 1: 2,2'-azobis[2-methylbutyronitrile] (EC:236-740-8)
- source substance 2 : 2,2'-Azobis(isobutyronitrile (EC: 201-132-3).

41 You have provided the following reasoning for the prediction of the toxicological properties: you state that the two source substances are "*the closest read-across substances*" to your Substance, based on the log Kow.

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

43 ECHA has assessed the provided information and noted the following deficiencies with regards to predictions of toxicological properties.

- *Read-across hypothesis*

44 A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[3]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

45 Your read-across hypothesis is based on the similarity in the partition coefficient (log Kow). You consider that this is a sufficient basis for predicting the properties of the Substance.

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

47 Without such justification, you have not provided a read-across hypothesis to establish a reliable prediction for a toxicological properties, based on recognition of the structural similarities and differences between the category members.

48 Therefore, the information from the source substances submitted under your weight of evidence adaptation is not considered reliable.

1.2.1.2. Methodological deficiencies of sources of information (ii) and (iii)

49 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

50 Studies (ii) and (iii) are reported as *in vivo* guinea pig maximisation tests and have been performed according to a test protocol similar to the OECD TG 406. This test guideline requires that:

a) a dose level selection rationale is provided;
b) the appropriate number of animals is included in the study: minimum 10 in test group and 5 in control, if negative results 20 in test group and 10 in control group highly recommended;
c) positive and negative controls are included to establish the sensitivity and reliability of the experimental technique.

51 The following investigations/specifications are not to the requirements of OECD TG 406:

a) no dose level selection rationale was provided (in both studies (ii) and (iii);
b) no information provided on the number of animals used (study (ii);
c) no information on positive and negative control groups was provided (in both studies (ii) and (iii).

[3] ECHA *Guidance* R.6: Section R.6.2.4.1

52 Based on the above, the results obtained from the studies (ii) and (iii) cannot be considered as reliable.

1.2.1.3. Conclusion on the weight of evidence

53 Taken together, while the sources of information provide relevant information on the key investigations, the deficiencies affecting the reliability of all sources of information prevent drawing conclusions on these investigations:

- the deficiency identified related to the use of information from Danish QSAR database,
- the deficiency identified related to the use of information on analogue substance and
- methodological deficiencies in the study design and/or reporting listed above affecting directly the reliability of the results of studies (ii) and (iii) and their contribution to the weight of evidence adaptation.

54 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on whether the Substance causes skin sensitisation.

55 Based on the above, your weight of evidence adaptation under Annex XI, Section 1.2. is rejected.

1.2.2. No assessment of potency

56 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).

57 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.

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

1.3. Study design

59 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.

60 In case no conclusion on the skin sensitisation potency can be made for the Substance based on 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.

61 In your comments to the draft decision you agree to perform the in vitro studies. ECHA notes, that in the event, the Substance is considered to be a sensitiser based on the *in vitro* methods to be performed and no potency can be derived, additional testing or other considerations are needed, as information on potency needs to be generated according to REACH Annex VII, section 8.1, column 1.

2. *In vitro* gene mutation study in bacteria

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

2.1. Information provided

63 You have provided the following information:

(i) Reference to the Danish QSAR database (2017);

(ii) *In vitro* gene mutation study in bacteria (2003) with the Substance.

64 Even though you did not explicitly specify, based on the information provided, we understand that you sought to adapt this information requirement according to Annex XI, section 1.2. weight of evidence.

2.2. Assessment of the information provided

65 In addition to the deficiencies identified in Section 0.1. ECHA identified endpoint specific issue(s) addressed below.

66 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.1 at Annex VII include:

- Detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies; and
- Data provided on 5 bacterial 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).

67 The sources of information (i) and (ii) provide relevant information on detection and quantification of gene mutation in bacteria. However, the reliability of the source of information (i) is significantly affected by the deficiencies identified and explained under Sections 0.1.2. of the Reasons common to several requests. In addition, the source of information (ii) has methodological deficiencies, explained below, that affect the reliability of its contribution to your weight of evidence adaptation.

2.2.1. Methodological deficiencies of study (ii)

68 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

69 Study (ii) is reported as *in vitro* gene mutation study in bacteria and has been performed to test protocol similar to the OECD TG 471. This test guideline requires that:

a) at least 5 doses are evaluated, in each test condition;

b) concurrent strain-specific positive controls, both with and without metabolic activation, are included in each assay and the number of revertant colonies per plate induced by the positive controls demonstrates the effective performance of the assay;

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) the mean number of revertant colonies per plate is reported for the treated doses and the controls;

70 In the source of information (ii), the following investigations/specifications are not to the requirements of OECD TG 471:

a) the dose levels are not provided;
b) concurrent strain-specific positive controls, both with and without metabolic activation were not included in the study;
c) a concurrent negative control was not included in the study;
d) the mean number of revertant colonies per plate for the treated doses and the controls was not reported;

71 Based on the above, the results obtained from the study (ii) cannot be considered as reliable.

2.2.2. Conclusion on the weight of evidence

72 Taken together, while the sources of information provide relevant information on detection and quantification of gene mutation in bacteria, the deficiencies affecting the reliability of all sources of information prevent drawing conclusions on this investigation:

- the deficiency identified related to the use of information from Danish QSAR database; and
- methodological deficiencies in the study design and/or reporting listed above affecting directly the reliability of the results of study (ii) and its contribution to the weight of evidence adaptation.

73 It is not possible to conclude, based on any source of information alone or considered together, on the information requirement for *in vitro* gene mutation in bacteria.

74 Therefore, your adaptation is rejected and the information requirement is not fulfilled.

2.3. Study design

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

76 In your comments to the draft decision you agree to perform the requested study.

Reasons related to the information under Annex VIII of REACH

3. *In vitro* gene mutation study in mammalian cells

77 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.

3.1. triggering of the information requirement

78 Your dossier contains (I) a negative result for *in vitro* cytogenicity study in mammalian cells, and (II) inadequate data for the *in vitro* gene mutation study in bacteria.

79 The *in vitro* gene mutation study in bacteria, provided in the dossier is rejected for the reasons provided in request 2.

80 The result of the request 2 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.

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

82 You have not submitted any information for this requirement.

3.2. Study design

83 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.

84 In your comments to the draft decision you agree to perform the requested study.

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 23 August 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]
[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

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

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

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

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

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

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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