

Decision number: CCH-D-0000003553-76-04/F

Helsinki, 10 April 2014

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006****For Amines, bis(hydrogenated tallow alkyl), 2-[[bis(hydrogenated tallow alkyl)amino]carbonyl]benzoates, CAS No 91745-35-6 (EC No 294-705-2), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Amines, bis(hydrogenated tallow alkyl), 2-[[bis(hydrogenated tallow alkyl)amino]carbonyl]benzoates, CAS No 91745-35-6 (EC No 294-705-2, submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 8.6.2. and 8.7.2. of the REACH Regulation.

This decision is based on the registration 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 submitted after 31 October 2013, 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 26 April 2013.

On 28 June 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 29 July 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 31 October 2013 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

## II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX, of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

- a. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408); and
- b. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **10 April 2016**.

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 fulfil 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. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

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.

## III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement.

(a) Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has proposed to adapt the information requirement of sub-chronic toxicity. In the justification of this proposed adaptation the Registrant claims that "further oral toxicity testing (90-day toxicity study identified in REACH Annex IX and chronic toxicity study identified in REACH Annex X) of the test substance is not appropriate, in view of the absence of toxicity in the 28-day oral toxicity study in rats despite the administration of doses of up to 1000 mg/kg/day. This proposal is made in accordance with Rule 8.6.2 of Annex IX and Rules 8.6.3 and 8.6.4 of Annex X of the REACH Regulation." However, ECHA notes that neither column 2 of Section 8.6.2. nor general rules for adaptation in Annex XI include the possibility to adapt this standard information requirement on the basis of the argument made by the Registrant.

ECHA stresses that in accordance with the first indent of column 2 of Section 8.6.2. of Annex IX, the availability of a reliable short-term toxicity study (argument raised by the Registrant above) makes the sub-chronic toxicity study only unnecessary if the 28 day study showed severe toxicity effects (further conditions for that adaptation apply). The absence of toxicity in the 28-day study does not allow for an adaptation of the standard information requirement of Annex IX, 8.6.2. Therefore, since the Registrant has not justified the proposed adaptation, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

The adaptation possibilities according to Annex X, 8.6.3 and 8.6.4 Column 2 refer to long-term repeated toxicity studies and further studies. These information requirements do not fall within the scope of the present compliance check decision and have therefore at this stage not been evaluated by ECHA.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In light of the physico-chemical properties of the substance (solid not irritating or corrosive to skin or eyes) and the information provided on the uses and human exposure (no spray application), ECHA considers that testing by the oral route is appropriate. According to the test method the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information on sub-chronic toxicity (90-day) in rats, oral route (test method EU B.26/OECD 408) derived with the registered substance subject to the present decision.

(b) Pre-natal developmental toxicity study (Annex IX, Section 8.7.2)

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. According to section 8.7.2. of Annex X subject to the Annex IX, 8.7.2. column 2 requirements of the REACH Regulation, a further pre-natal developmental toxicity study performed in a second species is required to fulfil the standard information requirements. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant provided information with which he sought to fulfil this standard information requirement. The provided information stems from a Reproduction/Developmental Toxicity Screening Test (OECD 421) with the registered substance. However, this study does not provide the information required by Annex IX, Section 8.7.2., because it lacks, amongst others, sound data on pre- and post-implantation losses, external, soft tissue and skeletal malformations, types and incidences of individual anomalies. The technical dossier neither contained a testing proposal nor an adaptation in accordance with column 2 of Annex IX, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers the default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to submit information on Pre-natal developmental toxicity on rats or rabbits (test method EU B.31/OECD 414) on the registered substance.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species (Annex X, 8.7.2.), the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species (Annex IX, 8.7.2.) 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.

#### IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

#### V. 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at <http://echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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