~~Confidential~~

Helsinki, 02 October 2023

Addressee(s)
Registrant(s) of 461-58-5_1-Cyanoguanidine as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
13/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Cyanoguanidine
EC/List number: 207-312-8

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 the deadline of ***7 January 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. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201)

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

2. 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.

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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 VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided in your dossier and in your comments:

Growth inhibition study on aquatic algae OECD 201 (1985) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline(s)

3 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Replicates of test concentrations

a) three replicates at each test concentration and at least three replicates for controls (including solvent controls, if applicable) are included.

Characterisation of exposure

b) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided.

c) Where it is likely that exposure concentrations will vary less than 20% from nominal concentrations during the test, analytical monitoring of the concentrations of the test substance at the start and end of the test, a low and a high test concentration and a concentration around the expected EC50 may be sufficient.

Reporting of the methodology and results

d) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

4 In your comments, you argue that the above rules are not applicable because the study was conducted and was compliant with the OECD TG 201 adopted June 1984 at the time the registration dossier was submitted in 2010.

5 In study (i):

Replicates of test concentrations

a) the number of replicates was two in each test concentration.

In your comments on the draft decision, you argue that with the available data from the study conducted with the OECD TG 201 adopted June 1984, an EC50 and a NOEC (both based on growth rate) could be calculated and therefore the relevant key values are available.

Characterisation of exposure

b) no analytical monitoring of exposure was conducted.

In your comments on the draft decision, you argue that as your Substance is stable, not readily biodegradable, and hydrolytically at pH values above 5, it can be assumed neither biodegradation nor hydrolysis will take place under the test conditions. Based on this you consider your Substance is stable and the use of nominal concentrations provided in the robust study summary are sufficient.

Reporting of the methodology and results

c) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

In your comments on the draft decision, you argue that the effect concentrations, the EC50 and the NOEC were determined based on growth rate, only. You consider the growth rates are the most relevant results of this study and can be used for classification under CLP regulation, whereas effect concentration based on biomass can be neglected.

6 Based on the above,

a. The version of the OECD TG 201 applicable to your dossier at the time of your registration was adopted March 2006 which include the above rules.

b. There are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you did not provide analytical characterisation of the exposure. As a result, there is no actual monitoring of the behaviour of the Substance in solution during the duration of the study. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material and thus the study is not reliable.

c. Regarding your comments on the draft decision, concerning the required three number of replicates at each test concentration, OECD TG 201 requires three replicates considering that the higher the number of replicates, the greater the level of statistical power and therefore the higher the level of confidence in your EC50 and the NOEC effect concentrations based on growth rate. You have not demonstrated the reliability of your EC50 and NOEC considering the lower statistical power of having two replicates, only and therefore you have not justified any deviation to the requirements for three replicates of the test concentrations in the OECD TG 201.

d. Regarding your comments on the draft decision, concerning stability, we note that if you considered your Substance stable, as per OECD TG 201, where it is likely that exposure concentrations will vary less than 20% from nominal values during the test, analysis of the concentrations of the test substance at the start and end of the test, a low and a high test concentration and a concentration around the expected EC50 may be sufficient. You have not provided any analysis. Therefore, you have not demonstrated that using nominal concentrations would be reliable for your Substance.

e. The reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

f. Regarding your comments on the draft decision, concerning daily tabulated data on the algal biomass, as per OECD TG 201, you need to tabulate the estimated

biomass concentration (daily tabulated data on the algal biomass) in test cultures and controls together with the concentrations of test material and the times of measurement, recorded with a resolution of at least whole hours. This allows ECHA to undertake an independent assessment of the "raw data"/ the biomass in the test vessels and to verify the generation of your growth rate (ErCx). You have not provided the daily tabulated data on the algal biomass. Therefore, you have not demonstrated reliability of your growth rate.

7 On this basis, the specifications of OECD TG 201 are still not met.

8 Therefore, the information requirement is still not fulfilled.

1.3. Information regarding data sharing

9 The registration of a member of the joint submission that has opted out for the Substance contains a growth inhibition study on aquatic algae (1998) which is adequate for this information requirement. In accordance with Title III of the REACH Regulation, you may request it from the member of the joint submission that has opted out and then make every effort to reach an agreement on the sharing of data and costs (see Guidance on data-sharing for any support).

10 ECHA acknowledges that you will try to get access to the OECD 201 study owned by the Japanese Authorities. However, currently, it has not been submitted to ECHA and therefore cannot be taken into account.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on fish

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

2.1. Information provided in your dossier and in your comments

12 In your dossier, you have provided:

(i) a long-term toxicity study on fish OECD 204 (1998) with the Substance.

13 In your comments on the draft decision, you have provided:

(ii) a second study with fish with the Substance (1998)

(iii) additional general non-specific adaptation(s):

1 The available studies show algae is the most sensitive species of the three trophic levels

2 With respect to animal welfare and animal protection and concept of reducing, refining, and replacing animal tests as per Directive 2010/63/EU

3 Instead of conducting an additional study to assess the Long-term toxicity to fish, you will perform literature research in order to find supporting data

2.2. Assessment of the information provided in your dossier and in your comments

2.2.1. The provided study does not meet the specifications of the test guideline(s)

14 To fulfil the information requirement, a study must comply with OECD TG 210 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Key parameter measured

a) parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage following exposure to the test substance are measured, including:

- the stage of embryonic development at the start of the test, and
- hatching of fertilized eggs and survival of embryos, larvae, and juvenile fish, and
- the appearance and behaviour of larvae and juvenile fish, and
- the weight and length of fish at the end of the test.

15 In study (i):

a. Your registration dossier provides an OECD TG 204 study in which only adults were exposed to the test material.

16 In study (ii):

a. You indicate that publicly available key values confirmed the submitted results, but you have provided no information to assess whether these key values relate

to OECD TG 210's key parameters. It is also unclear if you are referring to a second acute study or a second OECD 204 study since no specific data was submitted.

17 Based on the above,

- neither study provided cover the key parameter(s) required by the OECD TG 210.

18 On this basis, the specifications of OECD TG 210 are not met.

2.2.2. Adaptations without legal basis

19 A registrant may only adapt this information requirement based on either the general rules set out in Annex XI or the specific rules of Column 2, Annex IX, Section 9.1.

20 General adaptations (iii.1) and (iii.2) to omit the study does not refer to any legal basis and it is unclear to which legal basis they may relate to.

21 In any case, you rely on an available algae study which has been found to be unreliable (see request 1) and other studies, where no specific data has been provided.

22 Therefore, your adaptations (iii.1) and (iii.2) are rejected.

2.2.3. Future data cannot be taken into account

23 In the adaptation (iii.3), you intend to conduct a literature search.

24 This decision however addresses information available and cannot take into account future, hypothetical information.,

25 Therefore, this information is rejected.

26 Therefore, the information requirement is still not fulfilled.

2.3. Study design and test specifications

27 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 16 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).

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[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

(2) 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.

(3) 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.

(4) 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].

(5) 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

General recommendations for conducting and reporting new tests

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.

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

- 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 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[3].

[3] https://echa.europa.eu/manuals