

Helsinki, 29 August 2022

Addressees

Registrant(s) of JS 120-55-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision 07/09/2020

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

Substance name: Oxydiethylene dibenzoate

EC number: 204-407-6 CAS number: 120-55-8

Decision number: Please refer to the REACH-IT message which delivered this

communication (in format CCH-D-XXXXXXXXXXXXXXX/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 *5 June 2025*.

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. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)
- 2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

 Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

C. Information required from all the Registrants subject to Annex IX of REACH

- 1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)
- 2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)
- 3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216 and test method: EU C.22./OECD TG 217)
- 4. Short-term toxicity on terrestrial plants (Annex IX, Section 9.4.3; test method: OECD TG 208, with at least three species)

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



- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

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;
- 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.

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". 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 on Reasons common to several requests

1. Assessment of information on short-term toxicity to fish and to aquatic invertebrates, and on toxicity to aquatic algae

The same deficiencies apply to the information on short-term toxicity to fish and to aquatic invertebrates, and on toxicity to aquatic algae.

To fulfil the information requirements of Annex VII, Sections 9.1.1. and 9.1.2. and of Annex Annex VIII, Section 9.1.3. a study must comply with OECD TG 202, OECD TG 201 and OECD TG 203 respectively 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:

- OECD GD 23 notes the option for estimation of results of aquatic toxicity studies on the basis of the 'loading rates' only for UVCB substances which are poorly soluble in water;
- under the specific TGs, 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;
- biological results (e.g. the results of algal biomass determined in OECD TG 201 study, the number of immobilised daphnids in OECD TG 202 study, mortalities and sub-lethal effects in OECD TG 203 study) in each flask/test group measured at each time-point as required in specific TGs during the test period are reported in a tabular form.

You identify the Substance as organic mono-constituent. Your registration dossier provides:

- key OECD TG 201, key OECD TG 202 and two OECD TG 203 (key and supporting) studies where the Substance, based on the results of analytical monitoring of exposure concentrations, was not maintained within 20% of the nominal concentration and for the most test solutions not within 20% of the measured initial concentration throughout the test;
- the results of all above listed aquatic toxicity studies are based on nominal loading rates/concentrations;
- detailed biological results in each flask/test group measured at each time-point as required in specific TGs during the test period are not reported for above listed aquatic toxicity studies.

The Substance is difficult to test (low water solubility: 38.3 mg/L at 20 °C).

The Substance is mono-constituent, therefore estimation of results of aquatic toxicity studies on the basis of the 'loading rates' is not acceptable for the provided aquatic toxicity studies. Furthermore, the results of the provided toxicity studies should be based on the measured concentrations of the Substance as required in specific TGs. Finally, due to the missing information on the detailed biological results it is not possible to conduct an independent assessment of reliability of reported aquatic toxicity studies.

Therefore, the requirements of OECD TG 201, OECD TG 202 and OECD TG 203 are not met for the respective aquatic toxicity studies provided in the registration dossier.

In the comments to the draft decision, you indicate that you agree with the deficiencies of the studies.

2. Assessment of information on long-term toxicity to fish and to aquatic invertebrates

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The same deficiency applies to the information provided for both long-term toxicity testing on aquatic invertebrates and on fish, which are an information requirements under Annex IX, Sections 9.1.5. and 9.1.6. respectively.

You have provided the following information for these information requirements:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. Based upon the chemical safety assessment for this substance, adequate information has been provided to determine that the substance is not a PBT or vPvB, and does not meet the criteria for classification as dangerous according to Directive 67/548/EEC, 1999/45/EC, or 2006/121/EC. Therefore, and for animal welfare reasons, a long-term toxicity study is not proposed."

We have assessed this information and identified the following issues:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Furthermore, a registrant may only adapt these information requirements based on the general rules set out in Annex XI. Minimisation of animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

Your adaptation of information requirements on long-term toxicity testing on aquatic invertebrates and on fish is therefore rejected.

In the comments to the draft decision, you agree that there is a data gap for the information requirement of long-term toxicity to fish and to aquatic invertebrates. Furthermore, you indicate that you intend to adapt these information requirements.

In your comments, you consider the use of two strategies for adaptation.

i. Strategy relying on adaptations by means of grouping and read-across

You present a strategy relying on adaptation by means of grouping and read-across according to Annex XI, Section 1.5 of the REACH Regulation. You refer to a group (category) of three source substances:

- propane-1,2-diyl dibenzoate (EC 242-894-7);
- ethylene dibenzoate (EC 202-338-6);
- oxydipropyl dibenzoate (EC 248-258-5).

However, you provide no supporting information. You indicate your intention to provide it in the future update of your registration dossier.

As this strategy relies on a read-across approach that has not yet been fully described and justified, as well as on data which is yet to be submitted or generated for the proposed target substance (data on short-term toxicity to fish and Daphnia and a new OECD 201 study on the Substance), no conclusion on the compliance of the proposed adaptation can be made.

ii. Intention for adaptation based on exposure based considerations

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In the comments to the draft decision, you also indicate your intention to adapt this information requirement based on exposure considerations, according to Annex XI, Section 3 of REACH regulation.

In particular, you propose to update short-term aquatic toxicity information, Exposure Assessment, and risk characterisation of the Substance, and use a stepwise testing program (i.e., conducting the requested OECD TG 211 test before undertaking the requested OECD TG 210 test).

However, you provide no supporting information for this strategy. You indicate your intention to provide it in the future update of your registration dossier.

iii. Conclusion

The information in your comments is not sufficient for ECHA to make an assessment because you have only provided an intention to adapt without supporting information. You remain responsible for complying with this decision by the set deadline.

3. Assessment of information on effects on soil micro-organisms and on short-term toxicity on soil plants

The same deficiency applies to the information provided for both effects on soil microorganisms and on short-term toxicity to plants which are an information requirements under Annex IX, Sections 9.4.2. and 9.4.3. respectively.

You have provided the following information for these information requirements:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.4., Column 2. In support of your adaptation, you provided the following justification: "The test substance is not supposed to be directly applied to soil and an indirect exposure to soil via sewage sludge transfer is unlikely since the substance is readily biodegradable. For a substance being considered as 'readily biodegradable', it can be assumed that it will be biodegraded within the STP process and as a consequence a transfer to the soil compartment is not expected. Furthermore the result of the, Acute Toxicity to the Earthworm, 14d LC50 > 1000 mg/kg supports this premise."

We have assessed this information and identified the following issue:

Under Annex IX, Section 9.4., Column 2 toxicity studies with soil organisms may be omitted if direct and indirect exposure of the soil compartment is unlikely.

In the registration dossier you report a number of various industrial, professional and consumer uses of the Substance including use in agrochemicals (outdoor) by professional users and consumers and/or use in lubricant additives (outdoor) by professional users with non-industrial spraying applied etc. There is no exposure assessment and risk characterisation reported in the chemical safety report.

Based on the uses identified in the registration dossier direct (e.g. for outdoor uses of agrochemicals) and/or indirect (e.g. for outdoor uses of lubricants etc.) exposure of the soil cannot be ruled out. E.g. ECHA Guidance R.16 identifies worst-case release factor of 20% to soil for environmental release category (ERC) 8d which you assigned for use in lubricant additives. Furthermore, you have not reported any further justification (e.g. exposure assessment for soil compartment) which would support your adaptation on the basis of exposure considerations.

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Your adaptation of information requirements on effects on soil micro-organisms and on short-term toxicity to plants based on exposure considerations is therefore rejected.

In the comments to the draft decision you agree with ECHA's assessment.



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

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided an OECD TG 202 key study.

We have assessed this information and identified the following issue:

As explained in Appendix on Reasons common to several requests, Section 1 the requirements of OECD TG 202 are not met for the provided key study.

In the comments to the draft decision, you indicate that you plan to recalculate the effect concentrations using the mean measured concentrations and provide the biological observation data in tabular form based on the existing study report. You propose to update your dossier with the modified Robust Study Summary.

However, in your comments you have not provided any new scientific information that could address the deficiencies explained in the Appendix on Reasons common to several requests, Section 1.

On this basis the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility (38.3 mg/L at 20 °C). OECD TG 202 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 202. 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 solution.

2. 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 an OECD TG 201 key study.

We have assessed this information and identified the following issue:

As explained in Appendix on Reasons common to several requests, Section 1 the requirements of OECD TG 201 are not met for the provided key study.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you agree with the request.

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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.1.



Appendix B: Reasons to request information required under Annex VIII of REACH

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

You have provided two OECD TG 203 (key and supporting) studies.

We have assessed this information and identified the following issue:

As explained in Appendix on Reasons common to several requests, Section 1 the requirements of OECD TG 203 are not met for both provided studies.

In the comments to the draft decision, you indicate that you plan to recalculate the effect concentrations using the mean measured concentrations and provide the biological observation data in tabular form based on the existing study reports. You propose to update your dossier with the modified Robust Study Summaries.

However, in your comments you have not provided any new scientific information that could address the deficiencies explained in the Appendix on Reasons common to several requests, Section 1.

On this basis the information requirement is not fulfilled.

Study design

OECD TG 203 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.1.



Appendix C: Reasons to request information required under Annex IX of REACH

1. 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.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issues:

As explained in Appendix on Reasons common to several requests, Section 2 your adaptation of the information requirement is rejected.

In the comments to the draft decision you propose to submit an adaptation for the endpoint. Your comments relevant to this endpoint are addressed in Section 2 of Appendix on Reasons common to several requests.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 211 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.1.

2. 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.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issues:

As explained in Appendix on Reasons common to several requests, Section 2 your adaptation of the information requirement is rejected.

In the comments to the draft decision you propose to submit an adaptation for the endpoint. Your comments relevant to this endpoint are addressed in Section 2 of Appendix on Reasons common to several requests.On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 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.1.



3. Effects on soil micro-organisms

Effects on soil micro-organisms is an information requirement under Annex IX to REACH (Section 9.4.2.).

You have provided the following information for these information requirements:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

As explained in Appendix on Reasons common to several requests, Section 3 your adaptation of the information requirement is rejected.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested OECD TG 216 study. However, in your comments, you do not refer to the other test related to this information requirement, the OECD TG 217 study, also requested in this decision.

Study design

According to ECHA Guidance R.7c, Section R.7.11.3.1., the nitrogen transformation test is considered sufficient for most non-agrochemicals. However, as the substance has identified agrochemical uses, i.e. used as carrier for agrochemicals used by professional users and consumers, both the nitrogen (EU C.21./OECD TG 216) and carbon transformation (EU C.22./OECD TG 217) tests must be performed simultaneously.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the Equilibrium Partitioning Method (EPM) and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

4. Short-term toxicity on terrestrial plants

Short-term toxicity to soil plants is an information requirement under Annex IX to REACH (Section 9.4.3.).

You have provided the following information for these information requirements:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

As explained in Appendix on Reasons common to several requests, Section 3 your adaptation of the information requirement is rejected.

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

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a







reasonably broad selection of species to account for interspecies sensitivity distribution. For short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.



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

A. Test methods, GLP requirements and reporting

- 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.

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.
- 2. Information on the Test Material needed in the updated dossier
 - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
 - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess 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-quides

³ https://echa.europa.eu/manuals



Appendix E: Procedure

Substance evaluation was completed in 2019.

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 17 September 2020.

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.

Following tonnage upgrade by a registrant, the list of highest REACH Annex applicable in Appendix G was updated accordingly.

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.



Appendix F: List of references - ECHA Guidance⁴ and other supporting documents

Evaluation 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.

<u>Toxicology</u>

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 &}lt;a href="https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment">https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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

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 G: 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.