~~Confidential~~

Helsinki, 12 October 2023

Addressees
Registrant(s) of JS 271-233-5 EM Lead as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18/01/2018

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C8-10-iso-, C9-rich
EC/List number: 271-233-5

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 information under request 1 below by ***20 October 2025*** and all other information listed below by ***19 April 2027***.

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

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

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

2. 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)

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

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

The reasons for the decision(s) 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 addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 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 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 Mike Rasenberg, Director of Hazard Assessment

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

[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 decision

Contents

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

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 sections.

3 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.

4 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).

0.1.1. Predictions for toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

1-dodecanol,	EC 203-982-0, CAS 112-53-8
Alcohols, C7-9-branched, C8-rich,	EC 295-250-2, CAS 91994-92-2
Branched alcohols, C7-9, C8 rich,	EC 271-231-4, CAS 68526-83-0

7 You provide the following reasoning for the prediction of toxicological properties: ”similar chemical structure, manufacturing process, physicochemical properties and the same type of biological effects or trends among each of these substances”.

8 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.

9 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.1.1.1. Missing supporting information to compare properties of the substances

10 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 substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

11 Supporting information must include bridging studies to compare properties of the Substance and source substances.

12 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 substances 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).

13 For the source substances, you provide the studies used in the prediction in the registration dossier. You also provide a supporting study (OECD TG 422) with a source substance. Apart from those studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that it causes the same type of effects as the source substances, for information requirements (endpoints) that you adapt via grouping and read-across. This is relevant in particular for toxicity to reproduction and development.

14 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.2. Adequacy and reliability of source studies

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

(1) be adequate for the purpose of classification and labelling and/or risk assessment;
(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;
(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

16 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement sections 1 and 2. Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Comments to the draft decision

17 In your comments to the draft decision you explain that to substantiate your read-across approach your will apply a phased approach to testing. Reproductive and developmental endpoint studies will first be conducted on Exxal 8 (low end of carbon distribution) and sub-chronic toxicity studies (90-days) will be conducted on the intermediary substances (Exxal 9 and 10). The data from phase 1 will be assessed against the read-across hypothesis to inform actions in phase 2 (i.e., read-across hypothesis is valid or additional data generation is warranted).ECHA agrees that the information intended to be generated are useful information to fulfil information requirements for repeated dose toxicity (90-day) for the Substance. However, there is still no information available with the Substance to compare with the source substance/s important reproductive properties such as reproductive performance and pre- or postnatal development. In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have

similar properties for the endpoints relevant to this decision. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

18 As this strategy relies on a category approach that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members (including bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

0.1.3. Conclusion on the read-across approach

19 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

20 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

1.1. Information provided

21 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. Combined repeated dose toxicity study with the reproductive-developmental toxicity screening test (OECD TG 422, 1992) with the source substance 1-dodecanol (EC 203-982-0)

ii. 15-day repeated dose toxicity study (pre-guideline) 1961 in rabbits with the source substance Branched alcohols, C7-C9-iso, C8-rich (EC 271-231-4)

1.2. Assessment of the information provided

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

1.2.1. Read-across adaptation rejected

23 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issue(s) addressed below.

1.2.2. Source study not adequate for the information requirement

24 Under Annex XI, Section 1.5., the study to be read across must have an 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 408. Therefore, the following specifications must be met:

a. at least three dose levels with concurrent controls are tested, unless the study is conducted at the limit dose;
b. highest dose level should aim to induce toxicity or reach the limit dose.
c. at least 10 animals/sex are included for each dose and control group;
d. an exposure duration of at least 90 days;
e. at least weekly body weight and food consumption measurements;clinical signs observed daily and functional observations week 11 or after, i.e. sensory activity, grip strength and motor activity assessments;
f. the oestrus cycle in females at necropsy;
g. terminal organ and body weights;
h. gross pathology as specified in paragraphs 43-46 of the test guideline;
i. full histopathology as specified in paragraphs 47-49 of the test guideline.

25 The studies (i and ii) are described as a repeated dose toxicity studies. However, the following specifications are not according to the requirements of the OECD TG 408:

a. 2 dose levels (i.e., less than three dose levels) were tested and no concurrent controls were included (study ii);
b. the bioavailability via dermal route is unknown and effects were limited to local site of contact (ii);
c. 2 males/females (i.e., less than 10 animals/sex/dose) were included in each dose group (ii);
d. instead of daily administration during 90 days: daily administration during 37-43 days (i); 10 administrations during 15 days duration (ii);
e. data on body weights, body weight changes and food consumption are missing (ii);
f. data on clinical signs and functional observations are missing: nature, severity and duration (i, ii);
g. data on oestrus cycle are missing (i, ii);
h. data on terminal organ weights and organ/body weight ratios are missing (i, ii);
i. data on gross pathology findings are missing: incidence and severity (i, ii);
j. data on histopathology findings are missing: incidence and severity (i, ii).

26 Based on the above, the studies do not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 408 and the studies are not an adequate basis for your read-across predictions.

27 On this basis, the information requirement is not fulfilled.

1.3. Comments on the draft decision

28 In your comments to the draft decision you agree to perform the requested study.

1.4. Specification of the study design

29 Following 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 of the Substance; Guidance on IRs and CSA, Section R.7.5.6.3.2.

30 According to the OECD TG 408, the rat is the preferred species.

31 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

2. Pre-natal developmental toxicity study in one species

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

2.1. Information provided

33 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. Developmental toxicity study (similar to OECD TG 414), 1995, with the

source substance Alcohols, C7-9-branched, C8-rich (EC 295-250-2)

ii. Developmental toxicity study (similar to OECD TG 414), 1994, with the source substance Branched alcohols, C7-9, C8 rich (EC 271-231-4)

2.2. Assessment of the information provided

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

2.2.1. Read-across adaptation rejected

35 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

2.3. Comments on the draft decision

36 In your comments to the draft decision you propose to delay the initiation of this study until more data on Exxal 8 and 9 are available and the validity of your read-across approach can be assessed. ECHA has addressed the comment related to read-across in Section 0.1 above. Regarding your proposal to delay the initiation of the OECD TG 414 study in a first species ECHA notes that for the reasons explained above your dossier is currently not compliant with the information requirement and therefore, you remain responsible for complying with this decision by the set deadline.

2.4. Specification of the study design

37 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

38 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

39 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

Reasons related to the information under Annex X of REACH

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

40 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X, Section 8.7.2.

3.1. Information provided

41 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. "*Members of the Exxal group of alcohols are currently undergoing testing as part of an integrated testing strategy as agreed upon by ECHA (decision number CCH-D-2114342397-45-01/F) and we are awaiting the results to inform further testing.*"

3.2. Assessment of the information provided

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

3.2.1. Read-across adaptation rejected

43 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

44 In any case, the registration dossier mentions only an intent to adapt on the basis of future data; which, in the absence of current data, is insufficient to fulfil the requirements of Annex XI, Section 1.5.

45 Therefore, the information requirement is not fulfilled.

3.3. Comments on the draft decision

46 In your comments to the draft decision you propose to delay the initiation of this study until more data on Exxal 8 and 9 are available and the validity of your read-across approach can be assessed. ECHA has addressed the comment related to read-across in Section 0.1 above. Regarding your proposal to delay the initiation of the OECD TG 414 study in a second species ECHA notes that for the reasons explained above your dossier is currently not compliant with the information requirement and therefore, you remain responsible for complying with this decision by the set deadline. Specification of the study design

47 A PNDT study according to the test method OECD TG 414 should be performed in rabbit or rat as preferred second species, depending on the species tested in the first PNDT study (request 2 in this decision).

48 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

49 Based on the above, the study must be conducted in rabbit or rat 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.4 Evaluation of available information; ECHA (2011).
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).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***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).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 17 January 2022.

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

Based on the clarification provided in your comments to the draft decision, ECHA has removed the two following requests from this decision: Long-term toxicity testing on aquatic invertebrates and Long-term toxicity testing on fish.

ECHA took into account your comments as regards the remaining requests and did not amend them but extended the deadline.

In your comments on the draft decision, you requested an extension of the deadlines to provide the requested information. The deadlines of the draft decision were set based on standard practice for carrying out OECD TG tests. However, they have been exceptionally extended to take into account currently longer lead times in contract research organisations and aligning with the category members.

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: Addressees 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.

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.

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[2].

(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

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

(1) the boundary composition(s) of the Substance,
(2) 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.

Information on the Test Material needed in the updated dossier

a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex) and Annex XI Section 1.5 of REACH; namely all the constituents must be identified as far as possible as well as their concentration and the variability in these concentrations. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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

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[3].

[3] https://echa.europa.eu/manuals