~~Confidential~~

Helsinki, 01 October 2021

Addressees
Registrants of 68411-30-3_LAS_Na_10_13 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
13/08/2019

Registered substance subject to this decision ("the Substance")
Substance name: Benzenesulfonic acid, C10-13-alkyl derivs., sodium salts
EC number: 270-115-0
CAS number: 68411-30-3

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 ***8 January 2024***.

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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. If the test results of request A.1 are positive, then: same *In vivo* genetic toxicity study (triggered by Annex VII, Section 8.4., column 2) as also requested below in B.1 and C.1.

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

1. Same *In vivo* genetic toxicity study (triggered by Annex VIII, Section 8.4., column 2) as also requested below in C.1.

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

1. *In vivo* genetic toxicity study (triggered by Annex IX, Section 8.4., column 2) to be selected according to the following specifications:

   a) If the test results of request A.1 are **negative**:

   In vivo mammalian erythrocyte micronucleus test (test method: OECD TG 474) in mice or rats, oral route; OR In vivo mammalian bone marrow chromosomal aberration test (test method: OECD TG 475) in mice or rats, oral route; OR In vivo mammalian alkaline comet assay (test method: OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum;

b) If the test results of request A.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, oral route. For the comet assay the following tissues shall be analysed: liver, glandular stomach and duodenum;

2. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats.

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit).

D. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rat/rabbit).

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 X 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.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study 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". 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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- In vivo genetic toxicity study, (Annex VIII/IX, Section 8.4, column 2)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

For the above-mentioned information requirements, you have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements.

More specifically, you have provided:

- For the *in vivo* genetic toxicity information requirement, two studies with two source substances:
  i. Linear alkyl benzene sulfonate (LAS), Benzenesulfonic acid, 4-C10-13-secalkyl derivs., EC no. 287-494-3, CAS no. 85536-14-7;
  ii. Benzenesulfonic acid, C10-14-alkyl derivs., sodium salts, EC no. 274-070-8, CAS no. 69669-44-9

- For the sub-chronic toxicity study (90d-day) information requirement, three studies with three source substances:
  - Linear alkyl benzene sulfonate (LAS), Benzenesulfonic acid, 4-C10-13-secalkyl derivs., EC no. 287-494-3, CAS no. 85536-14-7;
  - Benzenesulfonic acid, C10-14-alkyl derivs., sodium salts, EC no. 274-070-8, CAS no. 69669-44-9
  - C10-13 magnesium linear alkylbenzene sulphonate (LAS-Mg), no identifiers

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

You have not provided any documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA is deprived from the possibility to verify that the properties of your Substance can be predicted from the data on the source substances.

In your comments to draft decision you inform that you will provide as part of an update of your registration dossier additional source material identification and a read-across justification prepared according to the RAAF guidance.

You explained that EC 287-494-3 is the free acid of the target substance and under physiological conditions the free acid and sodium salts are interchangeable. ECHA agrees that read across from an acid (source substance) to its sodium salt (target substance) can be considered plausible. However, with regard read-across from the other selected source substances, further justification is needed in the form of an adequate read-across demonstration. The justification should, among others, clarify the ambiguity on the composition of the selected analogue substances and address the impact of structural differences on the predictions.

Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

In spite of this critical deficiency, ECHA has nevertheless assessed the adequacy and reliability of the source studies under the respective information requirements (see below sections A.2., B.1., C.1. and C.2.).

2. Assessment of the weight of evidence adaptations under the requirements of Annex XI, section 1.2

In your comments to draft decision you have applied a generic weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2 for all the standard information requirement addressed in the draft decision.

In this context, you state that "*weight of evidence is applicable to the registration endpoints covered by ECHA in the Draft Decision, as there are multiple studies from independent sources available for each of the key endpoints, leading to the conclusions that the substance does nothave the hazardous property covered by the endpoints concerned by ECHA's Draft Decision. This further evidences that ECHA's information requests are not necessary. The number of studies included for each endpoint is summarized below:*
1) In vitro genetic toxicity –3 studies (Ames, CHO-gene mutation, CHO-chromosome aberration)
2) In vivo genetic toxicity study –4 studies
3) Sub-chronic toxicity study (90-day) –9 studies
4) Pre-natal developmental toxicity study in rodent and non-rodent species –3 studies (rat, mouse and rabbit)".

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given

is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, for each relevant information requirement, you have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information at the respective information requirement justified in the draft decision.

Your weight of evidence adaptation raises the same decifiency irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed this deficiency below, before assessing the specific standard information requirements in the following appendices.

- Use of existing data adaptation under Annex XI, Section 1.1.2.

The adaptation rule in Annex XI, Section 1.1.2 imposes a number of cumulative conditions for an adaptation to be valid, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
2. Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3);
3. Adequate and reliable documentation of the study is provided;
4. Adequacy for the purpose of classification and labelling and/or risk assessment.

In your comments to draft decision you have adapted the following standard information requirements by applying an adaptation under section 1.1.2 of Annex XI for all the information requirements addressed in the draft decision. More specifically, in reference to the studies relied upon in the context of your weight of evidence adaptation, you stated that: "*These tests were conducted in full accordance with guidelines available at the time the study was conducted (Annex XI, section 1.1.2). Due to the long use of LAS Na, many of the toxicological studies were conducted as early as the 1970's. These studies have been reviewed in depth by both the registrants and other regulatory agencies around the world, some of which recently (as detailed above),and are judged to be of sufficient quality (KL=2) by the registrants to warrant inclusion in the REACH dossier.*" You further stated that "*The abundance of existing information, including read-across information from analogue substances, multiple studies and consistent results for key endpoints increase confidence in endpoint conclusions, i.e. that ECHA's information requests are not scientifically necessary. On that basis, the registrants seek adaptationto the standard information requirements according to Sections 1.1, 1.2 and 1.5 of Annex XI to the REACH Regulation in that testing is not scientifically necessary*"

While you claim an adaptation under Annex XI, 1.1.2., you do not provide any justification, for any of the study, as to how each existing study is adequately and reliably covering the

key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3).

Therefore, in the absence of any justification for an adaptation under Annex XI, 1.1.2., each existing study is assessed against the relevant testing guideline currently applicable.

Furthermore, many of the robust study summaries submitted have limited reporting and deficiencies rendering the studies inadequate for the purpose of classification and labelling and/or risk assessment. These deficiencies are detailed in the respective endpoints.

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

1. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have provided a key study in your dossier:

i. *in vitro* gene mutation study in bacteria ([redacted] 1993) with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538 which all gave negative results.

We have assessed this information and identified the following issue:

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471[4] (1997). One of the key parameters of this test guideline includes:

- The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)

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

- results for the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

The information provided does not cover one of the key parameters required by OECD TG 471.

In your comments to draft decision you consider that testing in the strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is not necessary. You invoke as an argument the conclusions of the study of [redacted] 2019 that "*Of the mutagens detected by the full TG471 strain battery, 93% were detected using only strains TA98 and TA100; consideration of results from in vitro genotoxicity assays that detect clastogenicity increased the mutagens detected to 99%.*". Nevertheless, until this strategy becomes validated and incorporated into the OECD 471, the requirements of the current testing guideline apply.

Therefore, the information requirement is not fulfilled.

Test design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

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*[5] 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*

[4] ECHA Guidance R.7a, Table R.7.7–2, p.557
[5] ECHA Guidance R.7a, section R.7.7.6.3, p.570.

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.".

This decision requests an *in vitro* gene mutation test in bacteria (see above Appendix A, section 1), which could raise a concern for gene mutation in case of positive results. In such a case, ECHA considers that an appropriate *in vivo* follow up genotoxicity study would be necessary to address the potential gene mutation concern identified *in vitro*.

Therefore, if the test results in A.1 are positive, the same *in vivo* mammalian alkaline comet assay combined with *in vivo* mammalian erythrocyte micronucleus test requested in sections B.1 and C.1 (scenario b) is triggered. The selection of the requested test and the test design are further addressed in Appendix C.1.

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

1. 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.

The ECHA guidance R.7a 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* mammalian chromosomal aberration test which raise the concern for chromosomal aberration. You also provided *in vivo* studies in your dossier however they are inadequate studies for the reasons described under Section C.1.

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

The assessment of the information provided to fulfil this information requirement, the selection of the requested test and the test design are addressed in section C.1.

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

1. In vivo genetic toxicity study

Under Annex IX, Section 8.4, column 2 of REACH, the information requirement for an appropriate *in vivo* somatic cell genotoxicity study is triggered if 1) there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and 2) there are no appropriate results already available from an *in vivo* somatic cell genotoxicity study.

In relation to the first condition, your dossier contains positive results for the *in vitro* mammalian chromosomal aberration test which raise the concern for chromosomal aberration.

In relation to the second condition, your dossier contains the following *in vivo* studies, all flagged as key studies:

i. *in vivo* micronucleus assay (OECD TG 474) in mice, oral route, with the analogue substance Linear alkyl benzene sulfonate (LAS), Benzenesulfonic acid, 4-C10-13-secalkyl derivs., EC no. 287-494-3 ([redacted], 1991);
ii. *in vivo* chromosomal aberration assay (no TG) in mice, oral route, with the analogue substance Benzenesulfonic acid, C10-14-alkyl derivs., sodium salts, EC no. 274-070-8 (Inoue *et al*., 1976);
iii. *in vivo* cytogenicity study (no TG) in mice and rats, oral route, with the Substance (Masubuchi *et al*., 1976); and
iv. dominant lethal test (no TG) in mice with the Substance (Masubuchi *et al*., 1976).

In your comments on the draft decision in relation to the studies (ii.) - (iv.), you consider that "*These studies provide further weight to evidence that LAS Na is negative for in vivo genetic toxicity, including chromosomal aberrations".* We therefore understand that you invoke in your comments a weight of evidence adaptation under Section 1.2 of Annex XI of the REACH Regulation.

We have assessed this information and identified the following issue:

For the reasons explained in section 2 of the *Appendix on reasons common to several requests*, the your adaptation does not comply with the general rules of adaptation as set out in Annex XI.

To fulfil the information requirement, normally a study performed according to OECD TG 474/475 must be provided. OECD TG 474/475 requires the study to investigate the following key parameters:

- detection and quantification of micronucleus formation in erythrocytes sampled either in the bone marrow or peripheral blood cells of animals, usually rodents (OECD TG 474);
- detection and quantification of structural chromosome aberrations in bone marrow cells of animals, usually rodents.

All the studies contained in the dossier for this endpoint provide relevant information as they address micronucleus formation or chromosomal aberration *in vivo*.

In your comments to draft decision you argue that "*the first study in the dossier for this information requirement, the in vivo micronucleus assay ([redacted],1991) conducted according to OECD TG 474, fully complied with OECD test guidelines at the time the study was conducted*." and that "*Three additional studies for this information requirement (in vivo chromosomal aberration assay, in vivo cytogenicity study and dominant lethal test) were*

conducted, again according to generally accepted procedures at the time the studies were conducted.". Nevetheless, as explained under section 2 of the *Appendix on reasons common to several requests*, the reliability of the sources of information is impaired by significant deficiencies. In addition, the sources of information are also affected by the quality concerns identified below:

A. Read across adaptations

Studies (i.) and (ii.) above are conducted with analogue substances. For the reasons explained in section 1 of the *Appendix on reasons common to several requests*, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected. Following the subsmission of your comments on draft decision, we agree that the read-across to the acid (EC no. 287-494-3) is acceptable. However, there are issues with the source studies (i. and ii.) as explained in issue B. below.

B. Quality of Studies

To be considered adequate, the study has to meet the requirements of OECD TG 474 or 475, and the key parameters of this test guideline include:

- The study investigates chromosomal aberrations in somatic cells (bone marrow and/or peripheral blood cells of mice or rats.
- The study must include a minimum of three doses/groups of treated animals as well as a negative control group and a positive control group.
- The mitotic index must be determined as a measure of cytotoxicity in at least 1000 cells per animal for all treated animals (including positive controls), untreated or vehicle/solvent negative control animals.
- At least 4000 immature erythrocytes per animal must be scored for the incidence of micronucleated immature erythrocytes.
- At least 200 metaphases must be analysed for each animal for structural chromosomal aberrations including and excluding gaps.
- The proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes must be reported for each group of animals.
- The mitotic index and the mean number of cells with aberrations per group must be reported for each group of animals.

However, the above mentioned key parameter(s) are not met. More specifically:

The reported data in study (i.) does not include:

a) the appropriate number of doses;
b) information on the number of immature erythrocytes scored; and
c) data on the proportion of immature erythrocytes among total erythrocytes and the mean number of micronucleated immature erythrocytes for each group of animals.

The reported data in study (ii.) does not include:

a) data on the mitotic index and the mean number of cells with aberrations per group for each group of animals; and
b) the analysis of the adequate number of metaphases.

The reported data in study (iii.) does not include:

a) the appropriate number of doses;
b) a positive control group (or scoring control); and
c) the analysis of the adequate number of metaphases.

The reported data in study (iv.) does not include:

a) information on chromosomal aberrations in somatic cells;
b) the appropriate number of doses in studies;
c) a positive control group (or scoring control);
d) information on the number of immature erythrocytes scored; and
e) the analysis of the adequate number of metaphases.

Proper reporting on how the study was done (e.g. rationale for selection of doses, use of positive control) and of the results (e.g. information on the number of immature erythrocytes scored and their proportion among normochromatic erythrocites, mitotic index and number of cells with aberrations) were also prescribed by the original versions of the OECD 474 (1983) and OECD 475 (1984). Furthermore, as discussed under Appendix on Reasons common to several requests, section 3, due to the lack of an adaptation under Annex XI, 1.1.2. the studies were assessed individually against the relevant current testing guideline, which revealed further deficiencies (e.g. the analysis of the adequate number of metaphases).

On this basis, the information provided does not cover key parameters required by OECD TG 474 or 475. The reliability of the sources of information you invoked under a weight of evidence adaptation is significantly vitiated by these deficiencies.

As a result, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 474 or OECD TG 475. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Therefore, the conditions set out in Annex IX, Section 8.4, column 2 are met and the information requirement for an appropriate *in vivo* somatic cell genotoxicity study is triggered.

1) Test selection

According to the ECHA Guidance Chapter R.7a, Section R.7.7.6.3, the mammalian erythrocyte micronucleus test ("MN test", OECD TG 474) or the mammalian bone marrow chromosomal aberration test ("CA test", OECD TG 475) are suitable to follow up a positive *in vitro* result on chromosomal aberration if the Substance or its metabolite(s) will reach the target tissue. Alternatively, the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) is a suitable test to be performed.

This decision, however, also requests an *in vitro* gene mutation test in bacteria (see above Appendix A, section 1), which may raise a concern for gene mutation in case of positive results. In such a scenario where there are both concerns for chromosomal aberration and gene mutation, according to the ECHA Guidance R.7a, Section R.7.7.6.3, the comet assay is a genotoxicity indicator test that is suitable to follow up both concerns. However, the MN test 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, it is appropriate to wait for the results of the *in vitro* test requested under A.1. and, depending on these results, to conduct either the a) MN test or CA test or comet assay or the b) comet assay combined with the MN test. The deadline set in this decision allows for sequential testing.

2) Test design

Scenario A) If the test results of request A.1 are negative: MN test or CA test or comet assay

In case you decide to perform a MN or CA assay, according to the test method OECD TG 474 / OECD TG 475, the test must be performed in mice or rats. 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.

Regarding the exposure of the target tissue, the applicable test guideline (OECD TG 474 / OECD TG 475) 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.

In case you decide to perform the comet assay according to the test method OECD TG 489, the test must be performed in rats. 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 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.

Scenario B) If the test results of request A.1 are positive: Combined comet assay with MN test

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 the need for adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

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.

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 comet analysis alongside the requirements of tissue sampling for the mammalian erythrocyte micronucleus test (see OECD TG 489, e.g. Bowen *et al*. 2011[6]).

3) Germ cells

A subsequent germ cell genotoxicity study (TGR/OECD TG 488, or CA on spermatogonia/OECD TG 483, depending on the concern raised by the substance) may still be required under Annex IX/X of REACH, in case 1) an *in vivo* genotoxicity test on somatic cell is positive, and 2) no clear conclusion can be made on germ cell mutagenicity.

Therefore, in case you perform the comet assay, 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, in accordance to Annex IX/X, Section 8.4., column 2, 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. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is an information requirement in Annex IX, Section 8.6.2. to REACH.

You have provided the following key studies for this information requirement in your dossier:

i. Repeated dose oral toxicity study in rats ([redacted], 1976), no test guideline followed, with the analogue substance Linear alkyl benzene sulfonate (LAS), Benzenesulfonic acid, 4-C10-13-secalkyl derivs., EC no. 287-494-3;
ii. Repeated dose dermal toxicity study in rats ([redacted] 1978), no test guideline followed, with the analogue substance C10 - C13 linear alkylbenzene sulfonic acid magnesium salt (LAS-Mg) (no EC/CAS nos. reported);

In addition you also provided the following supporting studies:

iii. Chronic oral toxicity study in rats ([redacted], 1978), no test guideline followed, with the analogue substance C10 - C13 linear alkylbenzene sulfonic acid magnesium salt (LAS-Mg) (no EC/CAS nos. reported);
iv. Repeated dose oral toxicity study in mice ([redacted], 1976), no test guideline followed, with the analogue substance Linear alkyl benzene sulfonate (LAS), Benzenesulfonic acid, 4-C10-13-secalkyl derivs., EC no. 287-494-3;
v. Repeated dose oral toxicity study in rats ([redacted] 1972), no test guideline followed, with the analogue substance Benzenesulfonic acid, C10-14-alkyl derivs., sodium salts, EC no. 274-070-8;
vi. Sub-acute oral toxicity study in rats ([redacted] 1978), no test guideline followed, with the analogue substance C10 - C13 linear alkylbenzene sulfonic acid magnesium salt (LAS-Mg) (no EC/CAS nos. reported);
vii. Sub-acute oral toxicity study in rats ([redacted] 1978), no test guideline followed, with the Substance.

[6] 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

In your comments on the draft decision, you consider that "*taken as a whole (read-across, use of existing data and weight of evidence approach), the data currently part of the registration dossier fulfils the information requirement for Annex IX, Section 8.6.2 of REACH (sub-chronic toxicity study).*" We therefore understand that you invoke in your comments a weight of evidence adaptation under Section 1.2 of Annex XI of the REACH Regulation.

We have assessed this information and identified the following issue:

For the reasons explained in section 2 of the *Appendix on reasons common to several requests*, the your adaptation does not comply with the general rules of adaptation as set out in Annex XI.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.6.2 at Annex IX includes, at general level, information on systemic toxicity after 90-days repeated dose exposure in intact, non-pregnant and young adult males and females from: 1) in-life observations, 2) blood chemistry, 3) organ and tissue toxicity. Information should address effects on the following physiological systems: circulatory system, digestive/excretory system, endocrine system, immune system, integumentary system, musculoskeletal system, nervous system, renal/urinary system, reproductive system, and respiratory system. This information is covered by information similar to OECD TG 408.

All the studies but (vi.) and (vii.), provide relevant information as they address the systemic toxicity after repeated dose toxicity after 90-days or more of exposure. However, the studies (vi.) and (vii.) have a shorter duration than a sub-chronic study which is requested for this endpoint.

In your comments to draft decision you argue that "taken as a whole" the studies provided for this endpoint "*fulfils the information requirement for Annex IX, Section 8.6.2 of REACH (sub-chronic toxicity study)*. Nevetheless, as explained under section 2 of the *Appendix on reasons common to several requests*, the reliability of the sources of information is vitiated by significant deficiencies. In addition, the sources of information are also affected by the quality concerns identified below:

A. *Read across adaptations*
   Studies (i.) to (vi.) above are conducted with analogue substances. For the reasons explained in section 1 of the *Appendix on reasons common to several requests*, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected. Following the subsmission of your comments on draft decision, we agree that the read-across to the acid (EC no. 287-494-3) is acceptable. However, there are issues with these source studies as explained in issue 2. below.

B. *Quality of Studies*
   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 408. The following key parameters of this test guideline include, among others:
   a) dosing of the Substance daily for a period of 90 days until the scheduled termination of the study;
   b) Ophthalmological examination;
   c) sensory reactivity to various stimuli (including auditory, visual and proprioceptive, grip strength, and motor activity assessment) and functional observations of the animals;

d) clinical biochemistry (including investigation of the major effects on kidney and liver, performed on blood samples, including measurements of T3, T4, and TSH);
e) haematology; and
f) full detailed gross necropsy (including organ weight recordings) and subsequent histopathology of both types tissues.

However, the studies you have provided were not performed according to the criteria of the OECD TG 408. More specifically:

The reported data for studies (i.) to (vii.) do not include the following key parameters:
- Ophthalmological examination (point b above);
- sensory reactivity to various stimuli and functional observations of the animals (point c); and
- a full clinical biochemistry including measurements of T3, T4, and TSH according to OECD TG 408 (point d).

Moreover:
- Studies (i.) and (vii.) do not include histopathology examination and study (iv.) does not include haematology and histopathology examination (points e and f);
- Studies (vi.) and (vii.) do not include the required exposure duration of 90 days, because you indicated an exposure duration of 29 days for males and 30 days for females (point a).

On the basis of the above, the information provided does not cover key parameters required by OECD TG 408. The reliability of the sources of information you invoked under a weight of evidence adaptation is significantly vitiated by these deficiencies.

In your comments you accept that the studies (vi.) and (vii.) should be considered as supportive studies on the basis of exposure duration and proposed that the study (v.) would be considered as key study instead of (i.) and (ii.).

C. *Appropriateness of the dermal route of exposure*

As stated in Annex IX, Section 8.6.2. Column 2 of REACH, testing by the dermal route is appropriate if, among others, the following criterion is met:
(1) the physicochemical properties suggest a significant rate of absorption through the skin.

One of the key studies you provided (study ii.) in the dossier was performed with the dermal route. In your dossier, under the toxicokinetics section, you indicate that the absorption rate for the dermal route is 0.065% while for the oral route the absorption rate is 90%.

According to ECHA guidance Chapter R.7.a, section R.7.5.4.3.2, the oral route is the default route for repeated dose toxicity testing, because it is assumed to maximise systemic availability. The provided studies do not indicate that the Substance has a significant absorption rate through the skin, because a value of 0.065% for the rate of absorption is not considered to be significant. Therefore you have failed to fulfil the above condition.

Therefore testing by the dermal route is not the most appropriate route for this Substance.

In your comments you accept that the study (ii.) should be considered as supportive study only on the basis of aprorpriatness of the route of exposure.

The reliability of the sources of information you invoked under a weight of evidence adaptation is significantly vitiated by the above deficiencies. Therefore, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 408 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Based on the above, the information you provided does not fulfil the information requirement.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity. The Substance is a solid at room temperature. Although the information indicates that human exposure to the Substance by the inhalation route is likely, based on the chemical safety report, it is reported to occur as a dust (powder), without a significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm). Moreover, the Substance is a soluble powder.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

3. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2. to REACH.

You have provided the following key studies for this information requirement in your dossier:

i. Developmental toxicity study in rats with the Substance ([redacted], 1971), no test guideline followed; and
ii. Developmental toxicity study in mice with "LAS" ([redacted], 1975), no test guideline followed;

In addition you also provided the following supporting study:

iii. Developmental toxicity study in rabbits with "LAS" ([redacted], 1975), no test guideline followed.

In your comments on the draft decision, you consider that "that "*Taken as a whole (read-across, use of existing data and weight of evidence approach), the data currently part of the registration dossier fulfils the information requirement for Annex IX, Section 8.7.2 of REACH (pre-natal developmental toxicity in a first species) providing a key study in rats and supporting study in mice*". We therefore understand that you invoke in your comments a weight of evidence adaptation under Section 1.2 of Annex XI of the REACH Regulation.
We have assessed this information and identified the following issue:

For the reasons explained in section 2 of the *Appendix on reasons common to several requests*, the your adaptation does not comply with the general rules of adaptation as set out in Annex XI.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.7.2 at Annex IX includes similar information that is produced by the OECD TG 414 on one species. The following aspects are covered: 1) prenatal developmental toxicity, 2) maternal toxicity, and 3) maintenance of pregnancy.

All the studies contained in the dossier for this endpoint provide relevant information for this endpoint.

In your comments to draft decision you argue with regard to the rabbit study (iii.) that "*The study has been re-reviewed by the registrants which indicates the study should actually be assessed as a Klimisch 2 instead of the existing Klimisch 3 rating which was erroneously assigned. Following the recent re-review of this study, the registrants claim that it is sufficient to fulfil the registration requirements for the endpoint concerned. This study was conducted according to generally accepted procedures at the time the study was conducted*". Nevetheless, as explained under section 2 of the *Appendix on reasons common to several requests*, the reliability of the sources of information is vitiated by significant deficiencies. In addition, the sources of information are also affected by the quality concerns identified below:

A. Studies not adequate

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, the study has to meet the requirements of OECD TG 414. The criteria of this test guideline include e.g.

- 20 female animals with implantation sites for each test and control group;
- examination of the dams for weight and histopathology of the thyroid gland, thyroid hormone measurements and gravid uterus weight;
- examination of the foetuses for sex and body weight/external, skeletal and soft tissue alterations (variations and malformations)/number of resorptions and or live foetuses/ measurement of anogenital distance in live rodent foetuses (see scenario 6).

However, the studies you have provided were not performed according to the criteria of the OECD TG 414. More specifically:

a) The reported data in study (i.) does not include the number of pregnant animals tested. Study (ii.) was conducted in 20 mice however, no data was provided on how many pregnant mice were tested. Study (iii.) was conducted with 13 females for each test group. Therefore, the statistical power of the information provided appears not to be sufficient because it does not fulfil the criterion of 20 pregnant females for each test group set in OECD TG 414.
b) The reported data in studies (i.) to (iii.) does not include the weight and histopathology examination of the thyroid gland in dams and gravid uterus weight of the dams as required in OECD TG 414. Moreover, for studies (i.) and (ii.) there are no recorded thyroid hormone measurements as required in OECD TG 414.
c) In studies (i.) and (ii.) you have provided, the sex and body weight of the foetuses, the external, skeletal and soft tissue alterations (variations and malformations), number of resorptions and/or dead foetuses have not been recorded. In addition the anogenital distance has not been measured in live foetuses as required in OECD TG 414.

On this basis, the information provided does not cover key parameters required by OECD TG 414. The reliability of the sources of information you invoked under a weight of evidence adaptation is significantly vitiated by this deficiency.

B. Test material unclear

Moreover, for studies (ii.) and (iii.), you have identified the test material as "LAS", without further information, including composition.

In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed and you have not demonstrated that the test material is representative for the Substance. The reliability of the sources of

information you invoked under a weight of evidence adaptation is significantly vitiated by this deficiency.

As a result, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 414. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Based on the above, the information you provided does not fulfil the information requirement.

In your comments to draft decision you inform that "*the registrants will update, by April 26th the information on the key studies and the supporting study in line with ECHA guidance on IUCLID robust study summary reporting. Moreover, the registrants will further clarify that the study in rats ([redacted], 1971) is the key study for this endpoint, with the studyin mice ([redacted],1975) as a supporting study*."

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[7] administration of the Substance.

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix D: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X to REACH.

You have provided the same information as already described under Appendix C, section 3.

We have assessed this information and identified the following issues:

In your comments to draft decision you provided similar comments to those discussed in Appendix C.3.

For the reasons already explained under Section C.3, the information you provided does not fulfil the information requirement.

Test design

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred second species, depending on the species tested in the first PNDT study (request C.3 in this decision).

The study shall be performed with oral[8] administration of the Substance.

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix E: 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[9].

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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex).

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[10].

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

Appendix F Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS. Similarly the information requirement for a Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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 31 January 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.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments and referred the modified draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee unanimously agreed on the draft decision in its MSC-75 written procedure. ECHA adopted the decision under Article 51(6) of REACH.

Appendix G List of references - ECHA Guidance[11] 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)[12]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

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.

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

OECD Guidance documents[14]

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.

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

Appendix H 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
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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.