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Helsinki, 02 October 2023

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

Date of submission of the dossier subject to this decision
21/03/2022

Registered substance subject to this decision ("the Substance")
Substance name: Cyanoguanidine
EC number/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 ***7 January 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. 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 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.

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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. Long-term toxicity testing on fish

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

1.1. Information provided

2 ECHA understands that you have adapted this standard information requirement under Section 3.2 (b) of Annex XI to the REACH Regulation substance-tailored exposure-driven testing, by stating the following in your assessed dossier "Substance is only use as an intermediate. There will be no emissions to the aquatic environment and the acute NOEC for fish is 100 mg/L".

1.2. Assessment of the information provided

1.2.1. Substance-tailored exposure-driven testing adaptation rejected

3 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).

1.2.2. Incomplete exposure assessment

4 Under Annex XI, Sections 3(1) and (2), testing may be omitted based on the exposure scenario(s) developed in the chemical safety report (CSR) by providing an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment.

5 This also applies to monomers in polymer for which the justification must cover in particular absence of unreacted monomers and demonstration that the polymer does not degrade to monomers under use or waste stage (see Guidance for monomers and polymers, April 2012, Version 2.0), in particular Sections 2.2, 3.2.1 and 4.2, and the decision of Board of Appeal for A-001-2020 (in particular paragraphs 109 and 110).

6 In your comments to the draft decision, you indicate that you have fulfilled a substance-tailored exposure-driven testing adaptation of the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c) as outlined by the BoA decision A-001-2020, paragraph 109 & 110.

7 In your assessed dossier, and in your comments to the draft decision, you provide a number of statements, all of which are not stated below, including the following:

- As polymerisation takes place [redacted], there is no identified use [redacted] and no exposure assessment needs to be addressed.
- The polymer is only used in industrial applications for coagulation purposes.
- Under your exposure considerations in your CSR, you state that
  - The polymer is extremely stable and cannot degrade to reform the monomer since this would involve reforming of the double bond broken to form the polymer chain.
  - Residual substance, monomer present in the polymeric mixture will

go with the process water to the wastewater treatment plant. These emissions to water will be several orders of magnitude lower than DNEL or PNEC.

- You have stated that the unreacted monomer will be released from the polymer upon degradation, and result in exposure to man. The Substance is a monomeric unit of an [redacted] water-soluble polymer, [redacted] aqueous solution.
- The residual monomer contained in the aqueous solutions is always less than [redacted] based on active polymer.
- You identify that long term dermal exposure is the only relevant exposure to the general population via the dermal route is through bathing in the surface water into which treated water containing residual monomer was discharged.
- You state that regarding the exposure risk related to the release of the unreacted part of the monomer in the environment, based on the worst-case scenario in which the entire volume of the polymer is released in one river and [redacted] of monomer would be released into the environment - You indicate that the results of the exposure considerations based on this worst-case scenario demonstrates that there is no significant exposure.

- The acute NOEC is >100 mg/L

8 In your comments to the draft decision, you include statements already submitted in the dossier, used to assess the original decision, and covered by the brief outline above.

9 In your comments to the draft decision, you also indicate the following points:

a. That you included an exposure information and risk assessment of unreacted monomer in the imported polymers for a previous Decision, where a developmental toxicity endpoint was requested.

b. That you have demonstrated that the polymer cannot degrade to reform the registered substance under conditions of normal use or in the natural environment by stating that "Reforming of double bonds requires extremely high temperatures, which in turn would degrade the reformed monomer". That additionally, the request for information (exposure assessment) on the monomer as the degradation product of a polymer is not in line with Annex V of the Regulation, which exempts all substances resulting from a chemical reaction due to environmental factors such as air and sunlight as well as end-use.

c. That you did provide documentary evidence confirming that the maximum residual concentration in the [redacted] polymer is [redacted] Furthermore, there is no requirement in the legislation to provide information on the concentration of an impurity in a polymer produced from the registered substance. These provisions exist in other legislative texts (e.g., CLP) and are within the remit of the national authorities to control and enforce.

10 Regarding the BoA decision A-001-2020, para 109 & 110, it indicates that "in order to rely on an adaptation under Section 3 of Annex XI, the Appellant was required to provide a thorough and rigorous exposure assessment of the Substance covering all relevant exposures throughout the life-cycle of the Substance, including the potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer". However, in your comments to the draft decision

you repeat the statement(s) submitted from your dossier but without providing any new scientific information or documentary evidence.

11 Your statement that the provision of information regarding the concentration of impurities is not applicable under REACH. ECHA understands when you state "impurities" it is in the context of the monomer under REACH. ECHA agrees that under REACH, where no substance-tailored exposure-driven testing adaptation is proposed by a registrant, there is no requirement to fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c). However, in this dossier, you have proposed a substance-tailored exposure-driven testing adaptation under Annex XI, Sections 3(1) and 3(2), hence you are required under REACH to provide an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment.

12 You indicated you included an exposure information and risk assessment of the unreacted monomer in the [redacted] polymers for a previous decision, where a developmental toxicity endpoint was requested. However, this information is not available here. In any case, for that decision, also, your substance-tailored exposure-driven testing adaptation was rejected due to an incomplete exposure assessment, as you did not consider the unreacted monomer which may remain in the polymer; i.e. the quantities of the monomer substance which did not react during the polymerisation reaction and remained in the composition of the polymer.

13 You indicated you included a statement demonstrating that the polymer cannot degrade to reform the registered substance under conditions of normal use or in the natural environment by stating, "Reforming of double bonds requires extremely high temperatures, which in turn would degrade the reformed monomer". However, this is a statement without providing an adequate justification for this statement.

14 Regarding your reference to Annex V to REACH: you provided a substance-tailored exposure-driven testing adaptation under Annex XI, Sections 3(1) and (2) of REACH, hence you are required under REACH to provide an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment. The need to provide information on exposure to the Substance (the bound monomer in the polymer only; i.e. the quantities of the registered monomer substance which reacted during the polymerisation reaction to yield the polymer and the unreacted monomer which may remain in the polymer; i.e. the quantities of the monomer substance which did not react during the polymerisation reaction and remained in the composition of the polymer) does not stem from the registration obligation, but from the fact that you seek to rely on an exposure based adaptation.

15 You have not demonstrated that the polymer cannot be degraded into the registered monomer under normal use and/or environmental conditions.

16 You have not provided documentary evidence (e.g., laboratory report, confirmation from your supplier or reference to literature) confirming the total concentration of the residual unreacted monomer which may remain in the polymer.

17 In your dossier or in your comments to the draft decision, you have not provided a complete relevant exposure scenario(s) in the chemical safety report (cf. Annex XI, Section 3.1 of the REACH Regulation) with thorough and rigorous exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation covering whole life cycle of the substance (cf. Annex XI, Section 3.2 of the REACH Regulation).

18 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3.2 is rejected.

19 In your comments on the draft decision, you felt that ECHA failed to consider the long-term toxicity value for invertebrates used to derivate the PNECs. However, as stated above, you have not provided a thorough and rigorous exposure assessment.

1.2.3. Strictly controlled conditions not demonstrated

20 Under Annex XI, Section 3(2)(b)) it must be demonstrated and documented for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply (see further Guidance on Intermediates and Practical Guide 16).

21 To fulfil this adaptation, a description of strictly controlled conditions throughout the life cycle is required under Annex XI, Section 3.2.(b) of the REACH Regulation.

22 You have not provided such description.

23 Instead, you have submitted multiple statements some of which are identified under Incomplete exposure assessment, above. These are not substantiated without statements regarding strictly controlled conditions as set out in Art 18(4)(a) to (f) in the dossier.

24 The use of the Substance under strictly controlled conditions is not demonstrated.

25 In addition, you state in your submitted dossier and in your comments to the draft decision that the acute NOEC is >100 mg/L however, without providing an adequate justification for this statement.

26 PNEC determination is not relevant for Strictly controlled conditions.

27 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3.2(b) is still rejected.

1.3. Study design and test specifications

28 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 22 August 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 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 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.

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[3].

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