Addressee(s)
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22 August 2022

Registered substance subject to this decision ("the Substance")
Substance name: A dried sludge product resulting from the treatment process of domestic wastewater. The exact processes followed for the production of the dried sludge are: Preliminary + secondary treatment of the wastewater stream, thickening, dehydration and drying of the excess sludge.
EC/List number: 943-834-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by 10 June 2027.

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

Information required from all the Registrants subject to Annex IX of REACH
1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

Information required from all the Registrants subject to Annex X of REACH
5. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rat or rabbit)

The reasons for the decision(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 addressee(s) 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](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 decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

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\(^1\) 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 decision

Contents

Reasons related to the information under Annex IX of REACH .................. 4
1. Sub-chronic toxicity study (90-day) .................................................. 4
2. Pre-natal developmental toxicity study ............................................. 6
3. Long-term toxicity testing on aquatic invertebrates ............................. 7
4. Long-term toxicity testing on fish ...................................................... 8

Reasons related to the information under Annex X of REACH ............. 11
5. Pre-natal developmental toxicity study ............................................. 11

References .......................................................................................... 13
Reasons related to the information under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

1 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

1.1. Information provided

2 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

3 Your registration dossier does not include any information related to repeated dose toxicity.

4 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

5 ECHA received third party information concerning the testing proposal during the third-party consultation. The third party commented that the 'The composition of this material is highly variable but typically contains a high proportion of toxicologically inert organic matter (50-70%) and mineral components, with trace amounts of other components including heavy metals and numerous other known and unknown components. The majority of the known substance components are of low toxicity (some with nutritive value). While the presence of heavy metal components raises potentially concerns for toxicity, this could be addressed by reference to the available toxicological dataset for the individual components, also taking into account the level of variability in the content of individual components. Addressing the potential toxicity of the substance on this basis is scientifically sound, and avoids vertebrate testing with a complex UVCB substance which is unlikely to present a significant toxicity hazard.'

6 The information the third party provided does not include any study or information that would demonstrate that an adaptation under the specific rules in Annex IX, Section 8.6.2., column 2 or the general rules in Annex XI is met.

7 ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with the relevant conditions as established in Annex IX, Section 8.6.2., column 2 or in Annex XI.

8 Having regard of all the above, ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

1.2.1. Species

9 You proposed testing in the mouse.

10 According to the OECD TG 408, the rat is the preferred species to perform the study. If the parameters specified within OECD TG 408 are investigated in another rodent species, a detailed justification for the choice of species should be given, including adaptations to the parameters measured (OECD TG 408, paragraph 9).

11 You initially did not provide such a justification. Therefore, ECHA disagreed with your proposal and the study must be conducted in the rat.
In the comments to the draft decision, you provide a justification including the following arguments to use mouse as species in the OECD TG 408 study:

- ‘Mice are used in toxicological evaluation of chemicals and food ingredients and fall in the same category as rats in distinct guidelines. Numerous studies have demonstrated the high genetic similarity between mice and humans, particularly in genes related to metabolic processes, disease pathways, and immune responses. This genetic proximity makes mice a biologically relevant model for assessing toxicological responses in humans.’
- ‘Mice are smaller, reach sexual maturity earlier, and have shorter lifespans compared to rats. These characteristics reduce housing and maintenance costs, providing an economically viable option for toxicological research’.

The above two arguments are generic rather than substance-specific arguments. They do not scientifically justify why the use of mouse as a test species in the OECD TG 408 study, thereby accepting an increased variability in endpoint measurements, would provide more meaningful information than when rat is used.

You further argue that ‘the use of mice in accordance with the 3Rs principle (Replacement, Reduction, Refinement) aligns with ethical considerations by minimizing the number of animals required for toxicological studies’. However, you do not explain why the use of mice would minimise the number of animals. In fact, ECHA points out that the number of animals should not be reduced under the OECD TG 408 if mice would be used. ECHA further highlights that according to paragraph 9 in the OECD TG 408, the rat is the preferred test species, because ‘the use of smaller species may result in increased variability in endpoint measurements due to technical challenges of dissecting smaller organs’. This may compromise the later interpretation of the results and even lead to the need for an extension or repetition of a study for hazard assessment purposes.

Finally, you hypothesize that a higher oral bioavailability of the Substance, exhibiting a low solubility, could be achieved in mouse than in rat, because ‘mice have gall bladder and mice-specific mechanisms (collision transfer) that are related to bile acids metabolism, which may contribute to a higher oral bioavailability’. You thereby refer to the fact that the acute toxicity study that was conducted in rats rendered no toxicity. The lack of toxicity in the oral acute toxicity study with the Substance in rats does not inform on the bioavailability of the Substance in rats. Furthermore, you do not provide experimental-based evidence that supports your hypothesis or demonstrates that the oral bioavailability of the Substance is higher in mouse than in rat.

In conclusion, your justification does neither demonstrate that the use of mouse as test species in a study without modification of the test conditions under OECD TG 408 will provide more meaningful information for the hazard assessment nor that this would lead to a reduced number of animals. Therefore, ECHA maintains that rat as the preferred species under OECD TG 408 must be used.

1.2.2. Route of administration

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity (Guidance on IRs and CSA, Section R.7.5.4.3.2.).

1.3. Outcome

Under Article 40(3)(b) your testing proposal is accepted under modified conditions, and you are requested to conduct the test with the Substance, as specified above.
2. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

2.1. Information provided

You have submitted a testing proposal for a PNDT study according to the OECD TG 414 by the oral route with the Substance.

Your registration dossier does not include any information related to reproductive toxicity.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA received third party information concerning the testing proposal during the third-party consultation. The third party commented that the ‘The composition of this material is highly variable but typically contains a high proportion of toxicologically inert organic matter (50-70%) and mineral components, with trace amounts of other components including heavy metals and numerous other known and unknown components. The majority of the known substance components are of low toxicity (some with nutritive value). While the presence of heavy metal components raises potentially concerns for toxicity, this could be addressed by reference to the available toxicological dataset for the individual components, also taking into account the level of variability in the content of individual components. Addressing the potential toxicity of the substance on this basis is scientifically sound, and avoids vertebrate testing with a complex UVCB substance which is unlikely to present a significant toxicity hazard.’

The information the third party provided does not include any study or information that would demonstrate that an adaptation under the specific rules in Annex IX, Section 8.7, column 2 or the general rules in Annex XI is met.

ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with the relevant conditions as established in Annex IX, Section 8.7, column 2, or in Annex XI.

ECHA agrees that a PNDT study in a first species is necessary.

2.2. Specification of the study design

You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

2.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.
3. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5).

3.1. Information provided

You have submitted a testing proposal for a Daphnia magna reproduction test (test method: EU C.20/OECD TG 211).

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

3.2. Test selection and study specifications

The proposed Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

The Substance is difficult to test due to the low water solubility (<0.5 mg/L). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.
3.3. **Outcome**

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

**4. Long-term toxicity testing on fish**

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

**4.1. Information provided**

You have submitted a testing proposal for a Fish, Juvenile Growth Test (test method: OECD TG 215).

Your registration dossier does not include any information on long-term toxicity on fish.

ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that an appropriate study on long-term toxicity on fish is needed.

**4.2. Test selection and study specifications**

**4.2.1. Test selection**

The Fish Early Life Stage (FELS) toxicity test (test method: OECD TG 210) is the most suitable test guideline for addressing long-term toxicity on fish for most substances (ECHA Guidance R.7.8.2.).

As specified in ECHA Guidance R.7.8.2., the proposed Fish, Juvenile Growth Test (test method: OECD TG 215) is only considered as an acceptable test method if the following cumulative conditions are met:

- there are well founded justifications indicating that growth inhibition is the most relevant effect in fish, and
- the substance has a log Kow < 5.

In your registration dossier, you have not provided justification that growth inhibition is the most relevant effect in fish for the Substance.

Therefore, the OECD TG 215 has not been regarded as an acceptable test method for the Substance.

In the comments to the draft decision, you provided a justification that growth inhibition is the most relevant effect in fish for the Substance and therefore that the OECD TG 215 is the most suitable test method.

You provide two main arguments to justify the use of the OECD TG 215 test method:

- You state that the Substance is “characterized by a log Kow value below 5” suggesting that “it is less likely to bioaccumulate in aquatic organisms to a significant extent”. And you continue that the Substance “exhibits low solubility in water” and therefore be present in aquatic environment as undissolved particles or in a less bioavailable form. Based on above you conclude that the likelihood of
direct exposure of fish is reduced, and you consider that growth as a highly sensitive endpoint in fish toxicity testing is the critical endpoint to be tested for assessing potential risks of the Substance.

- You also refer to your testing proposal for long-term toxicity on aquatic invertebrates using OECD TG 211 test method with Daphnia magna and, based on four scientific papers you state that it is widely acknowledged that Daphnia species are highly sensitive to environmental contaminants. Based on this, you hypothesize that “Should the produced results indicate no toxicity of the Substance to these organisms in any of the tested concentrations and given that Daphnia magna is often more sensitive to chemical contaminants than fish, it could be strongly suggested that the Substance is unlikely to exert acute or chronic toxic effects on fish”.

However, the above arguments do not scientifically justify why the OECD TG 215 test method is more appropriate to investigate potential long-term hazardous effects in fish than the OECD TG 210 test method.

Your substance is a UVCB substance containing number of different organic and inorganic compounds. You report in your dossier that the logKow of the soluble part of the substance is -0.52. However, only few of the compounds of the UVCB substance are soluble and therefore you conclude that the partition coefficient of the whole substance should be considered indeterminate. Therefore, you have not actually demonstrated that logKow of all the constituents of your UVCB substance are below 5.

Furthermore, the reduced likelihood of direct exposure of fish is not a valid scientific argument to consider that growth in fish toxicity testing is the critical endpoint to be tested for assessing potential risks of the Substance. ECHA considers that for the endpoint of long-term toxicity testing on fish the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised eggs, through hatch to early stages of growth and it is therefore appropriate method to investigate potential hazardous effects caused by both direct and indirect exposure of fish.

As regards your statement that Daphnia species are highly sensitive and that potential lack of toxicity in Daphnia might indicate a lack of significant risk to fish species, ECHA finally does not consider that this provides any further justification for using an OECD TG 215 test method for fish toxicity. This is because aquatic invertebrates (e.g. Daphnia) and fish represent organisms at different trophic levels and the potential low toxicity in daphnids cannot be automatically extrapolated to fish. Furthermore, the main endpoints studied in an OECD TG 211 Daphnia test are the effects on reproduction and parent mortality though potential effects on growth can also be monitored. Therefore, any potential effects observed in the Daphnia test cannot be used as an argument to claim that growth inhibition is the most relevant effect for your substance and hence prefer OECD TG 215 fish growth inhibition test over OECD TG 210 FELS test.

In conclusion, your justification provided in your comments does not include proper scientific arguments demonstrating that growth inhibition is the most relevant effect in fish for your substance and OECD TG 215 is the most suitable test method.

Therefore, ECHA maintains that the long-term fish toxicity test must be conducted using the OECD TG 210 test method.

4.2.2. Study specifications

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under request 3, the Substance is difficult to test. Therefore, you must fulfil the requirements described in ‘Study design’ under request 3.
4.3. **Outcome**

Your testing proposal is rejected under Article 40(3)(d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.
5. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in two species is a standard information requirement under Annex X, Section 8.7.2. to REACH.

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement for pre-natal developmental toxicity at Annex X includes studies in two species but you have submitted a testing proposal for one species only. In case of a data gap for the second species, it is necessary to request a pre-natal developmental study in a second species as an additional test to ensure compliance with the information requirement.

5.1. Information provided

You have submitted a testing proposal for a PNDT study according to the OECD TG 414 only for a test in one species.

Regarding PNDT in a second species, you have provided an adaptation. You state that 'Results of the specific study will be used in order to derive an appropriate DNEL via extrapolation, in relation to prenatal developmental toxicity study in a second species (Rabbit). Comparison of this DNEL value with the results of the exposure assessment will be conducted in order to prove that the exposures are always well below the derived DNEL. In case that the derived Risk Characterisation Ratio is greater than 1, a testing proposal for "Prenatal Developmental Toxicity Study" in a second species will be submitted. In any case, the results of the prenatal developmental toxicity study of the first species will indicate the necessity of an additional test on a second species.'

ECHA understands you refer to Annex XI, Section 3.2(a) of substance-tailored exposure-driven testing. In order to omit testing, justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I, and all of the following conditions are fulfilled:

- the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5; and
- a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes.

Firstly, you have estimated exposure with a Tier 1 exposure tool (ECETOC TRA v. 3). In order to demonstrate the absence of or no significant exposure via inhalation or skin contact, measured data or higher tier exposure modelling must be used.

Secondly, a pre-natal developmental toxicity study in a second species is a standard information requirement at Annex X, unless one or more of the adaptations in Section 8.7 of Annex X or Annex XI apply, taking into account the results of the test in the first species or any other relevant available information. Currently, there is no suitable DNEL derived and risk characterisation is performed qualitatively.
You have not demonstrated that the results of the test in the first species or any other relevant available information enable adaptations in accordance with Section 8.7 of Annex X or Annex XI.

In the comments to the draft decision, you further reiterated your intention to adapt the pre-natal developmental toxicity study in a second species based on exposure considerations, according to Annex XI, Section 3 of REACH regulation. In the absence of existing supporting information and adequate documentation of such an adaptation, ECHA is however not yet in the position to evaluate it.

Therefore, your adaptation must be rejected on the basis of the available information.

ECHA concludes that there is a data gap for this information requirement.

5.2. Specification of the study design

Under the OECD TG 414, the rat or the rabbit are the preferred species (Guidance on IRs & CSA, Section R.7.6.2.3.2.). Therefore, a PNDT study according to the OECD TG 414 must be performed in rabbit or rat as the second species, depending on choice of species for the first PNDT study.

The oral route of administration is the most appropriate to investigate reproductive toxicity (Guidance on IRs & CSA, Section R.7.6.2.3.2.). Therefore, the study must be conducted using the oral route.

5.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to generate the additional information on the Substance, as specified above.

ECHA notes that the deadline to submit the requested information is set so that it allows sequential testing.
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.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).
  Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
- Chapter R.16 Environmental exposure assessment; ECHA (2016).

**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](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).


**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).
Appendix 2: Procedure

ECHA received your testing proposal(s) on 7 September 2022 and started the testing proposal evaluation in accordance with Article 40(1).

ECHA held a third-party consultation for the testing proposal(s) from 3 April 2023 until 22 May 2023. ECHA received information from third parties (see corresponding Appendix/Appendices).

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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 Annexes VII to X to REACH, for registration at more than 1000 tpa.

<table>
<thead>
<tr>
<th>Registrant Name</th>
<th>Registration number</th>
<th>Highest REACH Annex applicable to you</th>
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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.

(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

(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 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 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 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.

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.