~~Confidential~~

Helsinki, 10 November 2021

Addressees
Registrant(s) of JS_ETHYL_XANTHATE as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20/05/2013

Registered substance subject to this decision ("the Substance")
Substance name: Sodium O-ethyl dithiocarbonate
EC number: 205-440-9
CAS number: 140-90-9

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 ***15 February 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)

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

B. Information required from 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. If negative results are obtained in test performed for the information requirement of Annex VIII, Section 8.4.2. then: 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: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

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

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

1. 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)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; 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.

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

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". 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 standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study in a second species (Annex X, 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 R.6. and related documents[2,3].

- **Predictions for toxicological properties**

You have provided a read-across justification document in the chemical safety report (CSR).

You read-across between the structurally similar substances:

- potassium isopentyl dithiocarbonate (EC 213-180-2)
- carbon disulfide (referred to as CS2) (EC 200-843-6)

as source substances and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties:

"As the xanthates can be considered as a group of substances which have structural similarity and similar behaviour in contact with water and in the physiological processes, their irritation as well as acute and systemic adverse effects to human health are similar. Therefore, and in order to avoid the unnecessary animal testing, the read-across data from the analogue xanthates is used to evaluate the irritation/sensitisation and short term and/or long-term toxicological effects of the target substance.

As the target substance is an unstable compound, the apparent toxicity reflects to the toxicity of the degradation products. The selection of the most critical degradation products for the hazard assessment are based on the known decomposition reaction of the target substance

[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

and based on the physicochemical properties and toxicological properties of the degradation products."

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 shortcoming(s) with regards to prediction(s) of toxicological properties.

Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[4]. It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the structural similarity and similarity in behaviour in contact with water and in physiological processes between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance.

You have not provided any explanation or supporting information on the similarity in physiological processes.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar human health properties. The same applies to similarity in behaviour in contact with water while the similarity in physiological processes is not substantiated or explained and therefore cannot be assessed. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological property, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[5]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source

[4] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

substance(s).

Supporting information must include toxicokinetic information on the formation of the common compound, bridging studies to compare properties of the Substance and source substances, and information on the impact of exposure to parent compounds on the prediction.

Missing information on the formation of common compound and on the impact of non-common compounds

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, information characterising the rate and extent of the hydrolysis of the Substance and of the source substance(s) is necessary to confirm the formation of the proposed common hydrolysis product and to assess the impact of the exposure to the parent compounds.

You have not provided any experimental data or other adequate and reliable information about the hydrolysis of the source substance potassium isopentyl dithiocarbonate. Hydrolysis data provided for the Substance indicates the hydrolysis half-life is in range of 5.5 h to 274 days depending on the tested conditions (pH, temperature).

In the absence of information on the source substance, you have not provided supporting evidence establishing that the proposed common hydrolysis product is formed as assumed in your read-across hypothesis. In addition, in light of such a wide hydrolysis half-life range, the impact of exposure to parent compound and its potential toxic properties must be assessed. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Missing supporting information to compare genotoxic properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

You provided genotoxicity information only on the source substance while the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance to support your read-across hypothesis.

Further, you have not provided genotoxicity data from "*the selection of the most critical degradation products for the hazard assessment"* as described in your read-across justification.

In the absence of such information, you have not established that the Substance and of the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the 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 analogue substance. 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.

2. Assessment of your weight of evidence adaptation under Annex XI, Section 1.2

You have adapted the following standard information requirements by applying weight-of-evidence (WoE) approaches:

- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)

Your weight of evidence adaptation raises the same decifiencies irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed these deficiencies in the present Appendix, before assessing the specific standard information requirements in the following appendices.

ECHA assessed this information according to the requirements of Annex XI, Section 1.2 of the REACH Regulation and identified the following general issues with all of these adaptations:

1. Requirement for documentation of the WoE adaptations

Annex XI, Section 1.2 states that there may be sufficient weight of evidence (WoE) 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.

ECHA Guidance R.4.4 specifies that a WoE adaptation must involve an assessment of the relative values / weights of the several pieces of available information. This assessment must consider for instance the relevance and reliability of the information, the consistency of results/data, the nature and severity of effects. The lines of evidence should be integrated considering their relative values or weights in order to draw a conclusion. The assessment should be documented and included in your technical dossier.

However, you have not included a justification for your WoE adaptations, which would include an assessment of relative weights of the individual pieces of information and the subsequent conclusions drawn.

2. Reliability of the experimental information

ECHA Guidance R.4, Section R.4.2 informs on the criteria for assessing the reliability of information provided as part of WoE adaptations. The availability of raw data from the studies and an adequate description of the studies are listed among the key elements to be assessed to determine if and how the information can be used in the adaptation. This ECHA Guidance indicates that "*where critical supporting information is not reported (e.g. species tested, substance identity and dose procedure) the test data should be considered to be unreliable for the purposes of REACH*".

None of the study summaries provided by you, performed either on the Substance or an analogue substance, include any critical supporting information such as study design details, a description of the test solution preparation or other key parameters allowing to assess the validity of the test method applied. In the absence of this information the results of these studies referred to in your WoE adaptations are considered unreliable.

Additional issues related to weight of evidence are addressed under the corresponding 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 adapted the standard information requirement according to Annex XI, Section 1.5. Grouping of substances and read-across approach of REACH Regulation.

In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. *in vitro* gene mutation study in bacteria (2013) with source substance potassium isopentyl dithiocarbonate (CAS 928-70-1; EC 213-180-2)

ECHA assessed this information according to the requirements of Annex XI, Section 1.5 of the REACH Regulation 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 and the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

2. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

ECHA understands that you have provided an adaptation under Annex XI, Section 1.1.2 of REACH using the following information:

i. a key study (1988) performed according to OECD TG 202 on the Substance;
ii. 2 supporting studies (1977 and 1973) performed according to non-specified test method on the Substance.

We have assessed this information and identified the following issues:

Key study (i)

Under Annex XI, Section 1.1.2., an existing study must:

- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 202. Therefore, the following specifications must be met:

- the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
- the test duration is 48 hours or longer;
- at least 20 animals are used at each test concentration and for the controls;
- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;
- the concentrations of the test material are measured at least at the highest and lowest

test concentration, at the beginning and end of the test;
- the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

Your registration dossier provides an OECD TG 202 showing the following:

- there is not information on the percentage of immobilised daphnids at the end of the test
- the test duration was 24 hours;
- 7 animals were used at each test concentration
- there is no information on the concentrations tested
- You have not provided performance parameters of the analytical method
- the results of the analyses to determine the concentration of the test substance in the test vessels are not provided;
- tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;

Based of the above, the validity criteria of OECD TG 202 are not met and the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, you have not demonstrated adequate and reliable coverage of the key parameters of OECD TG 202.

Supporting studies (ii)

Your dossier contains data for this endpoint (ii), which according to the information you provided are taken from publications.

To adapt the information requirement, a there must be adequate and reliable documentation (Annex XI, Section 1.1.2 of REACH). In order to make an independent assessment of a key study, a robust study summary must be provided or, in the case of a supporting study, a study summary (Guidance on IRs and CSA, Section R.6.2.6; Art. 3(28)-(29) and 10(a)(vi)-(vii) and Annex I, Section 1.1.4/3.1.5 of REACH).

Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

Study summary must provide a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study (Article 3(29)).

In your technical dossier and CSR, you have identified studies (ii) as supporting studies but provided only the effect values.

Therefore, you have not provided a (robust) study summary and thus not provided information allowing for an (independent) assessment of the studies.

On this basis, the information requirement is not fulfilled.

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

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

You have adapted the standard information requirement according to Annex XI, Section 1.5. Grouping of substances and read-across approach of REACH Regulation.

In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. *in vitro* chromosome aberration test (2013) with source substance potassium isopentyl dithiocarbonate (CAS 928-70-1; EC 213-180-2)

ECHA assessed this information according to the requirements of Annex XI, Section 1.5 of the REACH Regulation 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 and the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, either *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) are considered suitable.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

i. Triggering of the study

Your dossier contains an adaptation for an *in vitro* gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or *in vitro* micronucleus study.

The information for the *in vitro* gene mutation study in bacteria and for the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study provided in the dossier are rejected for the reasons provided in section 2 of Appendix A and section 1 of this Appendix B.

The result of the requests for information in section 2 of Appendix A and section 1 of this Appendix B will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

ii. Assessment of information provided

You have adapted the standard information requirement according to Annex XI, Section 1.5. Grouping of substances and read-across approach of REACH Regulation.

In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. *in vitro* mammalian cell gene mutation test (2013) with source substance potassium isopentyl dithiocarbonate (CAS 928-70-1; EC 213-180-2)

ECHA assessed this information according to the requirements of Annex XI, Section 1.5 of the REACH Regulation 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 and the information requirement is not fulfilled.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

Study design

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

3. Screening for reproductive/developmental toxicity

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

You have provided an adaption in Section 7.8.1 of your dossier which ECHA understands is made to support a read-across adaptation under Annex XI, Section 1.5 and an exposure-based adaptation under Annex XI, Section 3 of REACH.
You conclude that "*Since CS2 is the most volatile and the most hazardous degradation product, it is the driving force for the hazard assessment of the target substance. Therefore, the exposure to CS2 via inhalation has been taken into account in the quantitative exposure assessment (sections 9&10 of CSR). The exposure assessment was done based on the monitoring data from end user sites as well as based on the modelled exposure estimates. According to the results of the assessment, the risks were considered controlled when appropriate OCs and RMMs with PPEs and safety practices are applied. According to the risk characterisation the amounts of CS2 released from the substance do not trigger the target substance to be classified as reproduction toxic, and the CSA does not indicate to further investigate the reproduction toxicity of the target substance.*

Furthermore, unnecessary vertebrate animal testing should be avoided and the animal testing must only be conducted as a last resort by the rules laid down in Annex XI".

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

1. Read-across adaptation

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

2. Exposure-based adaptation

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure

scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a),(b) or (c) shall be met. In particular:

- 3.2 (a) the manufacturer or importer demontrates and documents that all of the following conditions are fulfilled,
  - i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
  - ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
    - i. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

- 3.2 (b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for allrelevant scenariosthat throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply.

ECHA assessed this information according to the requirements of Annex XI, Section 3 of the REACH Regulation and identified the following issues:

First, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) for the substance.

You have, however, not provided exposure assessment for the Substance, only for CS2. ECHA notes that reliance on CS2 exposure is not acceptable because, as explained in the Appendix on Reasons common to several requests, your read-across approach under Annex XI, Section 1.5. is rejected.

Second, the first indent of criterion 3.2(a) requires "*absence of or no significant exposure in all scenarios of the manufacture and all identified uses*".

There is no exposure assessment for the Substance, only for its degradation product carbon disulphide (CS2). While the degradation of the Substance is not rapid (hydrolysis half-life range from 5.5 h to 274 days) and exposure to the Substance cannot be excluded in worker contributing scenarios 1 and 2 (charging PROC 8b and mixing PROC 3), the justification for waiving a standard requirement cannot be accepted. .

Third, the second indent of criterion 3.2(a) also requires that "*a DNEL or PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes*". You have, however, provided no relevant DNEL for the information requirement. ECHA notes that reliance on CS2 exposure is not acceptable for the reasons explained in the Appendix on Reasons common to several requests.

Fourth, the second criterion 3.2(b) requires a demonstration that "*throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)*" apply. The Substance is not

handled under strictly controlled conditions but the prevention of exposure is based on the use of personal protective equipment (PPE) in some tasks related to its use. Therefore criterion 3.2(b) for exposure-based adaptation is not satisfied. In particular, condition (a) as set out in Article 18(4) does not appear to be fulfilled because it has not been demonstrated that the substance is rigorously contained by technical means during its whole lifecycle.

Therefore, the adaptation you provided is not in line with the conditions specified in Annex XI, Section 3.

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

Information on study design

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.

4. Short-term toxicity testing on fish

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

You have adapted the standard information requirement according to Annex XI, Section 1.2. of REACH. In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. study (1986) performed according to a non-specified guideline on_the analogue substance (CAS 140-89-6),

ii. 5 studies (1974, 1975, 1976, 1977a and 1977b) performed according to non-specified guidelines on the Substance.

We have assessed this information and identified the following issues:

As explained in the Appendix on Reasons common to several requests your weight of evidence adaptation (Annex XI, Section 1.2) is rejected. In addition, the following endpoint-specific deficiency has been identified in your weight of evidence adaptation.

The weight of evidence must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

To fulfil the information requirement, normally a study according to OECD TG 203 must be provided. The key element investigated by this test is the concentration of the test material leading to the mortality of 50% of the juvenile fish at the end of the test.

All the sources of information you provided investigate this key element. Therefore, they provide information that would contribute to the conclusion on this key element.
However, the reliability of these sources of information is significantly affected by the deficiencies identified in Section 2 of the Appendix common to several requests.

Taken together, even if these sources of information provide information on the key element, their reliability is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, it is not possible to conclude, based on any source of information alone or

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

considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated by in an OECD TG 203 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

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

1. Pre-natal developmental toxicity study in one 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 provided an adaption in Section 7.8.2 of your dossier, which ECHA understands is made to support a read-across adaptation under Annex XI, Section 1.5 and an exposure-based adaptation under Annex XI, Section 3 of REACH. You conclude that "*Since CS2 is the most volatile and the most hazardous degradation product, it is the driving force for the hazard assessment of the target substance. Therefore, the exposure to CS2 via inhalation has been taken into account in the quantitative exposure assessment (sections 9&10 of CSR). The exposure assessment was done based on the monitoring data from end user sites as well as based on the modelled exposure estimates. According to the results of the assessment, the risks were considered controlled when appropriate OCs and RMMs with PPEs and safety practices are applied. According to the risk characterisation the amounts of CS2 released from the substance do not trigger the target substance to be classified as reproduction toxic, and the CSA does not indicate to further investigate the reproduction toxicity of the target substance.*

Furthermore, unnecessary vertebrate animal testing should be avoided and the animal testing must only be conducted as a last resort by the rules laid down in Annex XI".

ECHA has 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 and the provided hazard information is unreliable.

For the same reasons as explained under section 3 of Appendix B, the adaptation you provided is not in line with the conditions specified in Annex XI, Section 3.

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

Therefore your adaptation is rejected, and the information requirement is not fulfilled.

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.

2. Long-term toxicity testing on fish

You have adapted the standard information requirement according to Annex XI, Section 1.2. of REACH. In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. study (1976) performed according to a non-specified guideline on the Substance ;
ii. studie (1975) performed according to anon-specified guideline on the Substance.

We have assessed this information and identified the following issues:

As explained in the Appendix on Reasons common to several requests your weight of evidence adaptation (Annex XI, Section 1.2) is rejected. In addition, the following endpoint-specific deficiency has been identified in your weight of evidence adaptation.

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

The weight of evidence must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

To fulfil the information requirement, normally a study according to OECD TG 210 must be provided. The key elements investigated by this test are the parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage following exposure to the test substance are measured, including:

1) the stage of embryonic development at the start of the test, and
2) hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
3) the appearance and behaviour of larvae and juvenile fish, and

None of the sources of information you provided investigate these key elements. Therefore, they do not provide information that would contribute to the conclusion on these key elements. Furthermore, the reliability of these sources of information is significantly affected by the deficiencies identified in Section 2 of the Appendix common to several requests.

In addition, the reliability of sources of information (i) and (ii) is significantly affected for the following reason: According to you, these sources of information meet Klimisch criterion 3‘. ECHA agrees considering the use of secondary literature and the lack of reporting without further justification.

Taken together, f these sources of information do not provide information on the key element, in addition their reliability is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

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 property foreseen to be investigated by in an OECD TG 210 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

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 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.

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

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

Appendix E: 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 06 November 2020.

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

ECHA did not receive any comments within the commenting period.

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 F: 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)[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]

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

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

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.