Helsinki, 27 April 2021

Addressees
Registrants of 232-000-3_SrF2 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
30/04/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Strontium fluoride
EC number: 232-000-3
CAS number: 7783-48-4

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***3 November 2022***.

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

A. 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 route, with either the Substance or a fluoride salt containing a higher fluoride mass content and a counter ion posing no adverse effect, such as sodium fluoride (EC no 231-667-8). For the comet assay the following tissues shall be analysed: liver, glandular stomach and duodenum;

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 421/422) in rats, oral route.

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

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annex VIII of REACH".

Information required depends on your tonnage band

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

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Approved[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 on Reasons common to several requests

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

- *In vivo* somatic cell genotoxicity study (Annex VIII, Section 8.4., column 2)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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

Grouping of substances and read-across approach

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 (addressed under 'Scope of the grouping'). 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 (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have formed a group (category) of *'strontium cations (category 1) and fluoride anions (category 2)'*. You have provided a read-across justification document in IUCLID Section 13.

You provide the following reasoning for the grouping the substances:
"In a category approach, read-across is used among a number of structurally similar substances, i.e. soluble inorganic strontium substances and different fluoride substances, respectively. The structural similarity is based on the fact that the common (eco)toxicological moieties of concern are strontium cations (category 1) and fluoride anions (category 2). Within each category, as a result of the structural similarity, the specified toxicological and ecotoxicological properties are similar."

You define the applicability domain of the category as follows: *soluble inorganic strontium substances and different fluoride substances*.

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[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] 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)

[4] 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

B. Predictions for properties

a. Prediction for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties in the CSR: *"Reliable substance-specific information concerning the toxicity for strontium difluoride does not exist. Instead, toxicological information on fluorides (mainly sodium fluoride) substances and soluble inorganic strontium substances were extrapolated to strontium difluoride considering that the systemic effects mainly based on the concentrations of the Sr2+ and F- ions which are the key concern of strontium difluoride".*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substances.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. 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 source substance(s) and your Substance[5]. 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.

Your read-across hypothesis is that the Substance dissociates in water and the corresponding ions drives toxicity. You have provided solubility data to support this prediction.

Your read-across hypothesis is reliable and supported by evidence, therefore it is accepted.

ECHA notes, however, the following shortcomings with regards to predictions of toxicological properties.

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

With regard to your predictions for *in vivo* mutagenicity, your source study does not meet the above-mentioned criterion concerning the Fluoride ion (for details see the Appendix A, Section 1). Therefore, no reliable predictions can be made for this information requirement.

With regard to your predictions for Screening for reproductive/developmental toxicity, your source study does not meet the above-mentioned criterion concerning the Strontium ion (for details see the Appendix A, Section 2). Therefore, no reliable predictions can be made for this information requirement.

[5] *Guidance on information requirements and chemical safety assessment*, Chapter R.6: QSARs and grouping of chemicals.

C. Conclusions on the grouping of substances and read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance(s). 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.

Appendix A: 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 to 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.

In this case, there are positive results in the following *in vitro* genotoxicity studies in Annexes VII and VIII raising a concern for both gene mutation and chromosomal aberration:
(1) 10 positive *in vitro* cytogenicity tests and 4 positive *in vitro* gene mutation studies in mammalian cells for sodium fluoride (EC No. 231-667-8 / CAS No. 7681-49-4)and
(2) 1 positive *in vitro* cytogenicity test and 1 positive *in vitro* gene mutation studies in mammalian cells for potassium fluoride (EC No. 232-151-5 / CAS No. 7789-23-3).

You provided a read-across adaptation according to the Reasons common to several requests for adaptation of Annex XI, Section 1.5 referring to the following studies with the analogue substance sodium fluoride (EC No. 231-667-8):

- *In vivo* chromosomal aberration and/or micronucleus studies:
  - i. an *in vivo* study investigating mammalian somatic cell cytogenicity in erythrocytes (according to EPA OPPTS 870.5395 guideline) and chromosomal aberration in bone marrow (according to EPA OPPTS 870.5385 guideline) giving negative results (1994).
  - ii. a non-guideline cytogenicity study in osteoporotic patients giving negative results (1998).
  - iii. a supporting *in vivo* micronucleus test performed according to OECD TG 474 and giving negative results (1987).
  - iv. an *in vivo* micronucleus test performed according to EPA OPPTS 870.5395 guideline and giving negative results (1987).
  - v. a non-guideline *in vivo* chromosomal aberration study giving negative results (1979).
  - vi. an *in vivo* micronucleus test performed according to Japanese Guidelines for screening mutagenicity testing of chemicals and giving negative results (1988).
  - vii. an *in vivo* chromosomal aberration test performed according to EPA OPPTS 870.5385 guideline and giving negative results (1989).

- *In vivo* comet studies:
  - viii. a non-guideline *in vivo* study investigating DNA-strand breaks in testicular cells and giving negative results (1986).
  - ix. a non-guideline *in vivo* comet assay in peripheral blood, oral mucosa and brain cells giving negative results (2004).

- *In vivo* sister chromatid exchange studies:
  - x. an *in vivo* sister chromatid exchange assay performed according to EPA OTS 798.5915 guideline and giving negative results (1989).
  - xi. a non-guideline *in vivo* sister chromatid exchange study giving negative results (1987).
  - xii. a non-guideline *in vivo* sister chromatid exchange study giving negative results (1995).
  - xiii. an *in vivo* sister chromatid exchange assay performed according to EPA OTS 798.5915 guideline and giving negative results (1978).

- *In vivo* study investigating non-genotoxic endpoints:
  - xiv. a non-guideline study investigating mouse-sperm morphology and giving negative results (1989).

ECHA has assessed this information and identified the following issue(s):

In order to fulfill this information requirement, the *in vivo* somatic cell genotoxicity study must be appropriate and thus address the specific concern(s) raised by the *in vitro* positive results (Annex VIII, Section 8.4, column 2; ECHA Guidance R.7a, section R.7.7.6.3). In this case, the *in vitro* data provided on fluoride anions raise concern for both gene mutation and chromosomal aberration.

The *in vivo* sister chromatid exchange studies (x)-(xiii) and the study investigating mouse-sperm morphology (xiv) provided are not addressing the gene mutation or chromosomal aberration concerns raised by the *in vitro* data.

Therefore, these studies are not appropriate and they cannot be used to predict the properties of the Substance for gene mutation or chromosomal aberration.

For the reasons explained in the Appendix on general considerations, the *in vivo* study intended for addressing the gene mutation concern has to cover the key parameters of OECD TG 489 for an *in vivo* Mammalian alkaline comet assay or OECD TG 488 for a Transgenic rodent somatic and germ cell gene mutation assay. The key parameters of these test guidelines include:

a) Each group must have a minimum of 5 analysable animals (the test can be performed in either sex).
b) At least 150 cells must be analysed for each sample (per tissue, per animal).

You provided two non-guideline *in vivo* Comet studies (viii) and (ix) performed with the analogue substance sodium fluoride in order to follow up the concern for gene mutation raised by the *in vitro* results. However, the reported data for these studies do not include:

a) The appropriate number of animals in study (viii) (there were only 3 animals/group).
b) The analysis of the adequate number of cells in study (ix) (only 50 cells were scored per animal).

Therefore, the provided *in vivo* tests (viii) and (ix) are not adequate and they cannot be used to predict the properties of the Substance for gene mutation.

For the reasons explained in the Appendix on Reasons common to several requests, the *in vivo* study intended for addressing the chromosomal aberration concern has to cover the key parameters of OECD TG 474 for an *in vivo* Mammalian erythrocyte micronucleus test, OECD TG 475 for an *in vivo* Mammalian bone marrow chromosomal aberration test or OECD TG 489 for an *in vivo* Mammalian alkaline comet assay. The key parameters of these test guidelines include:

a) Each group must have a minimum of 5 analysable animals (the test can be performed in either sex).
b) 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.
c) 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). In an OECD TG 474 or OECD TG 475 study, 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).
d) In an OECD TG 475 study, at least 200 metaphases must be analysed for each animal for structural chromosomal aberrations including and excluding gaps.

You provided several *in vivo* studies (i)-(ix) performed according to a standard test guideline or not, with the analogue substance sodium fluoride, in order to follow up the concern for chromosomal aberration raised by the *in vitro* results. However, as explained above (section B), the provided *in vivo* Comet studies (viii)-(ix) do not meet the requirements of OECD TG 489.

In addition, the reported data for studies (i)-(vii) do not include:

a) the appropriate number of animals in study (iv) (there were only 4 animals/group).
b) the appropriate number of doses in studies (ii) and (iii) (only 2 doses were investigated).
c) a maximum studied dose that is the MTD or induces toxicity in the bone marrow in studies (ii), (v), (vi) and (vii).
d) the analysis of the adequate number of metaphases in studies (i) and (v) (only 50 metaphases were scored per animal).

Therefore, the provided *in vivo* tests (i)-(ix) are not adequate and they cannot be used to predict the properties of the Substance for chromosomal aberration.

In the absence of adequate and reliable coverage of the key parameters of the corresponding tests for the fluoride anion, your adaptation is rejected.

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

As your read-across hypothesis is accepted (see Appendix on Reasons common to several requests above), the fluoride ion is the cause of concern for mutagenicity. Therefore, testing may be performed with either the Substance or a fluoride salt containing a higher fluoride mass content and a counter ion posing no adverse effect, such as sodium fluoride (EC no 231-667-8).

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.

According to 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.

In line with 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.

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]).

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, 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. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

ECHA has assessed this information and identified the following issue(s):

As explained in the Appendix on Reasons common to several requests your adaptation according to Annex XI, Section 1.5 is rejected. In particular, the following endpoint-specific deficiency has been identified:

For the reasons explained in the Appendix on Reasons common to several requests, the study has to cover the key parameters of OECD TG 421 or 422. The key parameters of these test guidelines include:

- parameters for sexual function and fertility such as mating and fertility, duration of gestation, parturition and lactation, and examination of offspring parameters.

You provided a study (1977) using a protocol similar to the OECD TG 408 which did not investigate the above parameters.

Therefore, this study cannot be used to predict the properties of the Substance for Screening for reproductive/developmental toxicity.

[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 the absence of adequate and reliable coverage of the key parameters of the corresponding test for the strontium cation, your adaptation must be rejected.

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

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[7] administration of the Substance.

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

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

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[8].

B. Test material – testing with the Substance

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[9].

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

C. Test material – testing with an analogue substance

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) its representativeness towards the specified analogue substance,
   b) it supports the read-across prediction as as presented in the read-across justification document,
   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 analogue 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 all constituents of each Test Material and their concentration values.

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 Practical Guide on How to use alternatives to animal testing to fulfil your information requirements (Chapter 4.4.)[10].

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

Appendix C: 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 05 June 2019.

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

ECHA took into account your comments and did not amend the request(s).

The comment was an indication from a listed registrant in Appendix E, below, of a cease of manufacture. Following invalidation of the registration dossier, the registrant was removed from Appendix E, below.

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 also modified the deadline, to provide the information, from 12 to 18 months from the date of adoption of the decision take into account the time needed to perform the in vivo comet assay combined with the MN test.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s). You mention that you have downgraded the registration tonnage band of one registration on 8 February 2021. ECHA does not take into account new information on volumes or tonnage band after the date on which the draft decision is notified to the registrants according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide 'How to act in Dossier Evaluation and the notification letter of the draft decision' of 10 December 2019). Therefore, your comments on this matter do not impact the decision. ECHA has addressed the matter in a separate communication to you.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-73bis written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix D: 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)[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.

OECD Guidance documents[13]

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

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

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

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

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

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.