ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002456-73-05/F Helsinki, 20 December 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Alcohols, lanolin CAS No 8027-33-6 (EC No 232-430-1), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12 (1)(e) thereof for Alcohols, lanolin CAS No 8027-33-6 (EC No 232-430-1), submitted by [redacted] (Registrant),

- Long-term toxicity study in invertebrates (daphnia)
- Bioaccumulation in aquatic species
- 90-day oral toxicity (OECD 408). From section 7.8 of the IUCLID dossier ECHA understands that the Registrant proposes to conduct this study "with additional assessments of reproductive organs"
- Developmental toxicity study (OECD 414)

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 14 June 2012, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the registration at a later stage.

On 9 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 2 September 2011 until 17 October 2011. ECHA did receive information from third parties (see section III below).

On 25 April 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 25 May 2012 ECHA received comments from the Registrant. ECHA considered the Registrant's comments received and did not amend Section II of the draft decision. However, a response to the Registrant's comments has been provided in Section III of the draft decision.

On 14 June 2012 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

On 7 August 2012, the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 3 September 2012 in a written procedure launched on 22 August 2012 and ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on invertebrates (Annex IX, 9.1.5, test method: *Daphnia magna* Reproduction Test, EU C.20/OECD 211).

2. Bioaccumulation in aquatic species (Annex IX, 9.3.2.; test method Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305 draft 13 March 2012).

3. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2., test method: EU B.26/OECD 408). It is at the Registrant's discretion to perform the intended additional examinations during the testing program.

4. Pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414).

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 2 provisions of the respective Annex and those contained in Annex XI of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **20 December 2014** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall consider submitting a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance and on the information submitted by third parties (point 2.4).

1. Long-term toxicity on aquatic invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH Regulation. Column 2 of Section 9.1 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

Under the Test Guideline section, the Registrant provided the following justification for conducting the proposed test: "Based on this data, pending further investigation, the lanolin alcohols may be considered to have no chronic adverse effects on aquatic organisms. To confirm this assumption a long-term toxicity study in invertebrates (daphnia) is proposed."

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex

IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

2. Bioaccumulation in aquatic species

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

The Registrant has submitted a testing proposal to cover the endpoint Bioaccumulation in aquatic species, Annex IX, 9.3.2 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

ECHA notes that the Registrant did not specify the guideline to be used or the species to be tested for the proposed bioaccumulation study in aquatic species, under the 'guideline' section in IUCLID. Under 'principles of method if other than guideline' the Registrant states 'test on metabolism of Lanolin alcohols is being proposed to confirm that the lanolin alcohols are readily metabolised'. Also, the Registrant states in the chemical safety assessment that 'A definite assessment of the potential' aquatic secondary poisoning 'risk should be based on reliable toxicological information from a repeated dose toxicity study (derivation of PNECoral). In addition, experimental data on the aquatic and sediment 'bioaccumulation potential of the substance (e.g. OECD 305, 315) may be useful', but also that 'in order to assess the potential risk to terrestrial ecosystems appropriately it may be necessary to perform a test on the bioaccumulation potential of the substance in terrestrial oligochaetes (OECD 317)'. However, ECHA notes that the order of the testing is the responsibility of the Registrant.

ECHA notes that while there are a number of guidelines available covering aquatic, sediment and terrestrial bioaccumulation Annex IX, 9.3.2. of REACH Regulation states fish is the preferable species. Also REACH guidance on information requirements and chemical safety assessment Chapter R.7.10.3.1 recommends the Fish Dietary Accumulation test for certain types of substances due to their specific physical chemical properties (e.g. low water solubility, high log Kow value). For substances with log Kow >6, such as the registered substance (log Kow 6.73-10.79), a dietary study to estimate bioaccumulation is recommended following the draft OECD 305 Guideline: Bioaccumulation in Fish: Aqueous and Dietary Exposure (date of draft guideline 305: 13 March 2012; available at http://www.oecd.org/document/57/0,3746,en_2649_49389220_2348921_1_1_1_4938922 0,00.html).

b) Consideration of the third party information

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has proposed a strategy for ECHA to consider before further tests on animals are requested. The strategy outlines that a study of bioaccumulation is not justified due to the widespread natural occurrence and physiological presence of the major components of the substance in animal species.

However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy as such cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following test: Bioaccumulation in aquatic species according to draft OECD Guideline 305 Bioaccumulation in Fish: Aqueous and Dietary Exposure test using the registered substance. The Registrant is advised to consult the REACH guidance on information requirements and chemical safety assessment Chapter R.11.1.4.2 on PBT assessment of UVCB substances.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

3. Repeated dose toxicity study

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has submitted a testing proposal for a "90-day repeat dose toxicity study via the oral method". The Registrant did not specify the guideline to be used or the species to be tested. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate. According to the REACH guidance R.7.5.3.1 the preferred test method using oral administration is EU B.26/OECD 408. According to EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

The Registrant proposed to extend the sub-chronic toxicity study (90 day) by including additional examinations/parameters concerning reproductive toxicity. ECHA notes, that it is at the Registrant's discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance. However, the Registrant is reminded that the proposed extension of this study does not fulfil the standard information requirements in the registration dossier for reproductive toxicity set out in Annex X, 8.7.3 unless Annex X, 8.7 column 2 adaptation is applied.

b) Consideration of the third party information

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has proposed to adapt the standard information requirements for the sub-chronic toxicity study (90 days) on the basis of significant exposure to the major components of the substance as a result of normal physiological production and dietary intake.

However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for an adaptation, such as the one above, cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

4. Pre-natal developmental toxicity study

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 8.7.2 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant did not specify the species nor the route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat as a first species to be used.

b) Consideration of the third party information

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has proposed to adapt the standard information requirements for the pre-natal developmental toxicity study on the basis of significant exposure to the major components of the substance as a result of normal physiological production and dietary intake.

However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for an adaptation,

such as the one above, cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

c) Outcome

ECHA examined the comments submitted by the Registrant, which requested flexibility around the deadline for submission of the data for this endpoint following the final decision being issued. The Registrant accompanied the comments with a statement from a testing laboratory to support his request. Firstly, ECHA notes that the deadline for submission of the data requested in the decision is an integral part of such decision and cannot be agreed or modified after the final decision is issued. Secondly, following the examination of the supporting document of the testing laboratory, as provided with the comments by the Registrant, ECHA is of the opinion that the timeline of 24 months from the date of issue of the final decision is reasonable and sufficient to submit an updated dossier containing the information required by ECHA for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rats, oral route (test method: EU B.31/OECD 414) using the registered substance, according to the timelines outlined in this decision.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the study/studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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