~~Confidential~~

Helsinki, 24 May 2024

Addressee(s)
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
28 April 2023

Registered substance subject to this decision ("the Substance")
Substance name: Vinyl ethylene carbonate
EC/List number: 700-261-7

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 ***1 June 2026***.

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

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

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

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

3. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats.

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

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

   Under Article 26(3) of REACH, you must not repeat a study involving vertebrate animals conducted on the Substance.

   A pre-natal developmental toxicity study (2022), is available in the jointly submitted registration for the Substance. You must request it from the other registrant and then make every effort to reach an agreement on the sharing of data and costs.

5. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211).

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

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(s) of the decision and their 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)

Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5.:

- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Scope of the grouping of substances (category)

5 You provide a QSAR toolbox report and a prediction as attachments to the endpoint study record provided for each information requirement in IUCLID.

6 The QSAR toolbox reports provide information on the identity of the source substances and on the reasoning for grouping these substances together.

7 The prediction reports describe the outcome of the predictions and the details of the results obtained for each of the category members, including the Substance, for a set of profilers included in the QSAR Toolbox.

8 Further details on the identity of the category members is provided in the endpoint specific sections of this document.

9 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.

0.1.2. Predictions for toxicological properties

0.1.2.1. Missing supporting information to compare the properties of the substances

10 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

11 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration with the Substance and the source substance(s).

12 In this context, the supporting information should explain why the differences in the chemical structures do not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure and/or in composition 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.).

13 In your category justification document and in your prediction reports, you have identified the category members that you use as source substances to predict the properties of the Substance.

14 You list results of mechanistic similarity profilers obtained from the OECD QSAR toolbox for each of these source substances and for the Substance in order to establish that the substances are likely to have similar properties.

15 Based on the information provided in the documentation of your adaptations, the category members used as source substances are structurally significantly different from the substance. More specifically, the Substance is a cyclic carbonate with an alkyl substituent carrying a terminal unsaturation. None of the source substances include a cyclic carbonate function in their structure and only one source substance has a terminal unsaturation.

16 While the results obtained from the QSAR Toolbox for the different profilers are consistent between the Substance and the source substances, this information is derived from the analysis of fragments of the structures of each of these substances. This information does not, on its own, establish that these substances are likely to have similar properties. You have neither elaborated on the impact of the structural differences between the substances nor provided information, such as bridging studies, establishing that these structural differences do not impact the properties of the substances.

17 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties and that the properties of the Substance can be predicted from information on the structurally significantly different source substances. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2.2. Missing robust study summaries for the studies on the source substances

18 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.

19 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)).

20 In your category justification documents and in your prediction reports you have identified the category members that you use as source substances to predict the properties of the Substance.

21 In your prediction summaries, you indicate for the predicted endpoint “No effect specified; No duration specified; No guideline specified”.

22 You conclude with a negative predicted value for each of the properties under consideration.

23 However, you have not provided any information on the studies on the source substances, including details on the methods, results and conclusions, that you use to predict the properties of the Substance. In the absence of this information, no independent assessment of the source studies can be completed.

24 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.

0.1.3. Conclusion

25 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approaches under Annex XI, Section 1.5. are rejected.

Reasons related to the information under Annex VIII of REACH

1. *In vitro* micronucleus study

26 An *in vitro* mammalian chromosomal aberration study or an *in vitro* mammalian micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

1.1. Information provided

27 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the information on the following category members, extracted from the OECD QSAR Toolbox:

(i) Vinyl ethylene carbonate, CAS 4427-96-7;

(ii) Polysolvan O, CAS 7397-62-8;

(iii)1,2-Propanediol, diacetate, CAS 623-84-7;

(iv)Diallyl diglycol carbonate, CAS 142-22-3;

(v) 2-ethylhexyl (2S)-2-hydroxypropanoate, CAS 186817-80-1.

28 You indicate that the prediction "takes the mode value from the 4 nearest neighbours" and you conclude with a negative prediction for this property of the Substance.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

29 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the information requirement is not fulfilled.

1.3. Study design

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

1.3.1. Assessment of aneugenicity potential

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

32 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei

is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

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

1.4. Information regarding data sharing

33 Under Article 25(1), it is necessary to take measures limiting duplication of non-vertebrate test(s).

34 The jointly submitted registration for the Substance contains an *in vitro* mammalian chromosomal aberration test (2022) which is adequate for this information requirement. You may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs.

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

35 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.

2.1. Triggering of the information requirement

36 Your dossier contains (I) a negative result for *in vitro* gene mutation study in bacteria, and (II) no data or inadequate data for the other study (*in vitro* chromosomal aberration study in mammalian cells or *in vitro* micronucleus study in mammalian cells).

37 The *in vitro* chromosomal aberration in mammalian cells or *in vitro* micronucleus study in mammalian cells provided in the dossier is rejected for the reasons provided in request 1.

38 The result of the request 1 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.

39 Consequently, you are required to provide information for this information requirement, if the *in vitro* micronucleus study in mammalian cells provides a negative result.

2.2. Information provided

40 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the information on the following category members, extracted from the OECD QSAR Toolbox:

(i) Vinyl ethylene carbonate, CAS 4427-96-7;

(ii) ethyl 3-ethoxypropanoate, CAS 763-69-9;

(iii) polysolvan o, CAS 7397-62-8;

(iv) 1,3-divinylimidazolidin-2-one, CAS 13811-50-2;

(v) phenoxyisopropanol, CAS 770-35-4.

41 You indicate that the prediction "takes the highest mode value from the 4 nearest neighbours" and you conclude with a negative prediction for this property of the Substance.

2.3. Assessment of the information provided

42 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the information requirement is not fulfilled.

2.4. Study design

43 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.

2.5. Information regarding data sharing

44 Under Article 25(1), it is necessary to take measures limiting duplication of non-vertebrate test(s).

45 The jointly submitted registration for the Substance contains an *in vitro* mammalian cell gene mutation test (2022) which is adequate for this information requirement. You may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs.

3. Screening study for reproductive/developmental toxicity

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

3.1. Information provided

47 You have adapted this information requirement by using Annex VIII, Section 8.7.1., Column 2 whereby the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) referred to in Annex IX, point 8.7.2. is available.

48 You have adapted the information requirement of Annex IX, point 8.7.2 by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). You have provided the following information:

(i) A positive prediction obtained from the Developmental Toxicity model (CAESAR) 2.1.8;

(ii) A positive prediction obtained from the Developmental/Reproductive Toxicity library (PG).

49 To support the adaptation, you have provided prediction reports and documents describing the each of the models used.

3.2. Assessment of the information provided

50 Under Annex VIII, Section 8.7., Column 2, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) referred to in Annex IX, point 8.7.2. is available or proposed by the registrant.

51 You have predicted the pre-natal developmental toxicity properties of the Substance using QSAR models. However, for the reasons explained in request 4 the information that you have provided is not reliable.

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

3.3. Study design

53 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

54 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1., Column 1).

55 Therefore, the study must be conducted in rats with oral administration of the Substance.

3.4. Information regarding data sharing

56 The other registrants of the joint submission relied on an adaptation to meet this information requirement. You may consider sharing this information.

Reasons related to the information under Annex IX of REACH

4. Pre-natal developmental toxicity study in one species

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

4.1. Information provided

58 You have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). You have provided the following information:

(i) A positive prediction obtained from the Developmental Toxicity model (CAESAR) 2.1.8;

(ii) A positive prediction obtained from the Developmental/Reproductive Toxicity library (PG).

59 To support the adaptation, you have provided prediction reports and a guide to each of the models used.

4.2. Assessment of the information provided

4.2.1. The QSAR result is not equivalent to results obtained from the required experimental test

60 Results from (Q)SAR models are adequate for risk assessment or classification and labelling when they are equivalent to results obtained from the required experimental test. The corresponding study that must normally be performed for this particular information requirement is the OECD TG 414, which measure(s): 1) prenatal developmental toxicity, 2) maternal toxicity, and 3) maintenance of pregnancy.

61 You have provided predictions from the (Q)SAR models Developmental Toxicity model (CAESAR) and Developmental/Reproductive Toxicity library (PG), which both predict that the substance is "Toxicant, but the result may be not reliable".

62 The exact effects predicted by the models are not clear. Thus, ECHA cannot establish that all the measurements of the corresponding study for the endpoint have been considered. Therefore, the prediction is not adequate for the purpose of classification and labelling and/or risk assessment.

63 Based on the above, your QSAR adaptation under Annex XI, Section 1.3. is rejected and the information requirement is not fulfilled.

4.3. Study design

64 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

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

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

4.4. Information regarding data sharing

67 The jointly submitted registration for the Substance contains a pre-natal developmental toxicity study (2022) which is adequate for this information requirement. This study must not be duplicated. Therefore, you must request it from the other registrants and make every effort to reach an agreement on the sharing of data and costs.

5. Long-term toxicity testing on aquatic invertebrates

68 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

5.1. Information provided

69 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from QSAR, VEGA 1.2.0 BETA, 22/04/2023.

5.2. Assessment of the information provided

5.2.1. (Q)SAR adaptation rejected

70 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.

5.2.1.1. The substance is outside the applicability domain of the model

71 Under ECHA Guidance R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer.

72 You provide a predicted NOEC for Daphnia Magna by application of the VEGA 1.2.0 Vega, Daphnia Magna Chronic (NOEC) model IRFMN 1.0.2. In your dossier, you state that:

73 "Predicted NOEC is 11.85 mg/L, but the result may be not reliable:

- Only moderately similar compounds with known experimental value in the training set have been found
- a prominent number of atom centered fragments of the compound have not been found in the compounds of the training set or are rare fragments (1 unknown fragments found)"

74 We assessed your prediction. The model you have used provides the following list of warnings related to the applicability domain with the VEGA model report for the Substance:

75 - Only moderately similar compounds with known experimental value in the training set have been found

76 - Accuracy of prediction for similar molecules found in the training set is not optimal

77 - similar molecules found in the training set have experimental values that disagree with the predicted value

78 - the maximum error in prediction of similar molecules found in the training set has a moderate value, considering the experimental variability - a prominent number of atom centered fragments of the compound have not been found in the compounds of the training set or are rare fragments (1 unknown fragments and 2 infrequent_fragments found)

79 Therefore, as indicated by the warnings provided by the model, the prediction is not reliable for your Substance as the Substance is outside the applicability domain of the model.

80 Based on the above, your QSAR adaptation under Annex XI, Section 1.3. is rejected.

81 Therefore, the information requirement is not fulfilled.

6. Long-term toxicity testing on fish

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

6.1. Information provided

83 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from QSAR, VEGA 1.2.0 BETA, 22/04/2023.

6.2. Assessment of the information provided

6.2.1. (Q)SAR adaptation rejected

84 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.

6.2.1.1. The substance is outside the applicability domain of the model

85 Under ECHA Guidance R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer.

86 You provide a predicted NOEC for fish by application of the VEGA 1.2.0 Vega, Fish Chronic (NOEC) Toxicity model IRFMN 1.0.2. In your dossier, you state that:

87 "Predicted NOEC is 11.85 mg/L, but the result may be not reliable:

- Only moderately similar compounds with known experimental value in the training set have been found
- a prominent number of atom centered fragments of the compound have not been found in the compounds of the training set or are rare fragments (1 unknown fragments found)"

88 We assessed your prediction and the model you have used. The same list of warnings related to the applicability domain is provided in the VEGA model report as explained in Request 5.

89 Therefore, as indicated by the warnings provided by the model, the prediction is not reliable for your Substance and the Substance is outside the applicability domain of the model. Based on the above, your QSAR adaptation under Annex XI, Section 1.3. is rejected.

90 Therefore, the information requirement is not fulfilled.

6.3. Study design

91 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 01 September 2023.

A testing proposal for a sub-chronic (90-day) study is included in the dossier submission subject to this decision. This testing proposal will be examined and addressed in a separate decision. The information requirements of Annex VIII, 8.6.1 and Annex IX, 8.6.2 have therefore been descoped from this compliance check.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

ECHA did not receive any comments within the commenting period.

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

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

Appendix 3: Addressee(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[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 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