~~Confidential~~

Helsinki, 05 May 2022

Addressees
Registrants of JS_296-120-8 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
24/01/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo]-, ar-heptyl ar',ar''-Me derivs.
EC number: 296-120-8

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***12 August 2024***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex VII of REACH

1. Same *In vitro* mutagenicity study in mammalian cells requested below under B.1;

2. Same *In vivo* genetic toxicity study requested below under B.2.

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

1. In vitro cytogenicity study in mammalian cells (test method: OECD TG 473) or In vitro micronucleus study (test method: OECD TG 487);

2. In vivo genetic toxicity study to be selected according to the following specifications:

   a. If the results of the *in vitro* test requested under B.1 are **negative**:

   In vivo mammalian alkaline comet assay (test method: OECD TG 489) in rats or, if justified, other rodent species, oral route, on the following tissues: liver, glandular stomach and duodenum.

   b. If the results of the *in vitro* test requested under B.1 are **positive**:

   In vivo mammalian alkaline comet assay (test method: OECD TG 489) combined with *in vivo* mammalian erythrocyte micronucleus test (test method: OECD TG 474) in rats or, if justified, in mice, oral route. For the comet assay the following tissues shall be analysed: liver, glandular stomach and duodenum.

Reasons for the requests are explained in the 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 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.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

ECHA requests the same studies from registrants at different tonnages. Only one study per request is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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 can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] 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

This decision is based on the examination of the testing proposals you submitted.

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

Under Annex VII, Section 8.4, column 2 of REACH, further mutagenicity studies must be considered in case of a positive result in an *in vitro* gene mutation study in bacteria. The ECHA guidance R.7a[2] further specifies that "*REACH Annex VII substances for which only a bacterial gene mutation test has been conducted and for which the result is positive should be studied further, according to the requirements of Annex VIII*." This is for the reason that the *in vitro* cytogenicity test under Section 8.4.2 will allow to further investigate the mutagenicity of the substance in accordance with the REACH integrated testing strategy. The obtained *in vitro* data will inform on the genotoxic concern(s) associated with the Substance and help identify the most adequate follow-up *in vivo* study (same *in vivo* study requested under A.2. and B.2).

Your dossier contains positive results for the *in vitro* gene mutation study in bacteria with the Substance. Your dossier contains as well an *in vitro* chromosome aberration test and an *in vivo* micronucleus study. However, for the reasons explained under B.1, neither the *in vitro* chromosome aberration test nor the *in vivo* micronucleus study available in your dossier is considered reliable.

ECHA therefore considers that an appropriate *in vitro* cytogenicity or micronucleus study is necessary to further investigate the mutagenicity of the Substance and to help identify the most adequate follow-up *in vivo* study.

For the assessment, selection and specifications of the study to be performed, see section B.1.

2. In vivo genetic toxicity study

Under Annex VII, Section 8.4, column 2 of REACH, further mutagenicity studies must be considered in case of a positive result in an *in vitro* gene mutation study in bacteria.

The ECHA guidance R.*7a*[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*.".

Your dossier contains positive results for the *in vitro* gene mutation study in bacteria which raise the concern for gene mutation.

ECHA considers that an appropriate *in vivo* follow up genetic toxicity study is necessary to address the concern identified *in vitro*.

For the assessment, selection and specifications of the study to be performed, see section B.2.

[2] ECHA Guidance R.7a, section R.7.7.6.3, p.570.
[3] ECHA Guidance R.7a, section R.7.7.6.3, p.570.

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

This decision is based on the examination of the testing proposal you submitted.

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

Further, ECHA guidance R.7a, section R.7.7.6.3 (p.570) specifies that "*substances for which only a bacterial gene mutation test has been conducted and for which the result is positive should be studied further, according to the requirements of Annex VIII*." It is necessary to request an *in vitro* cytogenicity test as an additional test to further investigate the mutagenicity of the substance in accordance with the REACH integrated testing strategy. The obtained *in vitro* data will inform on the genotoxic concern(s) associated with the Substance and help identify the most adequate follow-up *in vivo* study.

1.1. Information provided to fulfil the information requirement

Your dossier contains negative results for the *in vitro* chromosomal aberration test (OECD TG 473, 1989) and positive results for the *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474, 1994).

We have assessed this information and identified the following issue(s):

a) Invalid in vitro chromosomal aberration study

To fulfil the information requirement, the study has to be an *in vitro* chromosomal aberration test or an *in vitro* micronucleus test, conducted in mammalian cells in accordance with OECD TG 473 or OECD TG 487, respectively[4]. The key parameters of these test guidelines include:

a) At least 300 well-spread metaphases must be scored per concentration.

The reported data for the OECD TG 473 study you have provided did not include:

a) the scoring of at least 300 metaphases per concentration since only 100 metaphases were scored.

The information provided does not cover one of the key parameters required by OECD TG 473.

Moreover, according to OECD TG 473, the test report should include information on the test chemical, and in particular, considering the Substance is a UVCB, the substance should be characterised as far as possible by chemical identity, quantitative occurrence and relevant physicochemical properties of the constituents.

In the dossier you indicate that no details on the test material were included in the report.

Therefore, based on the above, the information requirement is not fulfilled.

b) Invalid in vivo micronucleus study

Under Section 8.4.2., Column 2, first indent, Annex VIII to REACH, the study may be omitted "*if adequate data from an in vivo cytogenicity test are available*". ECHA Guidance[5] clarifies

[4] ECHA Guidance R.7a, Table R.7.7–2, p.557
[5] ECHA Guidance R.7a, R.7.7.6.3, p.568

that the *in vivo* somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively[6].

For the data from an *in vivo* somatic cell cytogenicity test to be considered adequate, the *in vivo* study you submitted has to meet the requirements of OECD TG 474, and the specifications/conditions of this test guideline include:

a) The highest dose studied must be the maximum tolerated dose (MTD), i.e. the highest dose that is tolerated without evidence of toxicity (e.g. body weight depression or hematopoietic system cytotoxicity, but not death or evidence of pain, suffering or distress necessitating humane euthanasia). The highest dose can also be a dose that produces toxicity in the bone marrow (e.g. a reduction in the proportion of immature erythrocytes among total erythrocytes in the bone marrow or peripheral blood).; and
b) At least 4000 immature erythrocytes per animal must be scored for the incidence of micronucleated immature erythrocytes.

The reported data for the OECD TG 474 study you submitted did not include:

a) a maximum studied dose that is a MTD or induces toxicity. The mid and high doses used (2500 and 5000 mg/kg bw/d for four days, respectively) were actually above the limit dose of 2000 mg/kg bw/d recommended in OECD TG 474 for administration periods of less than 14 days.; and
b) the analysis of the adequate number of cells. Only 1000 immature erythrocytes per animal were scored for calculation fo the incidence of micronucleated immature erythrocytes instead of 4000 as recommended in OECD TG 474.

The information provided does not cover specifications/conditions required by OECD TG 474.

In your testing proposal justification, you considered the OECD TG 474 study results as questionable due to the lack of test material purity (ca. 65%), its formulation ([redacted]), the dose selection, the number of cells scored for micronucleus frequency investigation, and the unavailability of body temperature information, which may influence micronucleus formation.

For the reasons explained above, ECHA agrees that these results are considered as unreliable.

Therefore, the requirements of Section 8.4.2., Column 2, first indent, Annex VIII to REACH for an adaptation of the *in vitro* cytogenicity or micronucleus study information are not met.

1.2 Test design

Either the *in vitro* cytogenicity study in mammalian cells (test method OECD TG 473) or the *in vitro* micronucleus study (test method OECD TG 487) are considered suitable.

1.3 Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test, as indicated above.

In your comments to the draft decision, you disagree with performing the *in vitro* cytogenicity or micronucleus study requested because you consider it unnecessary. You propose instead to directly perform the *in vivo* mammalian alkaline comet assay combined with an *in vivo* mammalian erythrocyte micronucleus test with the Substance, as initially indicated in your testing proposal submission.

[6] ECHA Guidance R.7a, Table R.7.7–3, p.558

However, according to the ECHA Guidance R.7a, section R.7.7.6.3 and Figure R.7.7-1 (*Flow chart of the mutagenicity testing strategy*), if there is a positive result in the gene mutation test in bacteria, the Substance should be studied further according to the requirements of Annex VIII. Therefore, the *in vitro* cytogenicity or micronucleus study must be performed first to determine which appropriate *in vivo* follow-up study is required for the Substance, as specified in section B.2. below.

2. In vivo genetic toxicity study

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* gene mutation study in bacteria (OECD TG 471; 1983a, 1983b, 1990 & 1999) which raise the concern for gene mutations.

Moreover, as explained in section B.1, the *in vitro* chromosomal aberration test (OECD TG 473, 1990) and the *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474, 1989) provided in your dossier are unreliable and cannot be used to conclude on a potential concern for chromosomal aberrations.

2.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for an *in vivo* mammalian alkaline comet assay combined with an *in vivo* mammalian erythrocyte micronucleus test to be performed with the Substance.

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

ECHA agrees that an appropriate *in vivo* follow up genotoxicity study is necessary to address the concerns identified *in vitro* and *in vivo.*

2.2 Test selection

ECHA notes that the proposed test is appropriate to investigate effects on gene mutations and chromosomal aberrations *in vivo* (ECHA Guidance R.7a, Section R.7.7.6.3. and Figure R.7.7-1*)*.

According to the ECHA Guidance Chapter R.7a, Section R.7.7.6.3, the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) combined with the *in vivo* micronucleus test ("MN test", OECD TG 474) is suitable to follow up a positive *in vitro* results on gene mutations and chromosomal aberrations.

However, as explained in Section B.1, the results of the *in vitro* chromosomal aberration study (OECD TG 473, 1989) and the *in vivo* mammalian erythrocyte micronucleus study (OECD TG 474, 1994) are considered unreliable. Therefore, by this decision, ECHA also requests an *in vitro* chromosomal aberration test, which may raise a concern for chromosomal aberration in case of positive results.

In case there is also a concern for chromosomal aberration, you must combine the comet

assay and the MN test into a single study. The MN test is a mutagenicity test that provides evidence on *in vivo* chromosomal mutagenicity, as the study detects both structural and numerical chromosomal aberrations. 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, you must wait for the results of the *in vitro* test requested in Section B.1. and, depending on these results, conduct either a) a comet assay if the test results of request B.1 are negative, or b) a comet assay combined with a MN test if the test results of request B.1 are positive. The deadline set in this decision allows for sequential testing.

2.3 Specification of the study design

*a) Comet assay (if the test results of request B.1 are **negative**)*

You did not specify the species to be used for testing. According to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified (OECD TG 489, para. 23).

You did not specify the route for testing. 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.

In your testing proposal, you indicated your intention to analyse the following tissues, as part of the comet assay: the liver, kidney and duodenum. You further justify analysis of the kidney as a known target for aromatic amines and azo-dyes.

In line with the test method OECD TG 489, the test must be performed by analysing tissues from the 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.

Regarding comet analysis of the kidney, please note that it is your discretion to perform this intended additional examination. According to OECD TG 489, it may be useful to examine multiple tissues in the same animals provided that tissue selection is justified and the laboratory has demonstrated proficiency with those tissues and competency in handling multiple tissues at the same time.

Germ cells

You may consider to collect the male gonadal cells 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.

*b) Comet assay combined with MN test (if the test results of request B.1 are **positive**)*

You did not specify the species to be used for testing. According to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified. According to the test method OECD TG 474, the test may be performed in mice or rats. Therefore, the combined study must be performed in rats or, if justified, in mice.

You did not specify the route for testing. Having considered the anticipated routes of human exposure and the need for adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

In your testing proposal, you indicated your intention to analyse the following tissues, as part of the comet assay: the liver, kidney and duodenum. You further justify analysis of the kidney as a known target for aromatic amines and azo-dyes.

In line with the test method OECD TG 489, the test must be performed by analysing tissues from the 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.

Regarding comet analysis of the kidney, please note that it is your discretion to perform this intended additional examination. According to OECD TG 489, it may be useful to examine multiple tissues in the same animals provided that tissue selection is justified and the laboratory has demonstrated proficiency with those tissues and competency in handling multiple tissues at the same time.

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[7]).

Germ cells

You may consider to collect the male gonadal cells 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.

2.4 Outcome

Under Article 40(3)(b) of REACH, you are requested to carry out the proposed test under modified conditions, as explained above, with the Substance.

[7] Bowen D.E. 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. Mutation Research 722 7–19

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[8].

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:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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

a) 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.
b) 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 dossiers[9].

[8] https://echa.europa.eu/practical-guides
[9] https://echa.europa.eu/manuals

Appendix D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 17 November 2020.

ECHA held a third party consultation for the testing proposal(s) from 16 December 2020 until 1 February 2021. ECHA did not receive information from third parties.

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

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 took the decision according to Article 51(3) of the REACH Regulation.

Appendix E: List of references - ECHA Guidance[10] 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)[11]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[12]

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.

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[12] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[13]
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.

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

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

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.