EUROPEAN CHEMICALS AGENCY

Helsinki, 2 September 2019

Addressee: [redacted]

Decision number: CCH-D-2114482139-42-01/F
Substance name: Amines, polyethylenepoly-
EC number: 268-626-9
CAS number: 68131-73-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28/06/2018
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.) with the registered substance;**

2. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance;**

3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**

4. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance provided that both studies requested under 2. and 3. have negative results;**

5. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the registered substance;**

6. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) in a second species (rabbit), oral route with the registered substance.**

You are required to submit the requested information in an updated registration dossier by ***9 September 2021*** except for the information requested under point 5, the Sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by ***9 September 2020***. For each deadline, you shall also update the chemical safety report, where relevant. The deadlines have been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

This decision does not address the information requirement of the Extended one-generation reproductive toxicity study according to Annex X, Section 8.7.3. of the REACH Regulation.

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.

Authorised[1] by Ofelia Bercaru, Head of Unit, 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 1: Reasons

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Your registration dossier contains for multiple endpoints adaptation arguments in the form of a grouping and read-across approach according to Annex XI, Section 1.5. of the REACH Regulation. ECHA has assessed first the scientific and regulatory validity of your grouping and read-across approach in general before the individual endpoints (sections 1-6).

Grouping and read-across approach

You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5, for the endpoints, subject to the current decision:

- Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.);
- *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1);
- *In vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2);
- *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.);
- Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2); and
- Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species.

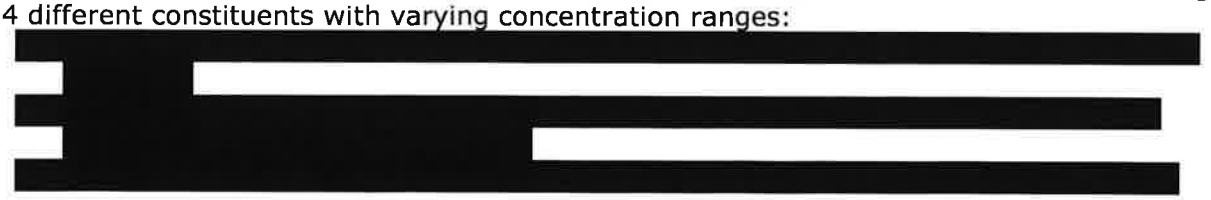
You consider to achieve compliance with the REACH information requirements for the registered (target) substance Amines, polyethylenepoly-, (CAS RN 68131-73-7; EC number 268-626-9) by using data on the following source substances

- Triethylenetetramine linear, cyclic and branched (CAS RN 90640-67-8; EC number 292-588-2; referred hereafter to as TETA); and
- N,N'-bis(2-aminoethyl)ethylenediamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-3 referred hereafter to as TETA x 2HCl); and
- Polyethylene polyamine, pentaethylenehexamine fraction (CAS RN 4067-16-7; EC number 223-775-9; referred hereafter to as PEHA);

and provide a read-across justification document in your technical dossier, containing your read-across hypothesis, justification and a data matrix for the target and source substances.

According to ECHA's understanding, your read-across approach is based on structural similarity between the constituents of the registered UVCB substance and the source substances i.e. you propose that the registered UVCB substance and the source substances belong to the ethylene amines (EA) which are characterized by long chain ethylene amines. Based on this structural similarity you assume that target and source substances have similar toxicological properties.

ECHA notes that you have registered your substance as Substances of Unknown or Variable Composition, Complex reaction products and Biological materials (UVCB substances). You have provided the detailed composition of your substance in your IUCLID dossier, consisting of 4 different constituents with varying concentration ranges:



[redacted]

ECHA observes that the constituents of the registered UVCB substance as well as the source substance TETA and PEHA are mixtures of linear, cyclic and branched polyethylene polyamines, which are not individually identified. In other words, the constituents of the registered and source substances are UVCBs themselves (or multi-constituent substance, i.e. the constituent d) of the registered substance), whereas the identity and the proportion of the structurally different compounds contained within each constituent is not established. Furthermore, ECHA observes that the source substance TETA x 2 HCl is a mono-constituent substance consisting of one type of linear ethylene amines with a well-defined structure (incl. number of amine functional group) and concentration range.

ECHA notes that your read across approach is lacking several aspects that are considered crucial to establish structural similarity between the sources and registered UVCB substance[2].

Firstly, in your read-across approach you do not address the impact of

- the proportions of the individual linear/cyclic/branched compounds within the constituents in the target and source substances;
- the number of the amine functional group within the individual linear/cyclic/branched compounds in each constituents of the target and source substances; and
- the variations of the constituents' concentrations in the target and source substances

on establishing structural similarity and the possibility to predict human health properties of the registered UVCB substance by using data on the source substances.

Secondly, you do not explain how you establish structural similarity between the mono-constituent source substance (i.e. TETA x 2 HCl) and the registered UVCB substance consisting of several structurally different compounds with varying concentration.

Structural similarity is a prerequisite for applying the grouping and read-across approach. ECHA considers that you have not established the structural similarity between the target and the source substances. In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substances.
This incompliance with the general rules of adaptation set out in Annex XI, Section 1.5. REACH alone leads to the rejection of you read-across approach.

In addition, ECHA notes that your read across approach does not address the following aspects that are considered crucial to establish why a prediction for a toxicological properties is reliable and can be based on the structural similarities and differences between the sources and registered substance[3].

You claimed that based on their structural similarity target and source substances would have common mode of action, common biological targets of common transformation products, common exposure of the transformation products and it is supported by the available data.

However, ECHA observes that:

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

(i) your data matrix does not contain toxicological studies relevant for the human health property(ies) of the source substance PEHA. Therefore, it is not possible to establish the toxicity profile of PEHA and compare the toxicity profile of the registered UVCB substance with this source substance. ECHA considers that it is not established that relevant properties of the registered substance can be predicted from data on this analogue substances.

(ii) your data matrix contains toxicokinetic data only on the source substance TETA as free base, its salt i.e. TETA 2 x HCl and additionally on a related substance, which is not used as a source substance in your read-across approach, i.e. N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6); no toxicokinetic data on the registered substance is available. Therefore, it is not possible to establish and compare the toxicokinetic profile of the registered UVCB substance with the source substances.

(iii) the studies indicated to be conducted with the source substance TETA, i.e. Triethylenetetramine linear, cyclic and branched (CAS RN 90640-67-8; EC number 292-588-2) (e.g. [redacted] 1981; [redacted] 1992; [redacted] 1982 and 1987; [redacted] 1986 [redacted] 1984; [redacted] 1988) were conducted with a different test material i.e. N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6). ECHA considers that you do not establish structural similarity between this analogue substance, the source substance TETA and the registered UVCB substance and do not explain how these studies are taken into account when predicting the properties of the registered substance.

Furthermore, the data matrix contains only one higher tier study with the registered UVCB substance i.e. a prenatal developmental toxicity study according to OECD TG 414 ([redacted] 2015). When comparing the results of this study with the results of the pre-natal developmental toxicity studies listed in your data matrix and according to conducted with the source substance TETA ([redacted] 1984 and [redacted] 1988) it appears that the toxicity profile of the registered UVCB substance is different from those observed in the [redacted] 1984 and [redacted] 1988 studies for TETA. For example, the registered UVCB substance exhibited severe maternal toxicity at 800 mg/kg bw/day leading to death or sacrifice of all females in this dose group between gestation days 10 and 17 ([redacted] 2015). On the contrary the administration of the test material, according to you the source substance TETA, at similar dose level i.e. 750 mg/kg bw/day ([redacted], 1984) did not induce maternal toxicity (except of slightly depressed food intake and body weight gain which, however when corrected body weights were evaluated no differences was observed).

Therefore, ECHA considers that you fail to demonstrate that based on their structural similarity the target and source substances would have common mode of action, common biological targets of common transformation products and common exposure of the transformation products. With other words, ECHA considers that you fail to demonstrate that based on their similar structure target and source substances would have the same toxicity.

Finally, ECHA notes, that in addition to the studies submitted in your IUCLID dossiers and/or presented in your read-across document, further higher tier studies are available on the source substance TETA 2 x HCl and are not part of your dossier's documentation without justification for such exclusion (Tanaka 1992 and 1993). These studies inform about the prenatal developmental toxicity of this source substance, showing adverse effects on fertility parameters and developmental toxicity (e.g. increased resorption and brain abnormalities of the fetuses), which you have not taken into account in your read-across approach.
ECHA considers that these data do not support your assumption that based on their similar structure target and source substances would have similar toxicity profile.

Hence, ECHA concludes that you have not established that relevant properties of the registered substance can be predicted from data on the source substances. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected and it is necessary to perform testing on the registered substance.

1. Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.)

The assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information is a standard information requirement as laid down in Annex VIII, Section 8.8.1. of the REACH Regulation.

ECHA notes that the registration dossier does not provide any assessment on the toxicokinetics properties of the registered substance. Although REACH does not specifically require generation of toxicokinetic information, it does require that all relevant available information is used to assess the toxicokinetic behaviour of a substance, and that human health hazard assessment considers the toxicokinetic profile of the substance. The toxicokinetic profile of a substance describes its absorption, distribution, metabolism and excretion.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records of
(i) a toxicokinetic study (Gibbs, 1986) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6);
(ii) a dermal absorption study (Oyen, 1953) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6); and
(iii) various toxicological studies (Kodoma, 1993; Maemura, 1998; Kobayashi, 1990; Jones, 1995; Takeda, 1995; Tanabe, 1996a and 1996b) with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-4).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: assessment of the toxicokinetic behaviour of the registered substance to the extent that can be derived from the relevant available information (Annex VIII, 8.8.1.).

Notes for your consideration

Guidance on Toxicokinetics is available in ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.7c, Section R.7.12.

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for Bacterial Reverse Mutation Assays (OECD TG 471; [redacted]1987 [redacted]2000; [redacted]1980; [redacted]1979; [redacted]2000; Takahashi, 1993; [redacted]1992) with the N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14./ OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

In your comment to the draft decision, you agreed to perform the requested study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14./ OECD TG 471)

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for
(i) combined *in vitro* Chinese Hamster Ovary (CHO) Mutation test, Sister Chromatid Exchange (SCE) test and assays for induction of Unscheduled DNA Synthesis (UDS), (similar to OECD TG 476, OECD TG 479 and OECD TG 482; [redacted]1981 (12 studies); [redacted] 1979; [redacted]1992) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6); and
(ii) *in vivo* Mammalian Erythrocyte Micronucleus tests (similar to OECD TG 474[redacted] 1987; [redacted]1992; Heinz, 1981) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are both appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

In your comment to the draft decision, you agreed to perform the requested study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

4. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

ECHA notes that the registration dossier does not contain appropriate study records for this endpoint. Adequate information *on in vitro* gene mutation in mammalian cells will however need to be present in the technical dossier for the registered substance to meet this information requirement provided that both studies requested under 2. and 3. have negative results. ECHA set the deadline for provision of the information to allow for sequential testing.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study record(s) for
(i) combined *in vitro* Chinese Hamster Ovary (CHO) Mutation test, Sister Chromatid Exchange (SCE) test and assays for induction of Unscheduled DNA Synthesis (UDS), (similar to OECD TG 476, OECD TG 479 and OECD TG 482 [redacted] 1981 (12 studies); [redacted] 1979; [redacted] 1992) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6); and
(ii) a Sex-linked Recessive Lethal Test in Drosophila melanogaster (OECD TG 477; [redacted] 1994) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6).

However, as explained above in Appendix 1, "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are both appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comment to the draft decision, you agreed to perform the requested study, provided that both studies requested under 2. and 3. have negative results.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that both studies requested under 2. and 3. have negative results.

5. 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 as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for repeated dose toxicity studies via oral route with various length and quality:
(i) with N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6); (Meyers, 1976); and
(ii) with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-3); (Yanagisawa, 1998 (2 studies); Greenman, 1996 and Maemura, 1998).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure (7.65E-4 Pa (5.74E-6 mmHg) at 20°C) and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In your comment to the draft decision, you agreed to perform the requested study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: OECD TG 408) in rats.

Notes for your considerations:

The results of the Sub-chronic toxicity study (90-day), among other relevant information, are considered crucial to inform and decide on the study design of the extended one-generation reproductive toxicity study (EOGRTS). Therefore you may also consider updating your testing proposal for an Extended one-generation reproductive toxicity study in light of the results of the requested Sub-chronic toxicity study (90-day). The testing proposal should include a justification for its study design following ECHA *Guidance on*

information requirements and chemical safety assessment Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

6. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity studies (test method OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

ECHA notes that the technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

You have sought to adapt the information requirement for a pre-natal developmental toxicity study in a second species according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for pre-natal developemtnal studies (similar to OECD TG 414) with the analogue substance, N,N'-bis(2-aminoethyl)ethane-1,2-diamine (CAS RN 112-24-3; EC number 203-950-6) ([redacted]1984[redacted]1988).

However, as explained above in Appendix 1, "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comment to the draft decision, you agreed to perform the requested study, provided that - after the study results of the studies as per request in section 2, 3, 4 and 5 will become available - the possibility of waiving or applying read across for the Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test 1 method: OECD TG 414) in a second species (rat or rabbit), oral route, turns out not to be possible.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a second species (rabbit) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section

8.7., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species with other available information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 25 October 2018.

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.

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 proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.