~~Confidential~~

Helsinki, 20 May 2024

Addressee
Registrant of Cyclopentadecanone as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08 January 2019

Registered substance subject to this decision ("the Substance")
Substance name: Cyclopentadecanone
EC/List number: 207-951-2

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 ***27 May 2026***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211).

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

2. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; 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 of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

1.1. Triggering of the information requirement

2 In the provided OECD TG 105 (2016), the saturation concentration of the Substance in water was determined to be 0.578 mg/L.

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

1.2. Information requirement not fulfilled

4 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

5 In your comments to the draft decision, you disagree to perform the requested study. You acknowledge therein that the the available data show a water solubility below 1 mg/L. Under the legal presumption in Annex VII, Section 9.1.1, Column 2 this shows that it is not likely that short-term toxicity testing would provide a true measure of the intrinsic aquatic toxicity of the substance and explains why ECHA under this provision may request long term testing. But you raise a number of additional points why you do not consider testing necessary, including reference to the Substance being classified as Aquatic Acute 1 (H400, M factor 1), Aquatic Chronic 1 (H410, M factor 1) and a statement that that: '*The current CSR of the substance indicates low RCRs for the aquatic environment after RMMs*'.

6 In the first place, you do not refer to any legal ground for adaptation under the specific or general rules for adaptation in the Annexes to REACH. In particular, no explicit adaptation rule exists for this information requirement that would allow omission of the required information where the Substance is classified. Also, minimisation of (vertebrate) animal testing is not on its own a legal ground for adaptation.

7 Regarding the general rules of adaptation, and your reference to the RCRs in the CSR, you may have intended to adapt the standard information requirement under Annex XI, Section 3.2 (a), substance-tailored exposure-driven testing.

8 With a view to such adaptation, we however identify the following issues:

9 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c).

1.2.1. Lack of appropriate PNEC

10 Your registration dossier provides the following aquatic toxicity data, short-term toxicity studies with fish, aquatic invertebrates and algae.

11 As already explained, the Substance is poorly soluble, therefore short-term aquatic toxicity data are not adequate to characterise the toxicity of the substance and therefore to derive a valid PNEC.

12 Therefore, you have not demonstrated that an appropriate PNEC can be derived.

1.2.2. Exposure always well below PNEC not demonstrated

13 Under Annex XI, Section 3.2.(a)(iii), the comparison of the PNEC with the results of the exposure assessment must show that exposures are always well below the PNEC.

14 The results of the exposure assessment must show that exposure concentrations are always well below the PNEC, i.e. RCRs must always be well below 1. This means that a high level of confidence is needed to demonstrate that every RCR is low enough to ensure that the risks are always controlled, under every plausible condition of the manufacture and all identified uses of the Substance. For this purpose, the possible sources of variability and uncertainty must be considered in the assessment of exposure (Guidance on IRs and CSA Chapter R.16, page 68).

15 Uncertainty must be taken into account, for example by carrying out the environmental exposure assessment using conservative assumptions and default values, which are provided in Guidance on IRs and CSA Chapters R.16. (Guidance on IRs and CSA Chapter R.19).

16 Alternatively, when the environmental exposure assessment is not based on these generic assumptions, a stepwise, tiered approach including an uncertainty analysis must be conducted. This analysis can be qualitative, deterministic, or probabilistic, to demonstrate that the risk is adequately controlled (Guidance on IRs and CSA Chapter R.19 provides a framework for carrying out a stepwise, tiered approach to uncertainty analysis). The results must be provided in the dossier to demonstrate that the application of such tiered uncertainty analysis gives a clear indication that the risk is always adequately controlled (e.g. an increased belief that the (distribution of the) RCR are well below 1).

17 You have provided an exposure assessment reporting 15 exposure scenarios:

18 First, the exposure assessments for all of those exposure scenarios (except ES6) are not based on the generic assumptions recommended in Guidance on IRs and CSA Chapter R.16. You have used less conservative input parameters, in particular for:

- the release factors (scenarios indicated below);
- the number of release days (scenarios indicated below).

19 The justifications for those deviations are not appropriate or altogether missing:

- The release factors in wastewaters do not cover worst-case conditions for ES1, ES 3 (except for ES 3, ENV CS 8), ES 11, and ES 15. The release factors selected are less conservative than the recommendations in Guidance on IRs and CSA, Chapter R.16.
- The release factors in air do not cover worst-case conditions for ES1-3 (except for ES 3, ENV CS 8), ES 4, and ES 8-9, and ES 14. The release factors selected are less conservative than the recommendations in Guidance on IRs and CSA, Chapter R.16.
- The release factors in soil do not cover worst-case conditions for ES 1-4, ES 4, and ES 8-15. The release factors selected are less conservative than the recommendations in Guidance on IRs and CSA, Chapter R.16.
- The number of release days are assumed without any justifications (ES 1 -8).

20 Second, you have not provided an uncertainty analysis for the environmental exposure assessment.

21 The application of recommended generic assumptions would result in RCR above 1 for the exposure scenarios ES 1 – 5 presented in your CSR.

22 Therefore, you have not demonstrated that exposure concentrations are well below the PNEC.

23 Based on the above, a substance-tailored exposure driven testing adaptation under Annex XI, Section 3. must be rejected on the basis of the available information.

24 Therefore, the information requirement is not fulfilled.

1.3. Study design

25 The Substance is difficult to test due to the low water solubility (0.578 mg/L) and/or adsorptive properties (log K_{oc} 4.16). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

Reasons related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

26 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

2.1. Triggering of the information requirement

27 As already explained in the reason for request 1 above, the Substance is poorly water soluble. Therefore, information on long-term toxicity on fish must be provided.

2.2. Information requirement not fulfilled

28 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

29 In your comments to the draft decision, you disagree to perform the requested study. You acknowledge therein that the the available data show a water solubility below 1 mg/L. Under the legal presumption in Annex VII, Section 9.1.1, Column 2 this shows that it is not likely that short-term toxicity testing would provide a true measure of the intrinsic aquatic toxicity of the substance and explains why ECHA under this provision may request long term testing. But you raise a number of additional points why you do not consider testing necessary, including reference to the Substance being classified as Aquatic Acute 1 (H400, M factor 1), Aquatic Chronic 1 (H410, M factor 1) and a statement that that: '*The current CSR of the substance indicates low RCRs for the aquatic environment after RMMs*'.

30 In the first place, you do not refer to any legal ground for adaptation under the specific or general rules for adaptation in the Annexes to REACH. In particular, no explicit adaptation rule exists for this information requirement that would allow omission of the required information where the Substance is classified. Also, minimisation of (vertebrate) animal testing is not on its own a legal ground for adaptation.

31 In your comments you also claim that: '*The current CSR of the substance indicates low RCRs for the aquatic environment after RMMs*'. ECHA understands that you intend to adapt the standard information requirement under Annex XI, Section 3.2 (a), substance-tailored exposure-driven testing.

32 However, for the same reasons as already explained in sections 1.2.1 and 1.2.2 above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

33 Therefore, the information requirement is not fulfilled.

2.3. Study design

34 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.).

35 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above (section 1.3), the Substance is difficult to test and correspondingly the requirements described under "Study design" in section 1.3 must be followed.

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 22 November 2022.

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).

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]

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

(1) Selection of the Test material(s)

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

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

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

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

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

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