~~Confidential~~

Helsinki, 18 April 2023

Addressee
Registrant listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
30/06/2021

Registered substance subject to this decision ("the Substance")
Substance name: [redacted]
EC/List number: [redacted]

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 ***25 April 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. Skin sensitisation (Annex VII, Section 8.3.)

   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and

   ii. only if the in vitro/in chemico test methods specified under point i.) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020)

3. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

5. 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)

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 of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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)

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Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

1 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

2 You have provided:

(i) Freund's complete adjuvant test ([redacted]) with paraffin solution of the Substance

1.2. Assessment of the information provided

1.2.1. Assessment whether the Substance causes skin sensitisation

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

3 To fulfil the information requirement, and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the EU Method B.6/OECD TG 406 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) a dose level selection rationale is provided;
b) the induction concentration is the highest causing mild-to-moderate irritation to the skin;
c) the challenge dose is the highest non-irritation concentration;
d) positive and negative controls are included to establish the sensitivity and reliability of the experimental technique.

4 In study (i) described as a Freund's complete adjuvant test:

a) no dose level selection rationale was provided, moreover it is not clear whether the concentration used in the study were calculated using 100% or concentration from the 6% solution in paraffin oil;
b) the concentration used for induction did not cause mild-to-moderate irritation and no justification was provided why higher concentrations were not used;
c) the challenge concentration (6% of the Substance in paraffin oil) was not the highest non-irritating concentration, as it was indicated that the dose of 25% in paraffin oil used for induction did not cause irritation;
d) no information on positive and negative control group(s) were provided. In addition, the negative control group appeared to be 100% paraffin, although challenge concentration should be used as negative control.

5 In your comments to the draft decision, you state that 6% concentration was chosen as this was the maximum concentration used in [redacted] products sold at the test times and that this concentration would simulate the real condition of use and exposure to the product. ECHA notes that, based on your comments, the test was designed to investigate the safe use of the Substance [redacted] rather than to investigate the intrinsic properties of the Substance as required for the purpose of hazard identification, as specified under REACH. For hazard identification purposes the concentrations used in the OECD TG

406 are the following: concentration causing mild to moderate irritation for induction (both intradermal and topical), unless neat substance does not cause irritation, highest non-irritating concentration for challenge. Same test conditions are also described in the Magnusson and Kligman method (1969) for liquid substances.

6 In your comments related to the negative control group, you reiterate that paraffin oil was used as a negative control group. ECHA notes that in the OECD TG 406, negative control group should be the same exposure condition to naïve animals that is applied to the challenge control group. Therefore, the negative control group data, as presented currently does not meet the OECD TG 406 criteria. Same test conditions for challenge exposure is also described in the Magnusson and Kligman method (1969) for liquid substances.

7 The information provided does not cover the specifications(s) required by OECD TG 406 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

1.2.2. No assessment of potency

8 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

9 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1. above), this condition cannot be assessed.

10 On this basis, the information requirement is not fulfilled.

2.3 Specification of the study design

11 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

12 In your comments to the draft decision, you indicate that, due to substance properties, the requested *in chemico/in vitro* methods may not be feasible for the Substance. ECHA notes that, in case *in chemico/in vitro* methods are not applicable for the Substance, an *in vivo* study can be performed, as specified in Annex VII, Section 8.3.1, column 2. However, in such case a detailed justification of that needs to be included in the dossier (e.g., statements from the testing laboratory).

13 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated *in vitro/in chemico* data, *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. In vitro gene mutation study in bacteria

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

2.1. Information provided

15 You have provided:

(i) an *in vitro* gene mutation study ([redacted]) with the Substance.

2.2. Assessment of the information provided

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

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

a) two separate test conditions are assessed: in absence of metabolic activation and in presence of metabolic activation;
b) 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).

17 In study (i) described as an *in vitro* gene mutation study on bacteria:

a) only one test condition (in presence of metabolic activation) was assessed. Although in your comments to the draft decision claim that testing in only one condition was the practice at the time study (i) was performed, the OECD TG requires testing both in the absence and in presence of metabolic activation for a proper detection of mutagenic properties in bacteria. In addition, your claim that "*most of the sensitizing substances need metabolic activation in order to be detected with the Ames test"* is not supported by any evidence provided in your comments and seems to contradict your assumption that the Substance is not sensitising. Therefore, your justification for testing the Substance only in presence of metabolic activation is not valid.
b) the test was performed with the strains S. *typhimurium* [redacted] (i.e. the strain S. *typhimurium* [redacted] is missing). In your comments to the draft decision, you claim that the missing test strain does not affect the validity of the results. However, all five strains are needed to properly cover the different gene mutation mechanisms in bacteria described in OECD TG 471. Therefore, in the absence of results in the strain S. *typhimurium* [redacted], mutagenic effects of the Substance in bacteria cannot be excluded.

18 The information provided does not cover the specification(s) required by the OECD TG 471 Therefore, the information requirement is not fulfilled.

2.2.2. Lack of documentation of the models and the predictions

19 In the comments to the draft decision, without referring to a specific or general rule for adaptation under REACH, you state that four *in silico* models of the VEGA software give negative predictions for mutagenicity for all the constituents of the Substance. You further indicate your intention to provide these predictions as supporting information to study (i) in a future update of your registration dossier.

20 ECHA understands that you intend to use these data as part of a Weight-of-Evidence adaptation under Annex XI, Section 1.2 of REACH.

21 However, there is currently no information provided in your dossier or in your comments to the draft decision to support the adaptation of the current information requirement.

22 Therefore the data gap remains.

2.3. Specification of the study design

23 To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

3. Long-term toxicity testing on aquatic invertebrates

24 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1, Column 2) if the substance is poorly water soluble.

3.1. Triggering of the information requirement

25 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

26 You have provided information which indicates that the Substance includes constituents that are poorly water soluble. Based on QSAR calculation performed with EPISUITE WSKOW (v1.42) available in the registration dossier, the water solubility of the Substance is [redacted].

27 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

28 You have provided short-term toxicity values calculated with two different QSARs (Daphnia magna LC50 48h with DEMETRA 1.0.4 and EPA 1.0.7) but no information on long-term toxicity on aquatic invertebrates for the Substance.

29 Only acute toxicity values for several constituent are available in the substance dossier, without any documentation to support the calculation. No assessment for the reliability of the calculation is therefore possible.

30 Therefore, the information requirement is not fulfilled.

3.2. Study design and test specifications

31 The Substance is difficult to test due to the low water solubility [redacted] 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.

32 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).

33 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 (Guidance on IRs and CSA, 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.

34 In your comments to the draft decision you agreed with the assessment on the provided information but disagreed on the requested study design and test specifications. You argued that, considering the nature of the Substance, it will be difficult to directly measure the substance concentration variation during tests. [redacted]. You referred to OECD 23:2019, specifying the section on the water accommodated fraction (WAF) preparation.

35 ECHA considers your proposal not sufficiently scientifically justified. In the registration dossier (analytical information) suitable analytical methods to identify and quantify the single constituens are reported. Moreover, it is noted that OECD 23 (Guidance document on aqueous-phase aquatic toxicity testing of difficult chemicals) states, in paragraph 7.9.2.4(150), "*Chemical specific analysis (e.g. usually via GC- or HPLC-MS) of the test solution is usually required to demonstrate attainment of equilibrium and stability of the UVCB during the test, which can be done based on a temporal comparison of peak areas as described previously*". Your proposal [redacted] is therefore rejected.

4. Growth inhibition study aquatic plants

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

4.1. Information provided

37 You have adapted this information requirement by using Column 2 of Annex VII, Section 9.1.2. To support the adaptation, you have provided following information:

(i) the Substance is highly insoluble in water [redacted])

4.2. Assessment of the information provided

4.2.1. The provided adaptation does not meet the criteria of Annex VII, Section 9.1.2., Column 2

38 Under Annex VII, Section 9.1.2., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. Guidance on IRs and CSA, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely. Therefore, the justification must demonstrate very low water solubility and low likelihood to cross biological membranes. For

the latter, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

39 Unless it can reliably be demonstrated that aquatic toxicity is unlikely to occur, the Substance must be considered as poorly water soluble.

40 Your registration dossier provides:

- information on the solubility of the Substance in water [redacted] based on EPISUITE WSKOW (v1.42) QSAR).

41 Even though the water solubility of the Substance is low, the following does not support your justification:

- the physico-chemical indicators provided do not support your conclusion of hindered uptake because for the two main constituents of the Substance, Dmax ~ 17.4 Å, MW << 1100 g/mol, log Kow << 10, which do not support the hypothesis of hindered uptake[2].

42 Therefore, you have not demonstrated that toxicity is unlikely to occur and your adaptation is rejected and the Substance must be considered as poorly water soluble.

43 Therefore, the information requirement is not fulfilled.

4.3. Study design and test specifications

44 OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above in section 3.2, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' in the above reasons for Request 3.

5. Ready biodegradability

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

5.1. Information provided

46 You have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from EPISUITE BIOWIN V.4.10 (2019).

[2] Calculated by software Catalogic: Dmax [redacted] for the main constituent [redacted], and [redacted] for the other main constituent [redacted] For both constituents, MW: [redacted]

5.2. Assessment of information provided

5.2.1. (Q)SAR results only are not sufficient to fulfil the information requirement under Annex VII, Section 9.2.1.1.

47 Guidance on IRs and CSA, Section R.7.9.5.1. explains that (Q)SARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation. However, when no useful information on degradability is available (either experimentally derived or estimated), (Q)SAR predictions can be used as supporting evidence of that the substance is not rapidly degradable.

48 Your dossier only provides a (Q)SARs prediction. You have used this information to conclude that the Substance is readily biodegradable. As explained above, a (Q)SARs prediction alone is not adequate to conclude on the persistence of the Substance. Therefore, this information does not fulfil the information requirement and your adaptation is rejected.

49 In your comments to the draft decision you disagreed on the assessment on the provided information. You argued that the reported data are the results of 7 different models, each model has been run on all the constituents and the interpolation of the results from all the models allows to conclude (for all constituents but one) that they are ready biodegradable. You submitted a document reporting the output of the models and their interpolation. Moreover, you disagreed with the information requested, arguing that it is possible to integrate the submitted QSAR calculations with literature data on the individual constituents and/or read across from other similar substances. Furthermore, you claimed that it is not possible to satisfy the request to test the individual constituents, since the substance is not manufactured by mixing individual substances but by as esterification reaction [redacted], so the constituents are not "physically" available.

50 It is noted that, as explained in the Guidance on IRs and CSA (Section R.7.9.5.1), (Q)SARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation as a methodology, independently by the number of different models used in the calculations. It is also noted that, according to the guidance, (Q)SAR predictions can be used as supporting evidence to consider a substance as not readily or not rapidly degradable, whereas when a substance is estimated to biodegrade fast further information gathering is normally necessary. Besides, it is noted that, according to the calculations submitted with your comments, a constituent representing the [redacted]% of total composition resulted as not readily biodegradable. This contradicts your conclusion on the ready biodegradability of the substance. In the comment you claimed that (Q)SAR calculations can be integrated with additional information on the single constituents, however, you do not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome. You remain responsible for complying with this decision by the set deadline.

51 Therefore, the information requirement is not fulfilled.

5.3. Study design and test specification

52 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 ready biodegradability test does not allow to conclude on the ready biodegradability of all constituents and therefore, does not fulfil the information requirement. [redacted]

[redacted]. The Substance is a complex substance and contains constituents with significant structural differences described above. Since the solubility of constituents is low, the test needs to be compliant with a design taking into account the poor solubility.

53 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.

54 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.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

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

The compliance check was initiated on 14 September 2021.

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 or the deadline.

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.

In the comments on the draft decision, you requested an extension of the deadline from 24 to 36 months from the date of adoption of the decision. However, you have not provided any justification for the extension of the deadline by another 12 months. On this basis, ECHA has not modified the deadline.

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

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

Appendix 3: Addressee 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]

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[3].

(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.

This information is needed to assess 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[4].

[3] https://echa.europa.eu/practical-guides
[4] 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.