~~Confidential~~

Helsinki,23 May 2023

Addressees
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
21 March 2022

Registered substance subject to this decision ("the Substance")
Substance name: Cyanoguanidine
EC 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 ***1 December 2025***.

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

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

1. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

The reasons for the decision(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 decision
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 decision

Contents

Reasons related to the information under Annex IX of REACH

1. Simulation testing on ultimate degradation in surface water

1 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

1.1. Information provided

2 You have adapted this information requirement on the basis that testing is not technically possible. To support the adaptation, you have provided following information:

(i) a justification to omit the study based on your claim that the Substance is inorganic.

1.2. Assessment of information provided

3 We have assessed this information and identified the following issue:

1.2.1. The provided adaptation of testing being not technically possible is not supported by any evidence for the claim that the substance would be inorganic

4 Under Section 2, Annex XI to REACH, the study may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. Guidance on IRs and CSA, Figure R.7.9-1 specifies that biodegradability studies are not required for inorganic chemicals as they cannot be tested for biodegradability.

5 In your IUCLID dossier, Section 1.1 (identification) you state that the origin of your mono-constituent Substance is inorganic. In section 1.2 (composition) of your IUCLID dossier you report that the molecular formula of the Substance is C2H4N4 (SMILES NC(=N)NC#N) and you report that DSL category is 'Organics'.

6 ECHA notes that you have not substantiated why you consider the Substance inorganic.

7 According to the Industrial Emissions Directive (2010/75/EU), organic substances are defined by being any compound containing at least the element carbon and one or more of hydrogen, halogens, oxygen, sulphur, phosphorus, silicon or nitrogen, with the exception of carbon oxides and inorganic carbonates and bicarbonates.

8 Based on the provided composition information, the Substance falls inside the definition set in the Industrial Emissions Directive (2010/75/EU) for organic compound.

9 Cyanoguanidine is a dimer[1] of cyanamide, which is the nitrile of carbamic acid[2]. Carbamic acid contains a cyano bond (-CN), so in this respect it is an aminoacid[3] and is hence regarded as an organic compound. Additionally, cyanoguanidine contains two moieties: guanidine and a cyano group (CN). Guanidine is an organic compound produced in nature

[1] A dimer is a substance synthetized by reacting two monomers (two molecules of the same substance).
[2] https://onlinelibrary.wiley.com/doi/epdf/10.1002/14356007.a08_139.pub2, page 7, section 2.2.
[3] https://reader.elsevier.com/reader/sd/pii/S1386142598002285?token=9E68926398A4527193D61B68F150B671721C76467A46F71A35BC7DCDBFDBC9AAF615FFC7FF175591503DFCAA911F63A8, page 1, paragraph 4.

in live organisms and it is found in urine as a normal product of protein metabolism. Adding a cyano[4] group to guanidine does not change the organic nature of the molecule.

10 Therefore, based on the composition described above the Substance is organic.

11 ECHA further points out that you also report that the Substance belongs to the 'Organics' DSL category.

12 Therefore, ECHA considers the Substance to be organic and that you did not demonstrate that because of the properties of the Substance it is technically not possible to conduct the study.

13 In your comments to the draft decision you reiterate your adaptation of the information requirement based on the claim that the Substance is inorganic and the simulation testing on ultimate degradation in surface water is technically not possible to conduct.

14 More specifically, you provided the following arguments in your comments.

15 First, you state that *"the key information in Annex 1, 4.2 of the Industrial Emissions Directive is that calcium carbide is inorganic. This is directly relevant to the present case, as will become apparent from the manufacturing process of cyanoguanidine"* and that "[redacted] *-both of which are inorganic (also as per Directive 2010/78/EU)-and the addition of nitrogen to an inorganic compound cannot transform it into an organic one*".

16 ECHA understands that your interpretation of the Industrial Emissions Directive is that a substance manufactured from inorganic starting materials is always an inorganic substance and this would also apply to cyanoguanidine where the starting materials of the manufacturing process, [redacted] are inorganic. ECHA agrees that the starting matarials of the manufacturing process, which is a sequence of reactions, are inorganic. However, in case of synthesis of cyanoguanidine (the subject of the ECHA decision), the last two reactions, *i.e.* synthesis of cyanamide and its dimerization to cyanoguanidine, are regarded as organic processes because both cyanamide and cyanoguanidine are treated as organic substances in the available scientific sources: scientific articles and academic books, as shown further[5]. There are also other examples of organic substances manufactured from inorganic starting materials (*e.g.* syntheses of urea from cyanic acid and ammonia through ammonium cyanate as intermediate (Wöhler, 1828) or from ammonia and carbon dioxide through ammonium carbamate as intermediate (Bosch-Meiser process, 1922)).

17 Second, you state in your comments that cyanamide is the amide of cyanic acid (inorganic) rather than nitrile of carbamic acid as indicated in the ECHA decision.

18 In response, ECHA points out that cyanamide is both the amide of cyanic acid and the nitrile of carbamic acid, depending on the reference substances invoked: cyanic acid or carbamic acid – (see respectively, "Ullmann's Encyclopedia of Industrial Chemistry", page 651, chapter 2.2 "Chemical properties" of "Cyanamide" where it is stated: *"Cyanamide can be regarded as the amide of cyanic acid or as the nitrile of carbamic acid.";* footnote 2 of this decision).

19 Third, in your comments you challenge ECHA's opinion that carbamic acid is an amino acid and hence is considered as organic compound, and you further specify your view by saying

[4] Cyano (-CN) is a functional group specific to organic substances and it is covalent bonded. On the other hand, inorganic substances comprise the anion cyanide NC^-, which gives ionic bond (e.g. sodium cyanide). Consequently, if cyanoguanidine had been inorganic, it should have contained the cyanide anion, but it is proven that "cyano" in cyanoguanidine is an organic functional group (e.g. the huge difference in chem-phys properties, such melting point: 209.5^{0}C for cyanoguanidine vs. 563.7^{0}C for sodium cyanide proves that cyanoguanidine is an organic substance).

[5] *Chimie Organica*, 8th Edition, C.D.Nenitescu, page 868 states: "**cyanamide may be considered as the nitrile of carbamic acid**".

that "*It would seem ECHA is confusing the presence of a substance made of an amine and a carboxyl group with the well-defined group of amino acids where there is a carbon atom (an α-carbon) next to the carboxyl group*". You also state that the sentence "*Carbamic acid could be seen as both an amine and carboxylic acid, and therefore an amino acid*" in the ECHA decision is a partial extract from the Wikipedia section on carbamic acid.

20 However, ECHA's statement that "*carbamic acid is an amino acid*" is based on the scientific paper ("Carbamic acid: molecular structure and IR spectra") referred to in footnote 3 of this decision. In this article on page 1, section 1, paragraph 3 it is explained that "*One of the most important structural features of carbamic acid is the existence of a CN bond; in this respect, it is an amino acid which is simpler than the simplest identified amino acid, namely, amino acetic acid or glycine. Carbamic acid is an important molecule in living systems where it is thought to be produced enzymatically from urea.*" Furthermore, ECHA's assessment that "*carbamic acid is an amino acid*" is based on the presence of both carboxylic and amino groups, specific for an amino acid and did not make any reference to "stable amino acids", which are α-, β-, γ-, etc. The sentence "*Carbamic acid could be seen as both an amine and carboxylic acid, and therefore an amino acid*" that you claim to be directly quoted from Wikipedia is not included in this decision.

21 Fourth, you state in your comments that "*In fact, both moieties of dicyandiamide – the guanidine and cyano groups – are inorganic*".

22 However, the statement that you provide in your comment is incorrect. First, "*guanidine*" is not a group but it is a substance, and it is well known that guanidine is organic and it is exclusively found in organic chemistry books such as *Chimie Organica*, 8th Edition and *Organic Chemistry*, 6th Edition. Second, the statement that "*cyano group is inorganic*" is not true. "*Cyano*" is a functional group specific to organic chemistry and defines a specific class of organic substances named "*nitriles*". It is depicted as "-CN" exclusively in organic substances and is a representation of an organic functionality with triple bond between carbon and nitrogen. In inorganic chemistry, the equivalent of a "*cyano*" functionality is the anion NC^-, called "*cyanide*", which is a real chemical entity, opposing the functional group "*cyano*", which is just an organic functionality. Therefore, stating that "*cyano group is inorganic*" is not correct, the correct statement is that "*cyanide is inorganic*".

23 Fifth, you list the following references at the end of your comments on your statement that dicyandiamide is inorganic:

24 1. Wikipedia: Carbamic acids (https://en.wikipedia.org/wiki/Carbamic_acid)

25 2. Inorganic Syntheses, Volume III, Edited by Ludwig F. Audrieth, McGraw-Hill Book Company, Inc.

26 3. Ullmann's Encyclopaedia of Industrial Chemistry, Wiley VCH

27 4. Kirk-Othmer's Encyclopaedia of Chemical Technology, Wiley Interscience

28 *5. Jurgens et al*., Inorganic Chemistry, Vol. 41, No. 19,2002.

29 ECHA notes that the references 3 and 4 are unsubstantiated as you do not provide any justification how they would support your claim that the Substance is inorganic.

30 Regarding references 2 and 5 you specify that dicyandiamide is mentioned in the reference text book of inorganic synthesis (Inorganic Syntheses, Volume III, Edited by Ludwig F. Audrieth, McGraw-Hill Book Company, Inc) and in an article published in a journal of inorganic chemistry (Jurgens et al., Inorganic Chemistry, Vol. 41, No. 19,2002). However, this does not mean that dicyandiamide is inorganic, because the simple association of "Ammonium Dicyanamide" (presumably regarded as inorganic because appears in an article of an Inorganic Journal) with "Dicyandiamide" does not make the latter an inorganic substance. As explained above with regard to the first argument presented by the

Registrant in their comments, an inorganic starting material does not neccessarily lead to an inorganic substance.

31 Regarding reference 1 to Wikipedia, ECHA reiterates that it did not rely on any Wikipedia article for its assessment.

32 ECHA would also like to point out regarding the reference 3 of Ullmann's Encyclopaedia of Industrial Chemistry that you mention above that under chapter 3.2 (Chemical Properties) the following text is found "*Dicyandiamide reacts with a variety of reagents. It is the simplest organic compound containing the C-N, C=N and C≡N groupings*". This supports the consideration that cyanoguanidine is an organic substance.

33 Sixth, in your comments you also refer to the results of the OECD 301 E screening test submitted by the lead registrant and also contained in the SIDS dossier. No biodegradation was observed in the test and you conclude that "*For an "organic" substance, the result of this test at 0% is quite unusual, to say at least. Organic substances rarely, if ever, do not degrade biotically at all*". You state that "*This is why the Registrant questioned the organic nature of the substance and changed it in its submission to inorganic*."

34 However, in response, ECHA points out that the OECD TG 301 E screening test investigates biodegradation under strict conditions. It is not unusual that organic substances under such screening test conditions do not show any biodegradation. Moreover, the nature of a substance, *i.e.* organic or inorganic, is determined by its chemistry, not by its behavior in the environmental fate testing.

35 Based on the above, the information provided in your comments does not change ECHA's assessment of your adaptation of testing being not technically possible. Therefore, your adaptation is rejected.

36 Finally, in your comments you claim that this endpoint (Simulation testing on ultimate degradation in surface water) also "*qualifies for waiving according to Annex XI of REACH since there is insignificant exposure to humans and the environment, the substance is not PBT/vPvB and the DNEL and PNEC values are several orders higher than worst-case exposure scenarios based on the concentration of residual monomer contained in the polymer*".

37 We acknowledge your statement for potentially waiving the information requirement according to Annex XI of REACH. However, you do not specify which Annex XI adaptation section you would potential use. Our understanding based on your comments is that your intention is to potentially adapt this information requirement based on exposure considerations, according to Annex XI, Section 3. A registrant who submits an adaptation must set out clearly the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds. However, in your comments you do not provide any further explanations on the detailed grounds for your potential adaptation.

38 Therefore, the information in your comments is not sufficient for ECHA to make an assessment, because you have not substantiated your potential adaptation. On this basis, ECHA cannot evaluate whether such potential adaptation would be sufficient to fulfil this information requirement.

39 For all these reasons, the information requirement is not fulfilled.

1.3. Study design and test specifications

40 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

41 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

42 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

43 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

44 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

1.4. Information regarding data sharing

45 The jointly submitted registration for the Substance contains an OECD Guideline 309 (Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test) study (2014) which is adequate for this information requirement. In accordance with Title III of the REACH Regulation, you may request it from the other registrants and then make every effort to reach an agreement on the sharing of data and costs (Guidance on data-sharing).

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).

All Guidance on REACH is 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

On 6 February 2020, ECHA took a compliance check decision requesting for a simulation study on ultimate degradation in surface water. The registrant appealed this request. On 29 June 2021, ECHA's Board of Appeal annulled this request in case A-001-2020 on the basis that the Agency has not provided sufficient justifications for this request and remitted the case to ECHA for further action in this regard. On this basis ECHA re-evaluated whether the dossier is compliant for this information requirement.

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 13 October 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).

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.

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.

Appendix 3: Addressees 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 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