~~Confidential~~

Helsinki, 06 June 2023

**Addressees**
Registrant of 10563-29-8_JS as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
23/04/2013

**Registered substance subject to this decision ("the Substance")**
Substance name: n'-(3-aminopropyl)-n,n-dimethylpropane-1,3-diamine
EC number/List number: 234-148-4

**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 ***13 June 2025***.

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

**Information required from all the Registrants subject to Annex VII of REACH**

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

2. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201)

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

**Information required from all the Registrants subject to Annex VIII of REACH**

4. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity requested below

5. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats. Due to reasons explained in Section 5 of Appendix 1, the test sample must be chosen to minimise gastrointestinal irritation and to allow investigation of intrinsic properties at adequate dose levels. This could be achieved by testing a neutral salt of the Substance.

The reasons for the request(s) are explained in Appendix 1.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

**How to comply with your information requirements**

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

**Failure to comply**

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

## Appendix 1: Reasons for the request(s)

**Contents**

**Reasons common to several requests**

*0.1. Read-across adaptation rejected*

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5.:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

*0.1.1. Predictions for toxicological properties*

5 You provide a read-across justification document in IUCLID Section 13.2.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

- DETA; Diethylenetriamine, EC 203-865-4 (source substance 1);
- DPTA; Dipropylenetriamine, EC 200-261-2 (source substance 2);
- [redacted]Diethylenetriamine dihydrochloride, CAS NR [redacted] (source substance 3).

7 You provide the following reasoning for the prediction of toxicological properties:

- "*This read-across is based on the hypothesis that source and target substances have similar chemical structure (low molecular weight alkyl amines), similar physicochemical properties and similar toxicological profiles*"
- "*A structure that contains only aliphatic organic substituents*"
- "*Three functional amine groups those are primary and secondary or primary, secondary and tertiary in nature*"
- "*Elemental compositions of only carbon, hydrogen and nitrogen*"
- "*A incremental change between DETA, DPTA and DMAPAPA consisting of increasing number of carbon atoms*"
- "*Molecular weights of < 200 Daltons*"

8 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

9 We have identified the following issue(s) with the prediction(s) of toxicological properties:

*0.1.1.1. Missing supporting information to compare properties of the substances(s)*

10 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6., Section R.6.2.2.1.f.).

11 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

12 For the source substances, you provide repeated dose toxicity studies (source substances 1 – 3) used in the prediction in the registration dossier. In addition, you provide a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) on the source substance 2. Apart from these studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects for repeated dose and reproductive toxicity.

13 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across for the information requirements listed above.

*0.1.1.2. Inadequate or unreliable studies on the source substance(s)*

14 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;

(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

15 Specific reasons why the studies on the source substances do not meet these criteria are explained further below under the applicable information requirement section 4. Therefore, no reliable predictions can be made for these information requirements.

*0.1.2. Conclusion on the read-across approach*

16 Based on the above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

**Reasons related to the information under Annex VII of REACH**

## 1. Short-term toxicity testing on aquatic invertebrates

17 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

*1.1. Information provided*

18 You have provided a short-term toxicity study on daphnia magna (1992) with the Substance.

*1.2. Assessment of the information provided*

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

19 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

*Characterisation of exposure*

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

*Reporting of the methodology and results*

b) the number of immobilised daphnids is summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

c) pH measured at least at the beginning and end of the test is reported.

20 In the provided study:

*Characterisation of exposure*

a) no analytical monitoring of exposure was conducted;

*Reporting of the methodology and results*

b) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;

c) pH measured at least at the beginning and end of the test is not reported.

21 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, analytical monitoring of the test material in the exposure medium was not performed. The measured concentrations are needed to confirm that the applied nominal concentrations are correct and that any experimental error did not cause deviations from the nominal test material concentrations.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. The number of immobilised daphnids is not reported and it is

not possible to assess reliability of the calculated effective concentrations or confirm that the immobility in controls remained below 10%. In addition, pH or its variability during the test is not reported. The pH variability during the test should be reported that the guideline requirement on the allowed pH range can be confirmed.

22 On this basis, the specifications of OECD TG 202 are not met.

23 In your comments on the draft decision, you provided the missing information listed under a), b) and c) above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

24 Therefore, this information requirement is currently not fulfilled.

## 2. Growth inhibition study aquatic plants

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

### *2.1. Information provided*

26 You have provided a growth inhibition study on aquatic algae (2004) with the Substance.

### *2.2. Assessment of the information provided*

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

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

*Reporting of the methodology and results*

a) the test conditions are reported (*e.g.*, composition of the test medium);

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

28 In the provided study:

*Reporting of the methodology and results*

a) on the test conditions, you have not specified composition of the test medium;

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

29 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of tabulated data on the algal biomass, ECHA cannot assess whether the validity criteria of the test guideline were met and verify the interpretation of the results. In addition, the composition of the test medium is not reported, and it is not possible to assess its impact on the reliability of the study.

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

31 In your comments on the draft decision, you provided the missing information listed under a) and b) above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

32 Therefore, the information requirement is currently not fulfilled.

## 3. Ready biodegradability

33 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

### *3.1. Information provided*

34 You have provided:

(i) a ready biodegradability study (1992) with the Substance;

(ii) a ready biodegradability study (1990) with the Substance.

### *3.2. Assessment of the information provided*

#### *3.2.1. The provided studies do not meet the specifications of the test guideline(s)*

35 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following specifications must be met:

*Technical specifications impacting the sensitivity/reliability of the test*

a) the test temperature is 22°C ± 1°C;

*Reporting of the methodology and results*

b) the suspended solid concentration is reported;

c) the bacterial cell density of the inoculum (cells/mL) is reported;

d) the concentration of added inoculum is ≤ 0.5 mL/L;

e) the pH and the test temperature are reported;

f) the number of replicates is reported;

g) the measured dilution water DOC is reported;

h) the results of measurements at each sampling point in each replicate is reported in a tabular form.

36 In studies (i) and (ii):

*Technical specifications impacting the sensitivity/reliability of the test*

a) the test temperature varied from 20 to 25°C ± 1°C in *study (i)*;

*Reporting of the methodology and results*

b) the suspended solid concentration is not reported in *study (i)*;

c) the bacterial cell density is not reported in *study (ii)*;

d) the concentration of added inoculum is not reported in *study (ii)*;

e) the pH or its adjustment are not reported in *study (i) and (ii)*, the test temperature is not reported in *study (ii)*;

f) the number of replicates is not reported in *study (ii)*;

g) the measured DOC of the dilution water is not reported in *study (ii)*

h) the results of measurements at each sampling point in each replicate is not reported in a tabular or any other form in *study (i) and (ii).*

37 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the results of study (i). More specifically, in study (i) the test temperature was higher than required by the test guideline. The applied non-standard test temperature may have influenced biodegradation rate of the test material by altering e.g. bacterial cell activity and degradation kinetics. Therefore, the result of the study cannot be considered to be sufficiently reliable to conclude on ready biodegradability.
- the reporting of the studies is not sufficient to conduct an independent assessment of its reliability. In both studies, no detailed data is reported to demonstrate that the difference of extremes of replicate values (defined above) met the validity criterion of the test guideline. Furthermore, in study (i) the concentration of suspended solids is not reported and as a result it is not known if the test guideline requirement on maximum suspended solid concentration is met. In study (ii) the applied bacterial cell density is not provided and it is not possible verify that the density followed the required density (approx. $10^5$ cells/mL) in the guideline. In study (i) and (ii) pH of the test medium is not reported and in study (ii) the test temperature is not reported. Both pH and temperature influence on degradation rate and they must be reported that the accordance with the standard conditions in the guideline can be assessed. Also, in study (ii) replication and the measured DOC are not reported and the information is needed to confirm that the guideline requirements were followed. In addition, the results of measurements at each sampling point for each replicate are not reported. Detailed reporting of the data is required that the variability of the results and degradation rate at different times of the test can be assessed. On this basis, the specifications of OECD TG 301 are not met.

38 In your comments on the draft decision, you provided the missing information for study (i) listed under a), b), e) and h) above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

39 Therefore, the information requirement is currently not fulfilled.

**Reasons related to the information under Annex VIII of REACH**

## 4. Short-term repeated dose toxicity (28 days)

40 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

### *4.1. Information provided*

41 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a sub-chronic toxicity study (1997) with the source substance Diethylenetriamine dihydrochloride, CAS NR [redacted];

(ii) a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (2012) with the source substance Dipropylenetriamine, EC 200-261-2 / DPTA;

(iii) Short-term repeated dose toxicity study (1970) with the source substance Diethylenetriamine, EC 203-865-4 / DETA;

(iv) Chronic toxicity study (1987) with the source substance Diethylenetriamine, EC 203-865-4 / DETA;

(v) Chronic toxicity study (1970) with the source substance Diethylenetriamine, EC 203-865-4 / DETA.

### *4.2. Assessment of the information provided*

#### *4.2.1. Read-across adaptation rejected*

42 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issue(s) addressed below.

##### *4.2.1.1. Inadequate or unreliable studies (i) and (iii) to (v) on the source substance(s)*

43 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed and cover an exposure duration comparable to or longer than the one specified in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 407. Therefore, the following specifications must be met:

a) testing is performed with at least three dose levels (unless conducted at the limit dose) and with concurrent controls;

b) at least 5 male and 5 female animals are used for each concentration and control group;

c) dosing of the test substance is performed daily for a minimum of 28 days;

d) body weight is measured at least weekly;

e) clinical signs (nature, severity, and duration) are observed daily and functional observations (i.e. sensory activity, grip strength and motor activity) are made during the fourth exposure week

f) haematological and clinical biochemistry tests are performed;

g) terminal organ and body weights are measured;

h) gross pathological examinations, including incidence and severity, are performed.

i) full histopathology, including incidence and severity, is performed.

44 In the studies (i) and (iii) to (v):

a) only one dose level was described for the studies (iii) - (v), also not clear whether concurrent controls were included in the study (iii);

b) only 2 males and 2 females were included in the test group in the study (iii),

c) the exposure duration was limited to 21 days in the study (iii) and dosing only 3 times per week in the study (iv);

d) body weights were not assessed in the studies (iii) and (iv);

e) the following functional aspects were not assessed: sensory activity, grip strength and motor activity in the studies (i) and (iii) – (v);

f) haematology was not performed in the study (iv) and clinical biochemistry was not performed in the studies (iii) – (v).

g) terminal organ weights and organ/body weight ratios were not recorded in the studies (iv) and (v);

h) no information on the gross pathology in the studies (iv) and (v);

i) limited histopathological examination in the study (iv) as only skin, liver, kidneys and lungs examined items were not studied: incidence and severity; no clear what histopathological examinations were performed in the studies (iii) and (v).

45 Therefore, the studies (i) and (iii) to (v) submitted in your adaptation, as currently reported in your dossier, do not provide an adequate and reliable coverage of the key parameter(s) and also studies (iii) and (iv) do not cover an exposure duration comparable to or longer than the one specified in the corresponding OECD TG.

46 Therefore, the information requirement is not fulfilled.

*4.3. Specification of the study design*

47 When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

48 The study design is addressed in request 5.

49 In your comments on the draft decision, you agree to perform the requested study.

## 5. Screening for reproductive/developmental toxicity

50 A screening study for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

*5.1. Information provided*

51 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a screening study for reproductive/developmental toxicity (2012) with the source substance Dipropylenetriamine, EC 200-261-2 / DPTA.

*5.2. Assessment of the information provided*

*5.2.1. Read-across adaptation rejected*

52 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

53 Therefore, the information requirement is not fulfilled.

*5.3. Specification of the study design*

54 A study according to the test method EU B.64/OECD TG 422 must be performed in rats.

55 The Substance is a corrosive liquid, and you apply a self-classification as Skin Corr. 1A (H314). Therefore, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1, and Guidance on IRs and CSA, Section R.7.6.2.3.2.). However, testing at concentration/dose levels causing corrosivity must be avoided. Testing of neutral salts of alkaline or acidic substances is therefore more appropriate as it allows the investigation of intrinsic properties at adequate dose levels.

56 The test sample must be chosen to minimise gastrointestinal irritation and to allow investigation of intrinsic properties at adequate dose levels. This could be achieved by testing a neutralised salt of the Substance.

57 If the Screening for reproductive/developmental toxicity study submitted in response of this decision does not deliver reliable results because of gastrointestinal irritation, further testing may be considered necessary in order to investigate the intrinsic properties at adequate dose levels. Therefore, if the Member State competent authorities consider that a concern must be clarified in that respect, they may decide to require further testing under Substance Evaluation.

58 In your comments on the draft decision, you agree to perform the requested study.

**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 14 March 2022.

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 you of the draft decision and invited you to provide comments.

In your comments on the draft decision, you require an extension of the deadline from 24 to 30 months based on the workload of the laboratories. ECHA notes that the standard deadline was already exceptionally extended by 12 months as described above.

ECHA took into account your comments and did not amend the requests or the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

**Appendix 3: Addressee(s) of this decision and their corresponding information requirements**

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa.

| 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

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

References to Guidance on REACH and other supporting documents can be found in Appendix 1.