Helsinki, 06 February 2020

**Addressees**
Registrant of 461-58-5_1-Cyanoguanidine listed in the last Appendix of this decision

**Date of submission for the dossier subject of this decision**
11 May 2018

**Registered substance subject to this decision, hereafter 'the Substance'**
Substance name: Cyanoguanidine
EC number: 207-312-8
CAS number: 461-58-5

**Decision number:** [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

## DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadlines provided.

### A. Requirements applicable to all the Registrants subject to Annex IX of REACH

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

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

3. 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 with the Substance.

### Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach

for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in points A.1-2 above in an updated registration dossier by ***13 August 2020***, and the information requested in point A.3 above by ***13 November 2020***.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant." You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

**Appeal**

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons for the requests to comply with Annex IX of REACH**

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

**1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)**

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided a key study for this endpoint in your dossier:

i. Subchronic toxicity study. 1988. The MAK-Collection Part I: MAK Value Documentations, Vol. 24. 2007. NOAEL 570 mg/kg bw based on clinical signs (blood).

We have assessed this information and identified the following issues:

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others:

1. At least 10 female and 10 male animals should be used at each dose level (including control group);
2. Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of body weight, hematology, clinical biochemistry, and pathology of sexual (male and female) organs, full detailed gross necropsy and subsequent histopathology of both types tissues.

The study you have provided neither provides evidence on the exact number of animals used per sex per test dose group, nor evidence for any control group animals used.

The study you have provided was not performed according to the criteria of the OECD TG 408, since the following key parameters are missing:

- Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of body weight, hematology, clinical biochemistry, and pathology of sexual (male and female) organs, full detailed gross necropsy and subsequent histopathology of both types tissues.

Based on the above, the information you provided does not fulfil the information requirement.

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a solid.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

Information on data sharing for studies involving vertebrate animals
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the

other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

ECHA considers six months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.

**2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species**

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided adaptions in Sections 5.9.1.1 and 5.9.2.1 of your Chemical Safety Report (CSR), and you conclude that the Substance *"has no identified uses or exposure to man or environment. It is only imported as a monomeric unit in polymers and not manufactured or imported in the unpolymerised form. Therefore, exposure is zero".*

**Exposure-based adaptation**

While an adaptation was not specifically indicated by you, ECHA has evaluated the above information under the rules set in Annex XI, Section 3. Substance-tailored exposure-driven testing.

As stated in Annex XI, Section 3, you may adapt the information requirement based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communigating the specific conditions of use through the supply chain. Any of the following criteria according 3.2.(a),(b) or (c) shall be met. In particular:

1. 3.2 (a) the importer demonstrates and documents that all of the following conditions are fulfilled, where the first condition is (i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.; and
2. 3.2 (c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions are fulfilled, where the first condition is (i) the substance is not released during its life cycle.

We have assessed this information and identified the following issue(s):

You have considered 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.

You have not considered the unreacted (unbound) 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.

You have neither considered the possibility that upon degradation of the polymer there may be release of the monomer.

The possible release of the monomer from the polymer can result in exposure to man. In this respect, you are also referred to the ECHA Guidance for monomers and polymers, in particular Sections 2.2, 3.2.1 and 4.2, and the judgement of the European Court of Justice in EU Case C 558/07 of 7 July 2009, paragraph 51.

However, the CSR does not contain any chemical risk assessment covering the entire life-cycle of monomer substance subject to this decision. Indeed, the CSR neither considers the possible presence of and exposure to unreacted monomers in the polymer nor considers the possible presence of and exposure to the monomer following the degradation of the polymer substance.

Reliable documentation and justification for the premise that there is no exposure to the monomer is currently missing. In particular, the following requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled:

a) you have not provided relevant exposure scenario(s) in the chemical safety report (cf. Annex XI, Section 3.1 of the REACH Regulation);
b) no rigorous exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation has been developed (cf. Annex XI, Section 3.2, 2nd sentence of the REACH Regulation);
c) you have not provided relevant life-cycle information and exposure scenarios relating to the unreacted monomer (cf. Annex XI, Section 3.2.(a)(i) of the REACH Regulation); and
d) you have not demonstrated and documented that the substance (the monomer) is not released during its life cycle e.g. via decomposition or degradation (cf. Annex XI, Section 3.2.(c)(i) of the REACH Regulation).

Therefore, the adaptations of the information requirements of Annex IX, 8.7.2 (pre-natal developmental toxicity) of the REACH Regulation provided by you cannot be accepted because several requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3. Therefore your adaptation is rejected, and the information requirement is not fulfilled.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral administration of the Substance.

Information on data sharing for studies involving vertebrate animals
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

ECHA considers six months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.

**3. Simulation testing on ultimate degradation in water (Annex IX, Section 9.2.1.2.)**

Simulation testing on ultimate degradation in surface water is a standard information requirement at Annex IX to REACH.

ECHA understands that you have sought to adapt this information requirement based on Annex XI, Section 2 (testing is technically not possible). You justified the adaptation by stating that the study is technically not feasible as the Substance is inorganic.

As provided in Annex XI, Section 2, you may adapt the information requirement, if it is technically not possible to conduct the study as a consequence of the properties of the substance. Biodegradability studies are not required for inorganic substances as they cannot be tested for biodegradability (ECHA Guidance R.7b Section R.7.9.5.4). Furthermore, if a substance is highly insoluble in water it may not be possible to conduct this study if the water solubility of the substance is very low (typically <1 µg/L) (ECHA Guidance R.11 Section R.11.4.1.1.3).

We have assessed this information and identified the following issue(s):

The Substance is organic.

Furthermore, you report that the Substance is very soluble in water with a water solubility of 40 g/L.

Therefore, the adaptation is rejected because ECHA considers that testing biodegradability is technically feasible. This is also indicated in by the data in the registration that is jointly submitted for the Substance.

Therefore, your adaptation does not fulfil the information requirement.

Possibility for data sharing

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

## Appendix B: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 29 January 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30 days.

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 C: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   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: 'How to report robust study summaries'[2].

4. Test material

   *Selection of the test material(s)*

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account 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.

   *Technical reporting of the test material*

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

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

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Guidance for monomers and polymers, (version 2.0, April 2012), referred to as ECHA Guidance for monomers and polymers in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

**Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them**

| Registrant Name | Registration number | (Highest) Data requirements to be fufilled |
|---|---|---|
| [redacted] | [redacted] | [redacted] |