~~Confidential~~

Helsinki, 04 June 2024

Addressees
Registrants of JS_FullTHPS as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
07 July 2021

Registered substance subject to this decision ("the Substance")
Substance name: tetrakis(hydroxymethyl)phosphonium sulphate(2:1)
EC/List number: 259-709-0

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 ***11 March 2027***.

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).

2. 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

3. Transgenic rodent somatic and germ cell gene mutation assays (triggered by Annex VIII, Section 8.4., Column 2; test method: OECD TG 488) in transgenic mice or rats, oral route on the following tissues: liver and glandular stomach; duodenum must be harvested and stored for up to 5 years. Duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive.

   OR

   In vivo mammalian alkaline comet assay (triggered by Annex VIII, Section 8.4., Column 2; test method: OECD TG 489) in rats, or if justified, in other rodent species, oral route, on the following tissues: liver, glandular stomach and duodenum.

4. Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below.

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

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 requests
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)

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:

(i) an *in vitro* gene mutation study in bacteria (1990), key study, with the Substance;

(ii) an *in vitro* gene mutation study in bacteria (1980), supporting study, with the Substance;

(iii) an *in vitro* gene mutation study in bacteria (1990), supporting study, with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided studies do 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 test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

b) triplicate plating is used at each dose level;

c) concurrent strain-specific positive controls, both with and without metabolic activation, are included in each assay and the number of revertant colonies per plate induced by the positive controls demonstrates the effective performance of the assay. 2-Aminoanthracene should not be used as the sole indicator of the efficacy of the S9-mix. If 2- aminoanthracene is used, each batch of S9 should also be characterised with a mutagen that requires metabolic activation by microsomal enzymes, e.g., benzo(a)pyrene, dimethylbenzanthracene.

4 In studies (i), (ii) and (iii):

a) the test was performed with the strains Salmonella typhimurium TA1535, TA 1537, TA 1538, TA97, TA98, TA100 (i.e., the strain(s) E.coli WP2 uvrA or S. typhimurium TA 102 are missing), for studies (i), (ii) and (iii);

b) triplicate plating was not used at each dose level, for studies (i), (ii) and (iii);

c) 2-aminoanthracene was the only positive control compound tested with metabolic activation, for studies (i) and (iii).

5 The information provided does not cover the specification(s) required by the OECD TG 471.

6 Therefore, the information requirement is not fulfilled.

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

2. Ready biodegradability

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

2.1. Information provided

9 In your dossier, you have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following experimental data:

(i) a study on Biodegradation in seawater according to OECD TG 306 (1994) with the Substance;
(ii) an inherent biodegradability study according to OECD TG 302B (1985) with the Substance.

10 In your comments to the draft decision, you provided a weight of evidence report which includes summaries of the following additional studies:

(iii) a simulation tests in freshwater/sediment under aerobic conditions according to EPA Guideline N 162-4 (1996) with the Substance
(iv) a simulation tests in freshwater/sediment under aerobic conditions anaerobic conditions according to EPA Guideline N 162-3 (1997) with the Substance.

2.2. Assessment of information provided

2.2.1. Weight of evidence adaptation rejected

11 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

12 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

13 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

14 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach.

15 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

16 In your comments to the draft decision, you provided a weight of evidence report. While the report considers the reliability of the source studies (i) and (ii), as well as of the additional studies (iii) and (iv), it does not address the relevance and coverage of the simulation studies (iii) and (iv) for concluding on the information requirement ready biodegradability. Furthermore, the weight of evidence report is currently not available in your registration dossier, hence the data gap remains.

17 Beside this critical deficiency, ECHA has also assessed the other aspects of your adaptation.

18 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 9.2.1.1. includes similar information that is produced by the OECD TG 301/310. OECD TG 301/310 requires the study to investigate the following key parameter:

a) the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation.

19 The sources of information (i) may provide relevant information on the above key parameter. However, the source of information (ii) does not inform on the above key parameter as it was conducted at an inoculum concentration (i.e. 0.5 g/L suspended solids) that is over 15 times higher than the maximum acceptable value indicated in ready biodegradability test guidelines.

20 The sources of information (iii) and (iv) provided in your comments investigate aerobic biodegradation under different inoculum conditions and test material concentrations compared to those specified in the OECD TG 301 or OECD TG 310. According to ECHA Guidance R.7b, ready biodegradation tests are considered stringent screening tests and a positive result in these tests can be considered indicative of rapid and ultimate degradation in most environments including biological sewage treatment plants. In studies (iii) and (iv), the inoculum originates from naturally occurring microorganisms from agricultural soils and the studies aim to simulate degradation under environment relevant conditions. Therefore, ECHA considers the studies (iii) and (iv) to be partially relevant for the weight of evidence adaptation.

21 However, the reliability of the source of information (i) is affected by deficiencies. These issues are described below.

2.2.1.1. Only one source of information provided

22 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information based on which a conclusion on the information requirement can be drawn.

23 In your dossier, you have only provided one source of information that provide information on the key parameter investigated in a ready biodegradability study. Therefore, independent of the issue identified under Section 2.2.1.2., as long as the dossier refers to only one relevant source of information, i.e., source of information (i), your adaptation does not meet this requirement of Annex XI, Section 1.2.

2.2.1.2. The provided source of information (i) does not meet the specifications of the test guideline

24 For a study according to OECD TG 306 using the closed-bottle method, the following specifications must normally be met:

a) if the test material is expected to be toxic to the inoculum, information on the toxicity of the substance to bacteria is needed for the correct interpretation of low biodegradation values. However, such information is not always sufficient for interpreting results obtained in the biodegradation test and a toxicity control, as described in paragraph 27 of the closed bottle method, is more suitable;
b) the results of measurements at each sampling point in each replicate is reported in a tabular form.

25 In the source of information (i)

a) you state that "*No biodegradation was observed (0%) after 28 days under the test*

conditions. However, a toxicity test performed with the test substance indicated that the test substance was inhibitory at the test concentration used". However, you have not reported the results of a toxicity control;

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

26 In your comments, you have provided further information on study (i) with regards to the toxicity control confirming that the substance had inhibitory effects at the test concentration (3.08 mg/L). You state that "*The available screening tests relevant for ready biodegradability and inherent biodegradability are invalidated due to toxicity of THPS towards the inoculum at the recommended test concentration*". However, no further data with regards to the results of measurements at each sampling point have been provided in the comments and in your dossier.

27 The missing information listed above affect significantly the reliability of this source of information and the weighing of the available information.

2.2.1.3. Conclusion of your weight of evidence adaptation.

28 The source of information (i) may provide relevant information on the above key parameter, however, ECHA understands that you consider that the study is not valid due to toxic effects of the Substance on the inoculum. In addition, the deficiency identified with the source of information (i) does not only significantly affect the reliability of the study, but also the overall weight of the study in the weight of evidence adaptation. With regards to the two additional studies that you provided they do not produce all the information to cover the key parameters of the screening tests OECD TG 301/310. You have not provided a justification how these simulation studies represent all those environment compartments that the ready biodegradation tests represent, nor is it explicitly explained which environment compartments are covered by the studies. In other words, you have not addressed the relevance and coverage of the additional information in your weight of evidence justification.

29 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for Ready biodegradability.

30 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

3. Transgenic rodent somatic and germ cell gene mutation assays or *in vivo* mammalian alkaline comet assay

31 Appropriate *in vivo* mutagenicity studies must be considered under Annex VIII, Section 8.4., Column 2 in case of a positive result in any of the *in vitro* genotoxicity studies under Annex VII or VIII.

3.1. Triggering of the information requirement

32 Your dossier contains positive results for the *in vitro* gene mutation study in mammalian cells ([redacted]) which raise the concerns for gene mutations.

33 Therefore, the information requirement is triggered.

3.2. Information provided

34 You have provided:

(i) an *in vivo* Rodent Dominant Lethal Test (1996) with the Substance.

3.3. Assessment of the information provided

3.3.1. Study not adequate for the information requirement

35 In order to be appropriate, according to the Guidance on IRs and CSA, Section R.7.7.6.3., the in vivo somatic cell genotoxicity study must address the specific concern raised by the in vitro positive result.

36 However, the *in vivo* study provided is not addressing the gene mutation concern raised by the *in vitro* data. Therefore, the provided *in vivo* test(s) is not appropriate.

37 Therefore, the information requirement is not fulfilled.

38 ECHA considers that an appropriate *in vivo* follow up genetic toxicity study is necessary to address the concern identified *in vitro*.

3.4. Test selection

39 According to the Guidance on IRs & CSA, Section R.7.7.6.3., either the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) or the transgenic rodent somatic and germ cell gene mutation assay ("TGR assay", OECD TG 488) are suitable to follow up a positive *in vitro* result on gene mutation.

3.5. Study design

3.5.1. Comet assay

40 In case you decide to perform the comet assay, according to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified (OECD TG 489, paragraph 23).

41 Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

42 In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as

sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

3.5.1.1. Germ cells

43 You may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other aforementioned tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells in the comet assay, you should consider analysing the slides prepared with gonadal cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

3.5.2. TGR assay

44 In case you decide to perform the TGR assay, according to the test method OECD TG 488, the test must be performed in transgenic mice or rats.

45 Also, according to the test method OECD TG 488, the test substance is usually administered orally.

46 Based on the OECD TG 488, you are requested to follow the 28+28d regimen, as it permits the testing of mutations in somatic tissues and as well as in tubule germ cells from the same animals.

47 According to the test method OECD TG 488, the test must be performed by analysing tissues from liver, as slowly proliferating tissue and primary site of xenobiotic metabolism, and from glandular stomach and duodenum, as rapidly proliferating tissue and site of direct contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for mutagenicity at the site of contact in the gastro-intestinal tract. However, duodenum must be stored (at or below −70 ºC) until the analysis of liver and glandular stomach is completed; the duodenum must then be analysed, only if the results obtained for the glandular stomach and for the liver are negative or inconclusive.

3.5.2.1. Germ cells

48 You may consider collecting the male germ cells (from the seminiferous tubules) at the same time as the other tissues, to limit additional animal testing. According to the OECD 488, the tissues (or tissue homogenates) can be stored under specific conditions and used for DNA isolation for up to 5 years (at or below −70 ºC). This duration is sufficient to allow you or ECHA to decide on the need for assessment of mutation frequency in the collected germ cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

49 In your comments to the draft decision, you agree to perform the "*In vivo* mammalian alkaline comet assay" (OECD TG 489).

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

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

4.1. Information provided

51 You have provided in your dossier:

(i) a sub-acute toxicity study (1989) with the Substance;

52 You have provided in your comments to the draft decision:

(ii) a sub-chronic toxicity study (1990) in rat, with the Substance;

(iii) a sub-chronic toxicity study (2006) in dog, 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

53 To fulfil the information requirement, a study must comply with the OECD TG 407 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) haematological and clinical biochemistry tests are performed as specified in paragraphs 32-39 of OECD TG 407;

b) full histopathology, including incidence and severity, is performed as specified in paragraphs 47-49 of OECD TG 407.

54 In study (i):

a) haematology and clinical biochemistry were not performed: incidence and severity with relevant base-line values;

b) the following histopathology items were not studied: incidence and severity.

55 The study (i) does not cover the specifications required by the OECD TG 407.

56 In your comments to the draft decision, you provided studies (ii) and (iii) which would fulfil the information requirement. 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.

57 Therefore, the information requirement is not fulfilled.

4.3. Study design

58 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.).

59 The study design is addressed in request 5.

5. Screening study for reproductive/developmental toxicity

60 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

61 In your dossier, you have adapted this information requirement by using Annex VIII, Section 8.7.1., Column 2. To support the adaptation, you have provided the following information:

(i) Oral (gavage) teratology study in the rat (1991) with the Substance.

(ii) Oral (gavage) teratology study in the rabbit (1991) with the Substance.

62 You have provided in your comments:

(iii) an Oral Gavage Two Generation Reproduction Study (1999) in rat, with the Substance.

5.2. Assessment of the information provided

5.2.1. The conditions of Annex VIII, Section 8.7., Column 2 are not fulfilled

63 Under Annex VIII, Section 8.7., Column 2, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) referred to in Annex IX, point 8.7.2. is available or proposed by the registrant.

64 More specifically, to be adequate for the adaptation, the chronic toxicity study has to meet the requirements of the OECD TG 414. Therefore, the following specifications must be met:

c) at least 20 female animals with implantation sites for each test and control group are included;

d) the exposure duration is at least from implantation until one day prior to scheduled caesarean section;

65 The studies (i) and (ii) are described as pre-natal developmental toxicity studies.

66 However, in study (i) the duration of treatment was from day 6 to day 15 of gestation. Animals maintained until day 20 of gestation at which time they were killed.

67 In study (ii):

a) only 16 females were included in each test and control group;

b) the animals were treated only from day 7 to 19 of gestation and were observed until day 29 of gestation.

68 The information provided does not cover the specifications required by the OECD TG 414.

69 Therefore, the provided study is not reliable.

70 Based on the above, your adaptation is rejected.

71 In your comments to the draft decision, you provided study (iii) which would fulfil the information requirement. 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.

72 Therefore, the information requirement is not fulfilled.

5.3. Study design

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

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

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 (2023).
***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 22 February 2023.

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 request(s).

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

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

Appendix 3: Addressees of this decision and their corresponding information requirements

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

- the information specified in 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]

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 (https://echa.europa.eu/practical-guides).
(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.

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).