EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 02 June 2021

Addressees
Registrant(s) of JS_EC 418-140-1 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
02/06/2016

Registered substance subject to this decision ("the Substance")
Substance name: 4-(1-oxo-2-propenyl)-morpholine
EC number: 418-140-1
CAS number: 5117-12-4

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 ***9 March 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. 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)

3. Ready biodegrability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

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

1. *In vivo* mammalian alkaline comet assay (Annex VIII, Section 8.4., column 2; test method: OECD TG 489) combined with *In vivo* mammalian erythrocyte micronucleus test (test method: OECD TG 474) in rats, oral/inhalation route. For the comet assay the following tissues shall be analysed: liver, oral: glandular stomach and duodenum

2. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity below

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

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

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

- Appendices entitled "Reasons to request information required under Annexes VII to VIII 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 Annexes VII and VIII to REACH, for registration at 10-100 tpa.

The registrant with Registration number: 01-2120102080-83-0004 is not requesed to provide the study requested under B.1., because it opted out from the joint submission for that specific information requirement. The information has been requested from that registrant in an other decision specificly addressed to it based on the assessment of the information submitted separately.

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.

Authorised[1] under the authority of Christel Schilliger-Musset, 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. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII, Section 9.1.1. to REACH.

You have provided an endpoint study record for a short-term toxicity study on aquatic invertebrates according to EG C.2/OECD 202 Teil 1 ([redacted], 1995) with the Substance.

We have assessed this information and identified the following issue:

To be considered compliant, a study has to meet the requirements of OECD TG 202. The key parameters of this test guideline include:

- validity criteria specified in the test guideline must be met:
  - the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
  - the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;
- the test design is reported (*e.g.* static or semi-static test, number of replicates, number of test concentrations and geometric progression used, age of daphnids);
- the test conditions and procedure are reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel);
- the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;
- the dissolved oxygen and pH measured at least at the beginning and 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 are provided.

Your registration dossier provides an OECD TG 202 study for which you have not reported the following:

- if the study meets the validity criteria;
- the test design;
- the test conditions and procedure;
- tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control;
- the dissolved oxygen and pH measured at least at the beginning and end of the test;
- the analytical method and the results of the analytical determination of exposure concentrations.

Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 202 are not met.

On this basis, the information requirement is not fulfilled.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is a standard information requirement in Annex VII, Section 9.1.2. to REACH.

You have provided an endpoint study record for a toxicity to aquatic algae and cyanobacteria

study according to EG C.3 / OECD 201 ([redacted] 1995) with the Substance.

We have assessed this information provided and identified the following issue:

To be considered compliant, a study has to meet the requirements of OECD TG 201. The key parameters of this test guideline include:

- validity criteria specified in the test guideline must be met:
  - exponential growth in the control cultures is observed over the entire duration of the test;
  - at least 16-fold increase in biomass is observed in the control cultures by the end 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 ≤ 35%;
  - the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata* or *Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%;
- the test design is reported (*e.g.*, number of replicates);
- the test conditions and procedures are reported (*e.g.*, composition of the test medium, test temperature, 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.

Your registration dossier provides an OECD TG 201 study for which you have not reported the following:

- if the study meets the validity criteria;
- the test design;
- the test conditions and procedure;
- the method used to determine algal biomass;
- tabulated data on the algal biomass determined daily for each treatment group and control;
- microscopic observations;
- the analytical method and the results of the analytical determination of exposure concentrations.

Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 201 are not met.

On this basis, the information requirement is not fulfilled.

3. Ready biodegradability

Ready biodegradability is a standard information requirement in Annex VII, Section 9.2.1.1. to REACH.

You have provided an endpoint study record for a ready biodegradability study according to

EG C.4-E / OECD 301D ([redacted], 1995) with the Substance.

We have assessed this information provided and identified the following issue:

To be considered compliant, a study has to meet the requirements of OECD TG 301 or 310. The key parameters of OECD TG 301 include:

- validity criteria specified in the test guideline must be met:
  - The degradation of the reference compound has reached the pass level by day 14;
  - The difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window is ≤ 20%;
  - In the toxicity control, the degradation of the reference substance has reached ≥ 35% (based on DOC) or ≥ 25% (based on ThOD or ThCO2) by day 14;
  - The test material is the sole source of added organic carbon;

  Additionally, for OECD TG 301D:
  - Oxygen depletion in the inoculum blank is ≤ 1.5 mg dissolved O2/L after 28 days;
  - The residual concentration of oxygen in the test bottles is ≥ 0.5 mg O2/L at any time;

- The source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
- The test design is reported (*e.g.*, test substance concentration, number of replicates, controls);
- The test temperature is reported;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;
- Any observed inhibition phenomena and/or abiotic degradation are reported;

Additionally, for OECD TG 301D:
- 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).

Your registration dossier provides an OECD TG 301D study for which you have not reported the following:
- if the study meets the validity criteria;
- information on inoculum as specified above;
- test design;
- test temperature;
- tabulated data on measurements at each sampling point in each replicate;
- observations on inhibition phenomena and/or abiotic degradation;
- calculation of ThOD;
- correction for nitrification or demonstration that nitrification did not occur.

Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 301D are not met.

On this basis, the information requirement is not fulfilled.

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

1. In vivo mammalian alkaline comet assay combined with In vivo mammalian erythrocyte micronucleus test

Under Annex VIII, Section 8.4, column 2 of REACH, the performance of an appropriate *in vivo* somatic cell genotoxicity study must be considered if there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII.

Your dossier contains positive results for the *in vitro* cytogenicity test (OECD TG 473) and *in vitro* gene mutation study in mammalian cells (OECD TG 490) which raise concerns for both gene mutations and chromosomal aberrations.

The ECHA guidance R.*7a*, Section R.7.7.6.3, states that following a positive result in an *in vitro* test, *"adequately conducted somatic cell in vivo testing is required to ascertain if this potential can be expressed in vivo. In cases where it can be sufficiently deduced that a positive in vitro finding is not relevant for in vivo situations (e.g. due to the effect of the test substances on pH or cell viability, in vitro-specific metabolism: see also Section R.7.7.4.1), or where a clear threshold mechanism coming into play only at high concentrations that will not be reached in vivo has been identified (e.g. damage to non-DNA targets at high concentrations), in vivo testing will not be necessary"*.

No data from an *in vivo* somatic cell genotoxicity study is available in the dossier. Furthermore, you did not provide any considerations explaining that the genotoxic potential of the substance cannot be expressed *in vivo*, based e.g. on lack of relevance for *in vivo* situations or the existence of threshold mechanism.

ECHA considers that an appropriate *in vivo* follow up mutagenicity study is necessary to address the concerns identified *in vitro*.

1.1. Test selection

The positive *in vitro* results available in the dossier indicate a concern for both chromosomal aberration and gene mutation. According to the ECHA Guidance R.7a, Section R.7.7.6.3, the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) is a genotoxicity indicator test that is suitable to follow up the positive *in vitro* result for both chromosomal aberration and gene mutation. However, the *in vivo* mammalian erythrocyte micronucleus test ("MN test", OECD TG 474) is a mutagenicity test that provides evidence of *in vivo* chromosomal mutagenicity, as the study detects both structural and numerical chromosomal aberrations. As also indicated in the ECHA Guidance, it is possible to combine the comet assay and the MN test into a single study. The combined study can help reduce the number of tests performed and the number of animals used while addressing both chromosomal aberration and gene mutation. Therefore, the comet assay combined with the MN test is the most appropriate study for the Substance.

1.2. Specification of the study design

According to the test method OECD TG 489, the test must be performed in rats. Therefore, the combined test (OECD TG 489 and OECD TG 474) must be performed in rats.

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

The combination of OECD TGs 489 and 474 should not impair the validity of and the results from each individual study. Careful consideration should be given to the dosing, and tissue sampling for the comet analysis alongside the requirements of tissue sampling for the mammalian erythrocyte micronucleus test (see OECD TG 489, e.g. Bowen *et al.* 2011 *[1]*).

MN test
Regarding the exposure of the target tissue, the applicable test guideline (OECD TG 474) states "*If there is evidence that the test substance(s), or its metabolite(s), will not reach the target tissue, it may not be appropriate to use this test*". Additionally, a negative test result can be considered reliable if "*Bone marrow exposure to the test substance(s) occurred*". Accordingly, if the Substance is negative in this test, but it is not possible to demonstrate that bone marrow exposure to the Substance occurred, then ECHA will consider any remaining uncertainty concerning the mutagenic potential of the Substance and whether to request any further information.

Comet assay
In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

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

References
[1] Bowen DE et al. (2011) Evaluation of a multi-endpoint assay in rats, combining the bone-marrow micronucleus test, the comet assay and the flow-cytometric peripheral blood micronucleus test. Muta. Res.;722:7–19.

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

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII, Section 8.6.1. to REACH.

You have provided an endpoint study record for a Short-term repeated dose toxicity study (28 days; [redacted] 1995) with the Substance.

We have assessed the information provided and identified the following issue:

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 407. The key parameters of this test guideline include:

- highest dose level must aim to induce some systemic toxicity, but not death or severe

suffering;
- 5 female and 5 male animals must be used at each dose level (including control group);
- Exposure duration of at least 28 days; and
- Examination of clinical and functional observations, body weight and food/water consumption measurements, hematology and clinical biochemistry; as well as gross necropsy and histopathology.

For the [redacted] study, you have not reported the following:
- Justification for dose level selection/what effects were observed at the highest dose level in the study (50 mg/kg/day)
- number of animals in each dose group
- exposure duration
- information on what was investigated in the study nor the results of these investigations

Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 407 are not met.

On this basis, the information requirement is not fulfilled.

1.2. Specifications for the study design

Following the criteria provided in Annex VIII, Section 8.6.1, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity and the preferred rodent species is rat (ECHA Guidance R7a, Section R.7.5.6.3.2 and Table R.7.5-1). The Short-term repeated dose toxicity study (28 days) must be performed according to the OECD TG 407, in rats and with oral administration of the Substance.

You must provide an OECD TG 407 and an OECD TG 421 in order to comply with the standard information requirements of Annex VIII, Sections 8.6.1 and 8.7.1. In order to prevent unnecessary animal testing these two tests are to be combined. Therefore, a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD TG 422) must be performed as specified under Screening fro reproductive/developmental toxicity below.

3. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant.

3.1. Information provided to fulfil the information requirement

You have not provided a study conducted according to OECD TG 421 or 422 and there is no information available in your dossier indicating that your Substance may be a developmental toxicant.

Therefore, the information requirement is not fulfilled.

3.2. Specification of the study design

A study according to the test method EU B.64/OECD TG 422 must be performed in rats. The study must be conducted with oral administration of the Substance (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

4. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII, Section 9.1.3. to REACH.

You have provided an endpoint study record for a short-term toxicity study on fish according to EG C.1 / OECD 203 ([redacted] 1995) with the Substance.

We have assessed this information provided and identified the following issue:

To be considered compliant, a study has to meet the requirements of OECD TG 203. The key parameters of this test guideline include:

- validity criteria specified in the test guideline must be met:
  - mortality in the control(s) is ≤ 10% (or one fish, if fewer than 10 control fish are tested) at the end of the test;
  - the dissolved oxygen concentration is ≥ 60% of the air saturation value in all test vessels throughout the exposure;
  - the analytical measurement of test concentrations is conducted;

- details on the test organisms (e.g. size of test fish);
- the test conditions and procedure are reported (*e.g.* number of test animals, test concentrations, composition of the test medium, fish loading);
- in static tests, the results of at least daily measurements of dissolved oxygen, pH, salinity (if relevant) and temperature measured daily in each test vessel are reported. The results TOC determinations at the beginning of the exposure in the dilution water are reported;
- mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided.

Your registration dossier provides an OECD TG 203 study for which you have not reported the following:

- if the study meets the validity criteria;
- size of the test organisms;
- the test conditions and procedure;
- results of measurements of dissolved oxygen, pH, salinity (if relevant), temperature and TOC, as indicated above for a static test;
- observations on mortalities and sub-lethal effects and frequency of observations;
- the analytical method and the results of the analytical determination of exposure concentrations.

Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 203 are not met.

On this basis, the information requirement is not fulfilled.

Appendix C: 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 summaries[2].

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 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 dossiers[3].

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

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 28 August 2020.

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

ECHA did not receive any comments within the notification period.

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

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 Guidance[4] 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)[5]

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 documents[6]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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[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] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.