Helsinki, 31 May 2024

**Addressee**
Registrant of JS_219-834-3 as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
25 April 2021

**Registered substance subject to this decision (“the Substance”)**
Substance name: Vinyl chloroacetate
EC/List number: 219-834-3

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

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**DECISION ON A COMPLIANCE CHECK**

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **8 June 2026**.

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

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

1. Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below.

2. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats.

The reasons for the requests are explained in Appendix 1.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

**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 requirements for testing and reporting new tests under REACH, see Appendix 4.

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of

**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 Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)  
Appendix 2: Procedure  
Appendix 3: Addressees of the decision and their individual information requirements  
Appendix 4: Conducting and reporting new tests under REACH

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\(^1\) 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 1: Reasons for the request(s)

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1. Short-term repeated dose toxicity (28 days) .................................................... 7
2. Screening study for reproductive/developmental toxicity .................................. 7

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Reasons common to several requests

0.1. Weight of evidence adaptation rejected

1 ECHA understands that you have adapted the following standard information requirements by using weight of evidence in accordance with Annex XI, Section 1.2.:

- Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

2 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

3 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

4 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

0.1.1. Lack of documentation justifying the weight of evidence adaptation

5 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach.

6 You have included expert assessment reports based on literature data on the degradation products of the Substance. However, you have not included a justification for your weight of evidence adaptation for each of the relevant information requirement, which would include an adequate and reliable (concise) documentation as to why the sources of information together provide similar information that is produced by the information requirements under consideration.

7 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration.

8 The common deficiencies are set out here:

0.1.2. Missing robust study summaries

9 Annex XI, Section 1.2. requires that whenever weight of evidence is used adequate and reliable documentation of the applied method must be provided. Such documentation must include a robust study summary for each source of information used in the adaptations.

10 A 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)).

11 In addition, for weight of evidence adaptations, the robust study summary must clearly indicate which key parameters of the study normally required for the information requirement are investigated in the study.
To support your adaptation, you have provided the following expert assessment reports based on literature data on the degradation products of the Substance:

(i) “Toxicity of Vinyl Chloroacetate following a short-term repeated exposure by the oral route” (2017);


In the expert assessment reports, you have provided only limited information on the studies, which ECHA understands are your sources of information. However, you have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of each source of information and contributing to the overall weight of evidence for the information requirement under consideration.

In the absence of robust study summaries, the coverage of the key parameters by these sources and the reliability of their contribution on these parameters to your weight of evidence adaptations cannot be evaluated.

0.1.3. Reliability of the information provided from analogue substances

For the information on analogue substances to reliably contribute to the weight of evidence approaches, it would have to meet the requirements for Grouping of substances and read-across approaches.

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.

Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.3.1. Predictions for toxicological properties

You have not provided a read-across justification document. However, ECHA understands that you aim to support read-across with the information provided in the expert assessment reports described under Section 0.1.2.

You predict the properties of the Substance from information obtained from the following source substances in a read-across approach as part of your weight of evidence adaptation:

- acetaldehyde, EC 200-836-8 (source substance 1);
- chloroacetic acid, EC 201-178-4 (source substance 2);

You provide the following reasoning for the prediction of toxicological properties:

- "The toxicokinetic behaviour of VCA was assessed and it was concluded that VCA would undergo rapid hydrolysis following oral exposure."

- "Therefore it is considered that the toxicity of the substance following a short-term oral exposure will be driven by the toxicity of its main degradation products."

- "Therefore it is considered that the toxicity of the substance to reproduction following oral exposure will be driven by the toxicity to reproduction of its main degradation products."
• *Subsequently, this Registration Assessment Report was based on available experimental data on chloroacetic acid and acetaldehyde.*

21 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

0.1.3.2. **Missing supporting information to compare the properties of the substances**

22 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substances (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

23 Supporting information must include information on the impact of exposure to parent compound on the prediction.

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

25 For the source substances, you provide information on the studies used in the prediction in your expert assessment reports. Apart from this information, the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both the Substance and source substances cause the same type of effects. Furthermore, you have not provided any information on the effects of source substances and/or the Substance on functional fertility and offspring.

26 In the absence of such information, you have not established that the Substance and the source substances are likely to have similar properties. Despite the rather rapid hydrolysis of the Substance to the source substances after oral intake, the exposure to the parent compound cannot be excluded. You have not provided any information how this and/or the co-exposure to both source substances affect the prediction. Furthermore, as described under Section 0.1.2., robust study summaries are missing for the source studies. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.3.3. **Conclusion on the read-across approach**

27 Based on the above, no reliable predictions can be made for these information requirements and your read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the information from the source substances cannot reliably contribute to your weight of evidence adaptations.

0.1.4. **Conclusion on the weight of evidence adaptation**

28 On this basis, your weight of evidence adaptation under Annex XI, Section 1.2. is also rejected.
Reasons related to the information under Annex VIII of REACH

1. Short-term repeated dose toxicity (28 days)

A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

1.1. Information provided

You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) Expert assessment based on literature data on the degradation products of the Substance (2017).

1.2. Assessment of the information provided

1.2.1. Weight of evidence adaptation rejected

Your weight of evidence adaptation is rejected for the reasons explained in Section 0.1. Therefore, the information requirement is not fulfilled.

1.3. Study design

When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

The study design is addressed in request 2.

2. Screening study for reproductive/developmental toxicity

A screening study for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

2.1. Information provided

You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) Expert assessment based on literature data on the degradation products of the Substance (2017).

2.2. Assessment of the information provided

2.2.1. Weight of evidence adaptation rejected

Your weight of evidence adaptation is rejected for the reasons explained in Section 0.1. Therefore, the information requirement is not fulfilled.

2.3. Study design
When there is no information available neither for the 28-day repeated dose toxicity study (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 1.

Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats.

As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1., Column 1).

Therefore, the study must be conducted in rats with oral administration of the Substance.
References

The following documents may have been cited in the decision.

**Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)**
- Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
  - Appendix to Chapter R.6 for nanoforms; ECHA (2019).
- Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
  - Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
- Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
  - Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
  - Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
- Chapter R.16 Environmental exposure assessment; ECHA (2016).

**Guidance for monomers and polymers**; ECHA (2023).
**Guidance on intermediates**; ECHA (2010).

All guidance documents are available online: [https://echa.europa.eu/guidance-documents/guidance-on-reach](https://echa.europa.eu/guidance-documents/guidance-on-reach)

**Read-across assessment framework (RAAF)**
- RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).


**OECD Guidance documents (OECD GDs)**
- OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
- OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
Appendix 2: 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 2023.

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

ECHA did not receive any comments within the commenting period.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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 3: Addressee of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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<tr>
<th>Registrant Name</th>
<th>Registration number</th>
<th>Highest REACH Annex applicable to you</th>
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Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.
Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 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 (https://echa.europa.eu/practical-guides).

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 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 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.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).