~~Confidential~~

Helsinki, 16 June 2023

Addressee(s)
Registrant(s) of JS-gamma decalactone as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
26/02/2020

Registered substance subject to this decision ("the Substance")
Substance name: Decan-4-olide
EC/List number: 211-892-8

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 ***23 March 2026***.

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

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

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

3. 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 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)

Contents

Reasons related to the information under Annex IX of REACH

1. Sub-chronic toxicity study (90 days)

1 A sub-chronic toxicity study (90 days) is an information requirement under Annex IX, Section 8.6.2.

1.1. Information provided

2 ECHA understands that you have adapted this information requirement by using Annex IX, Section 8.6.2., Column 2. To support the adaptation, you have provided the following information:

(i) No classification for human health

(ii) Assessments by other bodies such as the joint FAO/WHO Expert Committee on Food Additives (JECFA).

(iii) Exposures are always well below the derived DNEL or PNEC.

(iv) Short-term repeated dose toxicity study (2003) with the source substance hexan-4-olide, EC 211-778-8.

1.2. Assessment of the information provided

1.2.1. Column 2 criteria not met

3 Under Annex IX, Section 8.6.2., Column 2, Indent 4, the study may be omitted if the following cumulative conditions are met:

(1) the substance is unreactive, insoluble and not inhalable;

(2) there is no evidence of absorption; and

(3) no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure.

4 You have not provided any information to support that the Substance is unreactive, insoluble and not inhalable (1) as well as that there is no evidence of absorption (2). There is no exposure assessment in your CSR and an unsubstantiated statement that exposure is well below DNEL does not necessarily mean that there is limited human exposure.

5 Therefore, you have not demonstrated that the exposure is limited.

6 Based on the above, your adaptation is rejected.

7 Therefore, the information requirement is not fulfilled.

1.3. Comments on the draft decision

1 In your comments to the draft decision you agree to provide information in an update to the dossier that is adequate to meet the information requirement.

1.4. Specification of the study design

8 Following the criteria provided in Annex IX, Section 8.6.2., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.2., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance

9 According to the OECD TG 408, the rat is the preferred species.

10 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

12 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on an experimental data from the following source substance:

(i) a long-term toxicity study on *Daphnia magna* (2015) with source substance γ-undecalactone, EC 203-225-4.

13 You provide a read-across justification document in IUCLID Section 13.

14 You justify your read-across approach by explaining that the Substance (γ-decalactone) and the source substance (γ-undecalactone) are structurally similar and exhibit similar patterns for physico-chemical properties, environmental behavior, ecotoxicological and toxicological properties. You further explain that, according to the data available, the source substance can be considered to be more toxic than the Substance.

15 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance based on a worst-case approach.

2.2. Assessment of the information provided

2.2.1. Inadequate results on the source substance

16 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211.

17 Therefore, the following key parameter must be measured:

the concentrations of the test material leading to no observed effect (NOECs) or the concentration that would cause 10% reduction (EC_{10}) on the following parameters are estimated:

(i) the reproductive output of Daphnia sp. expressed as the total number of living offspring produced at the end of the test, and
(ii) the survival of the parent animals during the test.

18 With regard to the first of these key parameters (reproductive output of Daphnia sp. expressed as the total number of living offspring produced at the end of the test), the following is required under OECD TG 211:

the most conservative result is used between the two following response variables:

- the total number of living offspring produced per parent animal which did not die accidentally or inadvertently during the test;
- the number of living offspring produced per surviving parental animal.

19 OECD TG 211 explains that if the mortality of the parent animals does not follow a concentration-response pattern[2], then the replicates with parental mortality should be excluded from the analysis of the test result. However, if the mortality follows a concentration-response pattern, the parental mortality should be assigned as an effect of the test substance and the replicates should not be excluded from the analysis of the test result.

20 In study (i) on the source substance, you report a NOEC and an EC_{10} based on the mean number of living juveniles per surviving parental animal, i.e., replicates in which parental mortality occurred were excluded from the analysis.

21 However, the NOECs or the EC_{10} were not estimated on the following parameter:

- the reproductive output of Daphnia sp. expressed as the total number of living offspring produced at the end of the test.

22 The test item did induce parental mortality. The parental mortality is statistically significant for test concentrations above 0.138 mg/L, and there is a concentration-response pattern for parental mortality (the Cochran-Armitage trend test is highly significant with a p-value of 1.42E-09). Therefore, the observed parental mortality can be interpreted as an effect of the test substance and the corresponding replicates must have been included in the analysis of the test results.

23 Therefore, the results submitted for your adaptation do not provide an adequate and reliable coverage of all the key parameters of the corresponding OECD test guideline.

2.2.2. Results not adequate for the risk assessment and classification and labelling

24 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment. Then, the Substance must be classified and labelled and the risks assessed on the basis of those results.

25 You have proposed no classification and labelling and have not provided a risk assessment for the Substance.

26 You have provided a study performed according to OECD TG 211 on the source substance. Based on the mean number of living offspring per surviving parental daphnid, you have calculated an EC10 of 1.02 mg/L and a NOEC of 0.138 mg/L.

27 As explained above, those results do not provide an adequate and reliable coverage of all the key parameters of OECD TG 211. In particular, you have not calculated an EC_{10} or a NOEC based on the total number of living offspring produced at the end of the test.

[2] OECD TG 211 indicates that a statistical test like the Cochran-Armitage trend test may be used to verify whether such a pattern exists.

28 Based on the information reported in the robust study summary, it is possible to recalculate an EC_{10} of 0.14 mg/L (lognormal model) and a NOEC of 0.138 mg/L (Dunnett's test) for the number of living offspring produced per every parental animal.

29 Under your read-across hypothesis, those recalculated results would warrant the classification and labelling of the Substance as well as the requirement for providing a risk assessment for the Substance.

30 However, based on the results you have reported, you have proposed no classification and labelling and have not provided a risk assessment for the Substance.

31 Therefore, the results you have reported for this study are not adequate for the purpose of classification and labelling and risk assessment.

2.3. Conclusion

32 As explained above, you have not established that long-term toxicity of the Substance on aquatic invertebrates can be predicted from the results you have presented for the source substance. Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

2.4. Comments on the draft decision

33 In your comments to the draft decision you agree to provide information in an update to the dossier that is adequate to meet the information requirement.

3. Long-term toxicity testing on fish

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

3.1. Information provided

35 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) "*According to the test substance and the two other lactones used as read-across in this dossier (γ-nonalactone and γ-undecalactone), the test substance is not considered as the most toxic substance in acute studies. To reduce testing on vertebrate animals (in accordance with REACH regulation) and as the fish is not the most sensitive species in acute conditions, a test plan for long-term effects on fish is scientifically unjustified. To assess chronic effects of γ-decalactone, a worst case read-across approach was performed using long-term toxicity data on aquatic invertebrates and algae available on the most toxic lactone in acute studies (γ-undecalactone). As the chemical safety assessment indicates no need for further investigation, a long-term toxicity study on fish is not required*".

3.2. Assessment of the information provided

3.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

36 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

3.3. Conclusion

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

3.4. Comments on the draft decision

38 In your comments to the draft decision you agree to provide information in an update to the dossier that is adequate to meet the information requirement.

3.5. Study design and test specifications

39 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 (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 17 November 2021.

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

ECHA took into account your comments and did not amend the request(s) or the deadline.

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 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]
[redacted]	[redacted]	[redacted]
[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[3].

(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.

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

- 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).