Helsinki, 23 October 2020

Addressees
Registrants of JS_269-123-7 listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision
04/05/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Castor oil, sulfated, sodium salt
EC number: 269-123-7
CAS number: 68187-76-8

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 in B.3. below by ***30 April 2021*** and all other information listed below by ***2 November 2022***.

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

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Skin sensitisation (Annex VII, Section 8.3) ;

   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and

   ii. Only if the *in vitro/in chemico* test methods specified under point i.) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

2. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: generate an exposure assessment for identified uses and perform a risk characterisation accordingly.

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487)
2. Only if a negative result in Annex VIII, Section 8.4.2. is obtained, In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490);
3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 421/422) in rats, oral route.

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route;
3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211);
4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210).

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

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

Information required depends on your tonnage band

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

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 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". 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.

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 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 following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

1. Skin sensitisation (Annex VII, Section 8.3.)
2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
3. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
5. Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
6. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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.

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. 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. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances castor oil (EC no 232-293-8); rape oil, sulfated, sodium salt (EC no 281-978-8); oils, vegetable, sulfated, ammonium salt (EC no 281-976-7); and Oils, fish, sulfated, ammonium salt (EC no 262-992-3) as source substances and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties:
"Within the examined triglyceride structures, the similarity follows the parameters associated with the numbers of carbon atoms and unsaturations and the type of functional groups (as in

[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

the case of the -OH groups for the castor oil) present in the structures."

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

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

According to Annex XI, Section 1.5 there needs to be structural similarity between substances resulting in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties.

In your read-across justification document you address the structural differences between the Substance and of the source substances in two SAR studies.

In SAR study I, you demonstrate that the differences among triglycerids depends on the numbers of C, number of insaturations and on different functional groups present in the structure. The most different substances in the group appeared to be Castor oil, Ga-Ti-Er, and Ga-Ti-Ce molecules.

In SAR study II, which analysed different groups of structures (sulfated derivatives of fatty acids, esters, fatty alcohols, ethoxylated alcohols and triglycerides), you found similarities within the groups but differences across the groups.

You describe in your SAR analyses the structual differences between the Substance and the source substances. However, you have not explained how these differences could be expected to influence the hazardous profile of the substances.

Whilst this information may constitute relevant information in support of the read-across approach, considering the complexity of the endpoints under consideration these SAR studies cannot be seen, on their own, as evidence of similarity in the properties of these constituents. The data set reported in the technical dossier does not include relevant, reliable and adequate information on the properties under consideration for your Substance and the source substances, e.g. bridging studies of comparable design and duration. In the absence of such information, you have not established that the Substance and the source substances are likely to have similar properties. Therefore, you have not provided sufficient supporting information onthe rationale for the read-across.

Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the sourcesubstances. 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 VII of REACH

1. Skin sensitisation (Annex VII, Section 8.3.)

Skin sensitisation is a standard information requirement in Annex VII, Section 8.3. of REACH. Column 1 of Section 8.3. requires the registrants to submit information allowing a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and risk assessment, where required.

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

You have provided study records for the following studies carried out with source substance:

i) Five local lymph node assays: BrdU-ELISA according to OECD TG 442B (2012) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8);
ii) One skin sensitisation test according to OECD TG 406 (2012) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8);
iii) One local lymph node assay: BrdU-ELISA according to OECD TG 442B (2012) with the source substance oils, vegetable, sulfated, ammonium salt (EC no 281-976-7);
iv) One local lymph node assay: BrdU-ELISA according to OECD TG 442B (2012) with the source substance oils, fish, sulfated, Na salt (EC no 262-992-3).

In addition, you have provided a study with the Substance: Local lymph node assay: BrdU-ELISA according to OECD TG 442B (2012). This study has been given a reliability score of 3 (not reliable). As the reason for reliability 3, you have indicated that there are "*concerns for applicability of the method with this class of substances.*" However, although ECHA finds that the concerns for the applicability of the method with this class of substance have not been substantiated we have not included this study in the assessment, because of the reliability score of 3 assigned by you.

On the basis of these studies, you conclude that information on skin sensitisation is conclusive, but not sufficient for classification.

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

As explained in the Appendix on Reasons common to several requests, your adaptation under Annex XI, Section 1.5 is rejected. Therefore, studies i-iv cannot be used to fulfil the information requirements for this endpoint.

Therefore, the information requirement is not fulfilled, and your conclusion that the Substance does not cause skin sensitisation is rejected.

To fulfil the information requirement for the Substance, *in vitro/in chemico* skin sensitisation studies (OECD TG 442C, 442D and 442E) are considered suitable. In case the *in vitro/in chemico* methods are not suitable for the substance or the results cannot be used for classification and risk asssement an *in vivo* skin sensitisation study (OECD TG 429) must be performed.

2. Exposure assessment and risk characterisation for human health (Annex I, Sections 5. and 6.)

Under Articles 10(b) and 14(1) of REACH, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of REACH.

In the CSR that you provided the exposure assessment and risk characterisation for human health is missing.

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

Under Article 14(4), if the substance fulfils the criteria for any of the hazard classes listed in that provision, the CSA shall include exposure assessment and risk characterisation conducted in accordance with Sections 5 and 6 of Annex I of REACH.

You have classified the substance as Eye Damage 1 (H318), thus fulfilling the criteria set out in Article 14(4) of REACH to require an exposure assessment and a risk characterisation.

Therefore, exposure assessment and risk characterisation conducted in accordance with Sections 5 and 6 of Annex I of REACH for human health are needed to address the hazard identified for human health.

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

1. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have adapted the information requirement by using a read-across approach under Annex XI, Section 1.5. and provided a key study and two supporting studies in your dossier:

i. In vitro mammalian cell micronucleus test according to OECD TG 487 (2013) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8).
ii. In vitro mammalian chromosome aberration test, equivalent or similar to OECD TG 473 (1992) with the source substance castor oil (EC no 232-293-8).
iii. In vivo mammalian erythrocyte micronucleus test, equivalent or similar to OECD TG 474 (1992) with the source substance castor oil (EC no 232-293-8).

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

As explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

Possibility for data sharing for studies not involving vertebrate animals
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[5].

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

You have adapted the information requirement by using a read-across approach under Annex XI, Section 1.5. and provided a study with a source substance in your dossier.

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

1) Inadequate *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study

The adaptation using a read-across approach under Annex XI, Section 1.5 for the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study provided in the dossier is rejected for the reasons provided in the Appendix on Reasons common to several requests and section B.1 above.

The result of the request for information in section B.1. will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study under Annex VIII, Section

[5] https://echa.europa.eu/regulations/reach/registration/data-sharing

8.4.3 is triggered.

You have adapted the information requirement by using a read-across approach under Annex XI, Section 1.5. and provided a key study in your dossier:

i. In vitro mammalian cell gene mutation test according to OECD TG 476 (2013) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8).

As explained in the Appendix on Reasons common to several requests, your adaptation under Annex XI, Section 1.5 is rejected.

Consequently, you are required to provide information for this endpoint, if the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provides a negative result. The deadline set by this decision allows for sequential testing.

To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

Possibility for data sharing for studies not involving vertebrate animals
The other registrants of the joint submission relied on an adaptation to meet this information requirement. You may consider sharing this information[1].

3. 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 read-across approach under Annex XI, Section 1.5 and provided a combined repeated dose toxicity study with the reproductive/developmental toxicity screening test according to OECD TG 422 (2013) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8; 2013).

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

As explained in the Appendix on Reasons common to several requests your adaptation under Annex XI, Section 1.5 is rejected. Therefore, the information requirement is not fulfilled.

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[6] administration of the Substance.

Note for your information
The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[7].

ECHA considers six months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.

[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[7] https://echa.europa.eu/regulations/reach/registration/data-sharing

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by using a read-across approach under Annex XI, Section 1.5 and provided one 90-day repeated dose toxicity study equivalent or similar to OECD TG 408 (1992) and one 28-day repeated dose toxicity study according to OECD TG 422 (2013) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8; 2013).

We have assessed this information and identified the following issue(s):
As explained in the Appendix on Reasons common to several requests your adaptation under Annex XI, Section 1.5 is rejected.

Furthermore, 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 parameter(s) of this test guideline include, among others:
1. At least 10 female and 10 male animals should be used at each dose level (including control group), and
2. dosing of the Substance daily for a period of 90 days until the scheduled termination of the study.

The Reproduction/Developmental Toxicity Screening Test (OECD TG 422) you have submitted does not have the required exposure duration of 90 days as required in OECD TG 408, because you indicated an exposure duration of 5 weeks for males. Furthermore the number of animals examined per dose group for histopathology and clinical chemistry is significantly lower than required by the OECD TG 408 leading to lower statistical power.

Therefore, the information requirement is not fulfilled.

Information on the 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, because the Substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

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

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

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

You have adapted this information requirement by using a read-across approach under Annex XI, Section 1.5 and provided a combined repeated dose toxicity study with the reproductive/developmental toxicity screening test according to OECD TG 422 (2013) with the source substance rape oil, sulfated, Na salt (EC no 281-978-8; 2013). You have also provided an adaptation based on low toxicity. We understand that you intend to adapt

according to Annex IX, Section 8.7.2., Column 2, third intent, based on the study mentioned above.

We have assessed this information and identified the following issues:

A. As explained in the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5. is rejected.

B. In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species.

   You have not provided information following OECD TG 414. Instead, you have provided a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414).

   Therefore, this study does not fulfil the information requirement.

C. According to Annex IX, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, two of them being:
   - that there is no evidence of toxicity seen in any of the tests available; and
   - that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure.

You justified the adaptation by stating that the "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422) "*shows that the substance has no functional effect on developmental toxicity or the reproductive performance of both male and female rats".* However, the study was performed with an analogous substance. As stated above your read-across is rejected, and the study can therefore not be used to justify your adaptation.

In addition, you have not provided any toxicokinetic data to show that there is no systemic absorption.

Therefore, your adaptation Annex IX, Section 8.7., Column 2, third indent is rejected.

Conclusion
As explained above the information requirement is not fulfilled.

Information on the 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 administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

Data provided:
You have provided an adaptation based on a QSAR estimate for the Substance.

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

1. the substance falls within the applicability domain of the QSAR model.

You have provided a QSAR estimate for the Substance with ECOSAR v1.11 (2011).

- The Substance does not fall within the applicability domain of the model (see ECHA Guidance R.6, Section R.6.1.5, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.2):
  - the chain length of the target molecule with average 30 carbons makes it falls outside the applicability domain of the model.
  - QSAR predictions by the QSAR models for the special class of surfactants cannot be considered reliable either, due to the structural complexity of the target molecule and the shortcoming of the training set of the model.

The adaptation you provided does not fulfil the criteria specified in Annex XI, Section 1.3. and it is therefore rejected.

Therefore, the information requirement is not fulfilled.

Information on the study design
The Substance is difficult to test due to the surface activity properties (Surface tension of an structurally similar substance (rape oil, sulphated, Na salt, CAS N. 84082-30-4 / EC N 281-978-8): 33.2 mN/m). OECD TG 211 and 210 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your Substance. The approach selected must be justified and documented.

Due to the Substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the Substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

Appendix D & E includes further technical advice on testing UVCB substances.

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have provided a QSAR estimate for the Substance with ECOSAR v1.11 (2011).

Due to the same reasons as explained in the Appendix C, Section 3 above, your adaptation is rejected and the information requirement is not fulfilled.

Test design, as described in the Appendix C, Section 3 above, applies.

EUROPEAN CHEMICALS AGENCY

Appendix D: 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

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 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 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). Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers.
dossiers[9].

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

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.

Appendix F: 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 22 May 2019.

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

In your comments, you outlined a future registration dossier update and data sharing with the joint submission. As well as communicating directly with the registrant, ECHA has addressed the possibility for data sharing for studies not involving vertebrate animals under B.1. and B.2. Regarding future registration dossier updates, ECHA will assess the latest dossier update after the deadline set in the decision.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix G: List of references - ECHA Guidance[10] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[11]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[11]

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[12]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[12] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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

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

Appendix H: 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.