~~Confidential~~

Helsinki, 04 June 2021

Addressees
Registrant(s) of JS_262-980-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
11/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Acetic acid, esters with lanolin alcs.
EC number: 262-980-8
CAS number: 61788-49-6

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 ***9 September 2022***.

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 study(ies) for skin corrosion/irritation (Annex VII, Section 8.1.; test methods: OECD TG 430, or OECD TG 431, or OECD TG 435 and OECD TG 439)

2. In vitro study(ies) for serious eye damage/eye irritation (Annex VII, Section 8.2., following the testing strategy as outlined in the OECD GD on an Integrated Approach on Testing and Assessment for Serious Eye Damage and Eye irritation, Series on Testing and Assessment No.263.)

3. Skin sensitisation (Annex VII, Section 8.3.; test method: Skin sensitisation (Annex VII, Section 8.3.); test methods:

   i. in vitro/in chemico skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

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

4. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

5. Acute toxicity by oral route (Annex VII, Section 8.5.1.; test method: EU B.1 bis./OECD TG 420, or EU B.1 tris./OECD 423, or OECD TG 425)

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

7. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

8. Ready biodegrability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310)

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

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annexes VII 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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

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 adaptation under Annex III (Substances in the 1-10 t/y range

For substances registered in quantities between 1 and 10 tonnes, information requirements on toxicological and ecotoxicological properties should be provided for all non-phase-in substances and for phase-in substances meeting the criteria specified in REACH Annex III.

The criteria set in Annex III are the following:

(a) Substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII (i.e. the PBT or vPvB criteria)

or

(b) Substances:

(i) with dispersive or diffuse use(s) particularly where such substances are used in consumer mixtures or incorporated into consumer articles; and

(ii) for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any human health or environmental hazard classes or differentiations under Regulation (EC) No 1272/2008.

Specific rules apply to phase-in substances manufactured or imported in quantities between 1 and 10 tonnes, if they do not fulfil the criteria in Annex III. In this case, the standard information requirements are restricted to all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the physicochemical endpoints in Annex VII.

As the Guidance on information requirements and chemical safety assessment, Chapter R.2, Section R.2.2.2.1 indicates, the registrant needs to document thoroughly that the criteria of Annex III are not fulfilled, i.e. by submitting available and reliable information on properties relevant for the classification criteria and/or on the uses as appropriate.[2] All available information should be used in the evaluation of the toxicity and ecotoxicity of the substance including information from non-testing methods.

The registrant needs to obtain reliable information that allows the comparison with the criteria for all the Article 14(4) hazard classes, categories or PBT and vPvB properties. If based on the comparison it is concluded that the substance is likely to meet classification criteria for any effect endpoint or the criteria for CMR category 1A or 1B or the criteria for PBT or vPvB, then the substance should be considered as meeting the requirement (a) or (b) (ii) according to REACH Annex III.

Further, according to REACH Annex III if dispersive use or diffuse use (particularly where such substances are used in consumer mixtures or incorporated into consumer articles) cannot be excluded, the criterion (b) (i) should be considered as fulfilled (see ECHA Guidance, Chapter R12 for further explanation of dispersive and diffuse use).

You have submitted an adaptation under Annex III. Under the field "*Justification for not meeting the REACH Annex III criteria*" in section 14 of your IUCLID dossier, you have indicated that the criteria in Annex III are not fulfilled for your Substance. You have not submitted any

[2] See also ECHA Manual 'How to prepare registration and PPORD dossiers', Section 8.9.1. 'Section 14 Annex III criteria', p. 117-118.

documentation supporting your claim, i.e. you have not submitted any information on properties relevant for the classification criteria and/or on the uses as appropriate. In addition, you have indicated that dispersive use or diffuse use (particularly where such substances are used in consumer mixtures or incorporated into consumer articles) cannot be excluded.

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

As explained above, if it can be demonstrated from reliable information that the substance is not likely to meet either of the criteria for CMR category 1A or 1B or PBT/vPvB, or for any other classification endpoint (i.e. health and the environmental) and it has no dispersive or diffuse use, the standard information requirements are restricted to all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the physicochemical endpoints in Annex VII. All the gathered reliable information should be provided in the registration dossier.

You have not submitted any documentation supporting your claim that Annex III criteria are not fulfilled while you declare that dispersive use or diffuse use (particularly where such substances are used in consumer mixtures or incorporated into consumer articles) cannot be excluded.

In the absence of thorough documentation to substantiate your adaptation under Annex III, you have not demonstrated that the Substance does not meet Annex III criteria.

ECHA agrees that your substance is not included in the ECHA's inventory of substances likely to meet the REACH Annex III criteria. However, as indicated in the inventory[3], the fact that a substance is not in this list does not necessarily mean that the criteria for Annex III are not met.

Therefore your adaptation is rejected and the full information requirements specified in REACH Annex VII are required.

[3] https://echa.europa.eu/information-on-chemicals/annex-iii-inventory

Appendix A: Reasons to request information required under Annex VII of REACH

1. In vitro skin corrosion/irritation

In vitro skin corrosion/irritation is an information requirement under Annex VII to REACH (Section 8.1.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design
To fulfil the information requirement for the Substance, *in vitro* skin corrosion study (OECD TG 430/431/435) and *in vitro* skin irritation study (OECD TG 439) are considered suitable.

2. In vitro serious eye damage/irritation

In vitro serious eye damage/eye irritation is an information requirement under Annex VII to REACH (Section 8.2.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design
To fulfil the information requirement for the Substance, the *in vitro* test methods listed in the testing strategy as outlined in the OECD GD an Integrated Approach on Testing and Assessment for Serious Eye Damage and Eye irritation Series on Testing and Assessment No.263 must be followed. As specified in Annex VII, Section 8.2.1, column 2, "*if results from a first in vitro study do not allow a conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other in vitro study/ies) for this endpoint shall be considered*".

3. Skin sensitisation

Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Under Section 8.3., Column 1, the registrants must submit information allowing (1) A) a conclusion whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and (2) risk assessment, where required.

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance for skin sensitisation, *in vitro/in chemico* studies (OECD TG 442C, OECD TG 442D and EU Method B.71/OECD TG 442E) are considered suitable. In case in vitro/in chemico methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (EU Method B.42/OEDC TG 429) is considered as the appropriate study.

4. 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 this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, 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.

5. Acute toxicity by oral route

"Acute toxicity by oral route" is an information requirement under Annex VII to REACH (Section 8.5.1.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design

ECHA considers that acute oral toxicity tests according to test methods EU B.1 bis./OECD TG 420, EU B.1 tris./OECD TG 423, and OECD TG 425 are appropriate to address the standard information requirement of Annex VII, Section 8.5.1. of the REACH Regulation.

6. 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.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, *Daphnia* sp., Acute Immobilisation Test (test method OECD TG 202) is the most appropriate (ECHA Guidance R.7.8.4.).

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

7. Growth inhibition in aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, Freshwater Alga and Cyanobacteria, Growth Inhibition Test (test method OECD TG 201) is the most appropriate (ECHA Guidance R.7.8.4.).

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

8. Ready biodegradability

Ready biodegradability is an information requirement under Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement under Annex III. You have not provided any documentation supporting your claim that Annex III criteria are not fulfilled regarding the hazardous property foreseen to be investigated under this information requirement.

We have assessed this information and identified the following issue:

As indicated in the Appendix on Reasons common to several requests, your adaptation under Annex III is rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, Ready Biodegradability Tests (test methods OECD TG 301B/C/D/F or OECD TG 310) are the most appropriate (ECHA Guidance R.7.9.3.).

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

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

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

A. Environmental testing for substances containing multiple constituents

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

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

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

Appendix D: 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 16 July 2020.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day notification 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 E: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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.

Preparation of registration dossiers
Manual on how to prepare registration and PPORD dossiers (version 9.0, October 2020).

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[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[9]
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.

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

Appendix F: 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]
[redacted]	[redacted]	[redacted]