~~Confidential~~

Helsinki, 26 May 2023

Addressees
Registrants of JS_1187441-10-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
30/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, reaction products with phosphorus oxide
EC number/List number: 810-703-1

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 ***1 September 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. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020))

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310) on relevant constituent(s)/fraction(s) of the Substance, as described under the corresponding appendix on reasons for the request

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

3. *In vitro* micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional control group for aneugenicity on top of the control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei

4. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

5. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111)

The reasons for the requests 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 related to the information under Annex VII of REACH

1. *In vitro* gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

2 You have provided an in vitro gene mutation study in bacteria (2004) 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

3 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the number of revertant colonies per plate for the concurrent negative and positive control is inside the historical control range of the laboratory;

b) the mean number of revertant colonies per plate is reported for the treated doses and the controls;

c) negative results are confirmed in a repeat experiment with modification of study parameters to extend the range of conditions assessed, or a justification why confirmation of negative results is not considered necessary is provided.

4 In study the provided study:

a) no positive and negative historical control data was included in the study.

In your comments to the draft decision, you provide information on positive and negative historical control data;

b) the mean number of revertant colonies per plate for the treated doses and the controls was not reported.

In your comments to the draft decision, you provide information on the mean number of revertant colonies per plate for the treated doses and the controls;

c) no repeat experiment was performed to confirm the negative results and no justification was provided.

In your comments to the draft decision, you provide information on the repeat experiment to confirm the negative results of the first assay.

5 The information provided does cover the specifications required by the OECD TG 471.

6 The information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

7 Therefore, the information requirement is currently not fulfilled.

1.3. Specification of the study design

8 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471) is considered suitable.

1.4. Information regarding data sharing

9 Other registrants' registration for the Substance contains an in vitro gene mutation study in bacteria (2013) 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).

2. Ready biodegradability

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

2.1. Information provided

11 You have provided a ready biodegradability study according to OECD TG 301D (2016) with the Substance.

2.2. Assessment of the information provided

2.2.1. Ready biodegradation tests are normally intended for pure substances

12 The revised introduction to the OECD Guidelines For Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. which are composed of constituents expected to show similar degradation kinetics). However, such tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For complex substances, a single positive ready biodegradability test does not allow to conclude that all constituents are readily biodegradable. Therefore, such information does not fulfil the information requirement.

13 You have provided a study conducted on the Substance as a whole. Based on this single study, you conclude that the Substance is to be regarded as readily biodegradable. In Section 1.1. of your dossier you describe the Substance as UVCB. In Section 1.2, you describe the composition of the Substance as follow:

- 2-(Phosphonooxy)ethyl methacrylate (EC 246-342-6 / CAS RN 24599-21-1)
- Bis(methacryloyloxyethyl) hydrogen phosphate (EC 251-040-2 / CAS RN 32435-46-4)
- Trimer of 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate (EC number or CAS RN not provided)
- An undefined pyrophosphate mixture with constituents having molecular weight ranging from 178 to 626 g/mol

14 The Substance is a complex substance and contains constituents with significant structural differences described above. Therefore, the provided study does not provide unequivocal conclusion that all constituents can safely be regarded as readily biodegradable.

2.2.2. The provided study does not meet the specifications of the test guideline

15 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 solutions are prepared using an appropriate nutrient medium, which includes ammonium chloride;

Reporting of the methodology and results

b) the inoculum concentration in the test vessel is reported as cells/L in the test vessel and as volume of added inoculum (for OECD TG 301D, the concentration of the inoculum is set to reach a bacterial cell density of 10^4 to 10^6 cells/L in the test vessel. The volume of added inoculum is ≤ 5 mL);

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

16 In the provided study:

Technical specifications impacting the sensitivity/reliability of the test

a) you report that "*Ammonium chloride was not added to the river water to prevent nitrification*";

Reporting of the methodology and results

b) no information is reported on the inoculum density used to conduct the test;

c) the results of measurements at each sampling point in each replicate is not reported.

17 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not used a standard test medium as you report that Ammonium chloride was omitted from the test medium. This deviation is no considered acceptable as it may artificially reduce oxygen consumption and lead to underestimating respiration in the inoculum blank (i.e. one of the validity criteria of OECD TG 301D). ECHA notes that the validity criteria of the OECD TG 301D were set based on the use of a test medium that does contain ammonium chloride and that the method was validated through ring testing. High inoculum blank respiration (i.e. above the validity criteria of OECD TG 301D) could indicate that the inoculum density and/or the inorganic matter introduced with the inoculum was too high. This could indicate that the conditions of the test were too favourable. By omitting ammonium chloride a direct comparison with the OECD TG 301D limit value for inoculum blank respiration is no longer possible.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, as you have not reported inoculum concentration in the test vessel in cells/L and in volume of added inoculum, it is not possible to verify if the inoculum density was low enough to be consistent with the specifications of OECD TG 301D. Then, as you have not provided the results of measurements at each sampling point in each replicate, ECHA cannot conduct an independent assessment of whether the test met the validity criteria of the OECD TG 301D and of the interpretations of the results of the study.

18 On this basis, the specifications of OECD TG 301D are not met.

19 Therefore, the information requirement is not fulfilled.

20 In your comments on the draft decision, you agree with ECHA's assessment.

2.3. Study design and test specifications

21 For the reasons provided above, testing on the Substance as a whole does not fulfil the information requirement. For the generation of information on ready biodegradability, you must consider the level of information required for the purposes of classification and labelling and, if applicable to your registration, the PBT/vPvB assessment and the exposure assessment/risk characterisation. In order to conclude on which of constituents of the Substance are and which are not readily biodegradable, you may have to consider conducting more than one study using selected individual constituents and/or fractions. If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that their constituents within chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole in terms of degradation kinetics.

22 Justification for selection of relevant constituent and/or fractions for the testing, must consider degradation kinetics of constituents of the Substance based, as minimum, on the similarity/differences of the chemical structures and the physico-chemical properties of constituents of the Substance. For that purpose, tools and approaches mentioned in Guidance on IRs and CSA, Sections R.7b and R.11 should be considered.

2.4. Information regarding data sharing

23 Other registrants' registration for the Substance contains a ready biodegradability study (2013) 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 (see Guidance on data-sharing for any support).

24 You stated that "[a]*s the opting out registrant has a valid biodegradation study, it was agreed to use this study which we will obtain access to according to fair cost- and data-sharing principle*".

25 ECHA takes note of your intention to rely on the information submitted by an opt-out member of the joint submission. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

Reasons related to the information under Annex VIII of REACH

3. *In vitro* micronucleus study

26 An in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

3.1. Information provided

27 You have provided an in vitro cytogenicity study in mammalian cells (OECD 473, 2007, report number [redacted]) with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the specifications of the test guideline

28 To fulfil the information requirement, the study has to be an in vitro chromosomal aberration test or an in vitro micronucleus test conducted in mammalian cells. The study must comply with the OECD TG 473 or the OECD TG 487, respectively (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 300 well-spread metaphases are scored per concentration;

b) the positive controls induce responses compatible with those generated in the historical positive control database;

c) data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures is reported;

d) to conclude on a negative outcome, a negative response is obtained in all three experimental conditions described in paragraph 28 of OECD TG 473, using a short-term treatment with and without metabolic activation and long-term treatment without metabolic activation.

29 In the provided study:

a) 200 metaphases (i.e., less than 300 metaphases) were scored per concentration;

b) a historical positive control database was not provided;

c) data on the cytotoxicity and/or the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures were not reported;

d) one experimental condition described in paragraph 28 of OECD TG 473 (i.e., a long-term treatment without metabolic activation) is missing to conclude on a negative outcome.

30 The information provided does not cover the specifications required by the OECD TG 473.

31 Therefore, the information requirement is not fulfilled.

32 In your comments to the draft decision you agree with ECHA's assessment and agree to conduct a new study. ECHA reminds you that, as indicated in the notification letter accompanying the present decision, the same study has also been requested from an opt-out registrant in a draft decision concerning a testing proposal. You must make every effort

to reach an agreement on the sharing of data and costs (see Guidance on data-sharing for any support).

3.3. Specification of the study design

33 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the in vitro mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the in vitro mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations in vitro. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2). Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential in vitro. Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

3.3.1. Assessment of aneugenicity potential

34 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

35 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

4. Screening study for reproductive/developmental toxicity

36 A screening study for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

4.1. Information provided

37 You have provided a screening study for reproductive/developmental toxicity (2016) with the Substance.

4.2. Assessment of the information provided

4.2.1. The provided study does not meet the specifications of the test guideline

38 To fulfil the information requirement, a study must comply with EU B.63/OECD TG 421 or EU B.64/OECD TG 422 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) body weights are measured at least weekly;

b) food consumption is measured at least weekly;

c) terminal organ and body weights are reported;

d) parameters for sexual function and fertility such as lactation is reported.

39 In the provided study:

a) data on weekly body weights, body weight changes are missing.

In your comments to the draft decision, you provide information on body weights and body weight changes.

b) data on weekly food consumption are missing.

In your comments to the draft decision, you provide information on weekly food consumption.

c) terminal organ weights and organ/body weight ratios are not reported.

In your comments to the draft decision, you provide information on terminal organ weights and body weight ratios.

d) data on parameters for sexual function and fertility such as those for mating and fertility, duration of gestation, parturition and lactation are missing.

In the comments to the draft decision, you provide information on parameters for mating and fertility, duration of gestation and parturition but not on lactation.

40 The information provided does cover the specification(s) required by the OECD TG 422 (adopted 1996).

41 The information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

42 Therefore, the information requirement is currently not fulfilled.

4.3. Specification of the study design

43 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

44 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1).

45 Therefore, the study must be conducted in rats with oral administration of the Substance.

5. Hydrolysis as a function of pH

46 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

5.1. Information provided in your dossier

47 We understand that you have adapted this information requirement by using Column 2 of Annex VIII, Section 9.2.2.1. To support the adaptation, you have provided following justification: "the study does not need to be conducted because the substance is readily biodegradable".

5.2. Assessment of the information provided in your dossier

5.2.1. The conditions of Annex VIII, Section 9.2.2.1., Column 2 are not met

48 Under Annex VIII, Section 9.2.2.1., Column 2, first indent, the study may be omitted if the substance is readily biodegradable.

49 You claim that the Substance is readily biodegradable based on a ready biodegradability study on the Substance according to OECD TG 301D (2016).

50 For the reasons explained under request 2, the information on ready biodegradability is rejected.

51 Therefore, you have not demonstrated that the Substance is readily biodegradable and your adaptation is rejected.

52 Therefore, the information requirement is not fulfilled.

5.3. Information provided in your comments to the draft decision

53 In your comments to the draft decision you agree with ECHA's assessment. However, you indicate your intention to invoque an adaptation under Annex XI, Section 2 ('Testing is technically not possible'). In support of your adaptation, you provide the following justification:

(1) "*The substance is a multi-constituent substance and not a pure substance with a purity of 'at least [redacted]%'; it furthermore contains structurally related constituents*" and "*Hydrolyzed, formed hydrolysis products could be the same as already present constituents of the substance, which will make reliably monitoring the decay of these constituents impossible*".

(2) "*Despite the availability of specific analytical methods to quantify the concentrations of the main constituents (possibly down to 10 % or less of the initial concentration), due to the possibility of an equilibrium reaction during degradation/formation of the main constituents, these methods were not considered suitable to support the hydrolysis test*".

(3) "*The expected hydrolysis product methacrylic acid (MA) is known to easily polymerize in the presence of (strong) acids and/or at elevated temperatures. This polymerization is also dependent on monomer concentration and ionic strength of the test solution. Considering that phosphoric acid is typically present in this UVCB substance (2-10%), and that the hydrolysis preliminary tests is conducted at 50°C, polymerization of MA with itself, or other reactive groups, is expected to occur*". You refer to the publication by [redacted] (1960), [redacted] (2017) and [redacted] (2007) to support your claim.

5.4. Assessment of the information provided in your comments to the draft decision

54 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 111, more specifically on the technical limitations of a specific method, shall always be respected.

55 The OECD TG 111 provides in particular that this test is applicable to chemical substances (unlabelled or labelled) for which an analytical method with sufficient accuracy and

sensitivity. It is applicable to slightly volatile and non-volatile compounds of sufficient solubility.

56 You claim that the study is no technically feasible for the reasons already described in Section 5.3. above.

57 In your dossier, you report that the Substance is well soluble and has negligible volatility. This indicate that the Substance falls in the generic description of the applicability domain of the test method. With regard your justification as to why the test cannot be conducted:

- on point (1) above, the fact that the Substance includes more than one constituent is not a valid basis to omit this information requirement. Appendix 4, Section 2.1 of this draft decision already describes approaches to conduct environmental testing for substances containing multiple constituents;
- on point (2) above, you have provided no experimental information to support your claim;
- on point (3) above, the formation of hydrolysis product subject to some degree of polymerization is not a valid basis to omit the test. Polymerisation of the expected hydrolysis product methacrylic acid may complicate the identification of final hydrolysis products (*i.e.*, Tier 3 test in the OECD TG 111). However, it is unclear why such observation would prevent from determining the hydrolysis constant of the parent compound(s) (*i.e.*, Tier 2 test in the OECD TG 111). Likewise, the fact that methacrylic acid polymerization rate varies with pH, temperature, and ionic strength, as described in the publication you referred to, does not constitute a valid justification as to why testing is not technically feasible.

58 Based on the above, your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method. Therefore, your adaptation is rejected.

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 25 August 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.

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

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;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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 constituenton the test results for the endpoint to be assessed. For example, if a constituent/of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent.

(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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as

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

far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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.

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).

2. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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