

Helsinki, 08 February 2022

Addressees

Registrants of JS_DiC16-18methylamine as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision

21/02/2018

Registered substance subject to this decision ("the Substance")

Substance name: N-C16-18 (even numbered)-alkyl-N-methyl, C16-18 (even numbered)-alkyl-1-amine

EC number: 627-132-7

CAS number: 1227096-04-9

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 the deadline of **16 May 2023**.

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

A. 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 (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and
 - ii. Only if the *in vitro/in chemico* test methods specified under point 1.i. 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. 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)
3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)
4. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301/B/C/D/F or OECD TG 310)

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annex VII of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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.

Authorised¹ under the authority of Mike Rasenberg, Director of Hazard Assessment

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 A: Reasons to request information required under Annex VII of REACH

1. Skin sensitisation

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

You have provided the following information:

- i. a key study according to OECD TG 406 with the Substance (█████ 1991)

In addition, we understand that you have submitted a justification for an adaptation under Annex VII, Section 8.3.1., column 2 according to which "A reliable without restriction Guinea-pig maximisation test is already available (█████, 1991)".

We have assessed this information and identified the following issue:

A) Assessment whether the Substance causes skin sensitisation

Non-compliant study

To be considered compliant and enable concluding whether the Substance causes skin sensitisation, a study has to meet the requirements of the EU Method B.6/OECD TG 406. The following key parameter(s) of this test guideline include:

- Positive control to establish the sensitivity and reliability of the experimental technique (OECD TG 406, paragraph 11)

However, in the provided study (i), no information on positive control group is provided.

Therefore the study (i) does not fulfil one of the key parameters set in the EU method B.6./OECD TG 406 and cannot be taken into account in the assessment of whether the Substance causes skin sensitisation.

In your comments on the draft decision, you agree that in the study (i) no information is included on the performance of a positive control. You also provide information on two reliability checks performed with dinitrochlorobenzene in guinea-pigs in the same testing facility as the study (i). Both reliability checks indicate adequate performance of the positive control. You propose to "update the current IUCLID summaries with the additional information on results on positive controls".

The information you have provided in your comments give information relating to the issues identified above for the study (ii). However, as the information is currently not available in your registration dossier, the non-compliance remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

Based on the above, the information provided in the technical dossier does not enable to conclude whether the Substance causes skin sensitisation.

B) Assessment whether the Substance can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A)*No assessment of potency*

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

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

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance for skin sensitisation, *in vitro/in chemico* studies (OECD TG 442C, OECD TG 442D and EU Method B.71/OECD TG 442E) are considered suitable. In case *in vitro/in chemico* methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (EU Method B.42/OECD TG 429) is considered as the appropriate study.

2. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2)

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

You have provided the following studies but no information on long-term toxicity on aquatic invertebrates for the Substance.

- i. an OECD TG 202 study (performed on the Substance), [REDACTED] 1990;
- ii. a non-guideline short-term toxicity study on aquatic invertebrates (with analogue N-methyldioctadecylamine, EC No 223-819-7), [REDACTED] 1991;
- iii. an ISO 6341 study (performed on the Substance), [REDACTED] 1991; and
- iv. another OECD TG 202 study (on the Substance), [REDACTED] 1990

We have assessed this information and identified the following issues:

- A. Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does 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 (ECHA Guidance R.7.8.5).

You have provided information which indicates that the Substance includes constituents that are poorly water soluble with your water solubility estimation of 5.36×10^{-7} mg/L using KOWIN model.

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

B. Absence of read-across documentation

In addition to the issue identified above, Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies) (ECHA Guidance R.6.2.6.1).

Study (ii.) has been conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance.

On this basis, the information requirement is not fulfilled.

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

Study design

The Substance is difficult to test due to the low water solubility (5,36 10⁻⁷ mg/L) and adsorptive properties (estimated log *K*_{ow} 16.78). 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.

Furthermore, 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. Growth inhibition study aquatic plants

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

You have provided the following information:

- i. a DIN 38412 study (with analogue N-methyldioctadecylamine, EC No 223-819-7), [REDACTED] 1991;
- ii. an OECD TG 201 key study (with the Substance), [REDACTED] 1990; and
- iii. another OECD TG 201 as supportive study (with the Substance), [REDACTED] 1991;

We have assessed this information and identified the following issues:

A. Absence of read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies) (ECHA Guidance R.6.2.6.1).

Study (i.) has been conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance.

B. Adequacy and reliability of source studies

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Requirements applicable to difficult to test substances

- if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions is determined;
- if the test material is forming dispersion or emulsions (e.g. certain surfactants, aliphatic amines), the dispersibility limit or the critical micelle concentration of the test material in the specific test solution under the test conditions is determined;
- demonstration that the stock solution preparation method:
 - 1) is of adequate quality (e.g. water solubility limit is reached when targeted), and
 - 2) allows to produce reproducible stock solutions (i.e. acceptable variation between preparations);

However, you have not provided the results of preliminary solubility study in the test medium and an adequate description of the test solutions preparation method, for any of the studies (i. ii. and iii.) and therefore they do not meet the requirements of the OECD GD 23;

Characterisation of exposure

- for some substances (e.g. adsorbing substances), the results may only be expressed based on nominal concentrations if the decrease in measured concentrations of the test substance during the test is not accompanied by a decrease in growth inhibition. If a reduction in growth inhibition is observed, a suitable model describing the decline of the concentration of the test material must be used;
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

However, from the information submitted in your dossier no analytical monitoring of exposure was conducted for any of the studies (i. ii. and iii.);

Reporting of the methodology and results

- the test design is reported (e.g., number of replicates, number of test concentrations and geometric progression used);
- the test conditions are reported (e.g., composition of the test medium, test temperature, test species, biomass density at the beginning of the test);
- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;
- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

However for the studies (i. ii. and iii.):

- the test design is not described, no information on the number of replicates is provided;
- microscopic observation of inoculum culture and at the end of the test is not reported;
- correlation between determination of biomass and with dry weight is not reported;
- tabulated data on the algal biomass determined daily for each treatment group and control are not reported,
- no analytical monitoring of exposure concentrations was reported;

In addition, for studies i. and ii., no biomass density was provided at the beginning of the test.

Furthermore, for studies i. and iii., on the test procedure, the composition of the test medium and the methods used to prepare stock and test solutions are not reported.

Validity criteria

- exponential growth in the control cultures is observed over the entire duration of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is $\leq 35\%$;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is $\leq 7\%$ in tests with [*Pseudokirchneriella subcapitata* / *Desmodesmus subspicatus*].

In the absence of tabulated data on the algal biomass determined daily for each treatment group and control, is it not possible to verify that the validity criteria of the test guideline were met and that the interpretation of the study results is appropriate.

- Based on the above listed deficiencies, none of the studies provided do meet the information requirement that are consistent with the specifications of the OECD TG 201.

On this basis, the information requirement is not fulfilled.

In your comments, you agree to perform a new OECD TG 201 using OECD GD 23 and WAF while acknowledging the difficulties and deficiencies of the monitoring and measurements in the Algae test performed by Gancet (2008).

ECHA notes your agreement to perform the test.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.3.

4. Ready biodegradability

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

You have provided:

- i. OECD TG 301 D key study with the Substance , [REDACTED] 1987;
- ii. OECD TG 301 B as other study with the Substance, [REDACTED] 1992.

We have assessed this information and identified the following issue:

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

Technical specifications impacting the sensitivity/reliability of the test

- The use of solvents or emulsifying agents is only permitted to increase the homogeneity of test solutions when testing poorly soluble solids. A blank run containing the auxiliary substance is included in the test design which must demonstrate that the solvent or emulsifier:
 - 1) is not toxic to bacteria, and/or
 - 2) is not biodegraded, and/or
 - 3) does not cause foaming under the test conditions;

However, the study (i.) you submitted shows that the substance is a solid and that you have used solvents or emulsifying agents (Genapol and nonylphenol). However, you have not provided any justification or supporting evidence that the solvent or emulsifier:

- 1) is not toxic to bacteria, and/or
- 2) is not biodegraded, and/or
- 3) does not cause foaming under the test conditions

Reporting of the methodology and results

- The concentration of the inoculum in the test (in Cells/mL) is reported;
- The test temperature is reported;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;
- The calculation of the ThOD is described and justified;
- For nitrogen-containing test materials, correction for nitrification is applied on the theoretical oxygen demand (*i.e.* ThOD_{NO3}) unless it can be demonstrated that nitrification did not occur (*e.g.* by monitoring changes in concentrations in nitrite and nitrate);

However, the study (i.) you submitted shows that:

- You have not reported the concentration of the inoculum in the test (in Cells/mL) ;
- The test temperature is not reported;
- The results of measurements at each sampling point in each replicate is not reported in a tabular form;
- The calculation of the ThOD is not described nor justified;
- You have not reported whether a correction for nitrification on the theoretical oxygen demand (*i.e.* ThOD_{NO3}) was applied and you have not provided any justification or supporting evidence that nitrification did not occur;

Therefore, in the absence of justification that the solvents or emulsifiers did not bias the study results, this study does not meet the validity criteria of OECD TG 301. Furthermore, as you have not provided adequate reporting for the study, we are not in a position to further assess the study reliability.

On this basis, the information requirement is not fulfilled.

ECHA notes your agreement to perform the test.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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 summaries².

B. 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 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 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 dossiers³.

² <https://echa.europa.eu/practical-guides>

³ <https://echa.europa.eu/manuals>

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (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.

Appendix D: 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 18 November 2020.

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

In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 12 months from the date of adoption of the decision. You considered that an extension of 3 months is needed to refine the testing procedures for ecotoxicological testing and lower the limit of quantification, of your substance. You also detailed that the substance is expected to be difficult to test due to its high sorption potential and very low water solubility, therefore you motivate your request to extend the deadline also due to the difficulties to conduct the test and to develop an analytical method.

ECHA acknowledges the difficulties in conducting the tests for your Substance.

On this basis, ECHA has granted the request and extended the deadline to 12 months.

ECHA took into account your other comments and removed the request for the in vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.), but did not amend the other 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 E: List of references - ECHA Guidance⁴ and other supporting documentsEvaluation of available information

Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping

Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)⁵

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)⁶

Physical-chemical properties

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment

Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing

Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents⁷

⁴ <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

⁵ <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

⁶ https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

⁷ <http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm>

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

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

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
██████████	██████████	██████████
████████████████████	██████████	██████████
████████████████████	██████████	██████████

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.