Helsinki, 5 November 2018

Addressee: [redacted]

Decision number: CCH-D-2114449968-26-01/F
Substance name: AA 15
List number: [redacted]
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04/09/2017
Registered tonnage band: 100-1000 (submission number [redacted] with latest tonnage band)

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Name or other identifier of the substance (Annex VI, Section 2.1.);**
   - **Chemical name**
   - **Manufacturing process**
2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **12 November 2019**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[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

IDENTIFICATION OF THE SUBSTANCE

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the cornerstone of all the REACH obligations.

Pursuant to Annex VI section 2.1.4 of the REACH Regulation a registrant shall provide, if available, a CAS name and CAS number.

'*Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, March 2017)*, referred to as "the SID Guidance" thereinafter, clarifies the difference between well-defined substances and UVCB substances. As specified in the SID Guidance, page 24, Chapter 4.1: substances can be divided into two main groups:

1. "Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2.

2. "UVCB substances": Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified by the above parameters.

As specified in the SID Guidance, page 46, Chapter 4.3.2.1, Substances with variation in the carbon-chain lengths are for example UVCB substances.

As further specified in the SID Guidance, page 37, Chapter 4.3:
UVCB substances, cannot be sufficiently identified by their chemical composition, because:

- The number of constituents is relatively large and/or
- The composition is, to a significant part, unknown and/or
- The variability of composition is relatively large or poorly predictable.

As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances shall consist of two parts: (i) the chemical name and (ii) a more detailed description of the manufacturing process, as described in chapter 4.3 of the SID Guidance.

Indeed, for UVCB substances the description of the manufacturing process shall include information on the chemical identity of the starting materials and information on the most relevant steps of the process.

ECHA observes that you did not provide sufficient information on the naming of the registered substance and its manufacturing process (as explained under points (i) and (ii) thereinafter).

(i) Information you shall submit regarding the chemical name:

You have included in the "IUPAC name" and "CAS name" field in your reference substance in IUCLID section 1.1 the following chemical name: "[redacted]."

ECHA further notes that in section 1.1 of the IUCLID dossier you have identified the registered substance as a well defined (multi-constituent) substance. However, the information, which you have included in IUCLID sections 1.2 and 1.4, indicates that your substance is a complex reaction product, which contains a high number of branched and linear constituents with variable alkyl chain lengths and different ethoxylation degrees.

ECHA notes in addition that you have provided a CAS name for the substance without reference to its respective CAS number.

Please note that the term "poly" in the chemical name would indicate that the substance is a polymeric type substance. However, the analytical information provided in IUCLID section 1.4 confirms that your substance consists mainly of oligomeric reaction products.

In addition, you have named your substance as "Reaction mass of [...]" which according to the SID Guidance should be used for well-defined multi-constituent substances. However, from the information set out in IUCLID sections 1.2 and 1.4 of the IUCLID dossier you should be regard your substance as a UVCB substance due to the variation in the carbon-chain lengths. For further information on substances with variation in the carbon-chain lengths, please see also the SID Guidance, page 46, Chapter 4.3.2.1. As your substance appears to be of type "UVCB substance", ECHA considers this naming as not appropriate.

The "CAS name" field should also include the CAS index name for a specific CAS number. It however appears that the CAS name provided does not actually refer to a CAS index name.

Consequently you are requested to revise the name of your substance as described in chapter 4.3 of the SID Guidance reflecting the oligomeric nature of your substance and reflecting that the substance is in fact a UVCB substance, *i.e.*, by, amongst others, removing the terms "poly" and "reaction mass of".

In addition, you should also remove the name from the "CAS name" field as the name, which you have included in this field, does not refer to a CAS index name. Furthermore, as there does not appear to be any CAS number for your substance, the CAS name field should remain empty as well. Alternatively, if available, you should provide the correct CAS name and CAS number for the registered substance.

Therefore, ECHA requests you to revise the information on your reference substance in IUCLID section 1.1.

(ii) Submit a detailed manufacturing process description:

You have provided the following description of the manufacturing process: "[redacted]."

As explained in section (i) above and according to the information provided, ECHA considers your substance a UVCB-type substance. ECHA notes that the provided manufacturing process description is not detailed enough as certain elements are missing. Therefore, you need to provide information that is more detailed on the manufacturing process.

More specifically, you did not provide information on the molar ratio of the starting materials, the identity of the catalysts and relevant process parameters (e.g. temperature and pressure).

In your comments to the draft decision, you did not provide any comments regarding this request. You did submit a dossier update (submission number [redacted] and date 02 February 2018). No assessment of the updated registration has occurred.

You are reminded that this decision does not take into account any updates submitted after the notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore you are required to provide as a minimum the following information:

- The molar ratio between the different starting materials used.
- The identity or type of the catalysts used during the manufacturing process.
- For each step, all relevant process parameters (e.g. temperature and pressure) that may affect the composition and therefore the identity of the substance.

Please include this information in the "description of composition" field of your legal entity composition in IUCLID section 1.2.

TOXICOLOGICAL INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

In the technical dossier you have provided a key study record for a "reproduction/developmental toxicity screening test" (test method: OECD TG 421) ([redacted], 2010). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations.

Additionally, while you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 3.2.(a) (substance-tailored exposure driven testing).

Annex XI, section 3.2.(a) provides the following cumulative conditions for an exposure based waiving to succeed:

(i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;
(ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;
(iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC

According to footnote (1) to the second criterion (ii) for 3.2.(a) in the REACH Regulation, *"a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study*".

You provided the following justification for the adaptation:

"The available developmental toxicity screening study gave no hints on adverse developmental effects of the substance AA 15 up to an oral dose of 1000 mg/kg bw/day. The exposure assessment has shown that low exposure of workers is anticipated with the identified uses of the substance. The major route of exposure for workers is the dermal route. Workers wear appropriate dermal and eye protection in all situations where direct exposure to the substance may occur due to the irritating effects of the substance. On the basis of the physicochemical properties of the substance and the available acute dermal toxicity study in rats it may be predicted that the substance has low potential for skin penetration. Dermal exposure is likely to result in low systemic exposure to the substance. The risk characterisation ratios obtained for occupational dermal exposure are not exceeding [redacted] for manufacture, transfer and use of substance in formulation. The dermal DNEL used in the risk characterisation was derived from an oral NOAEL obtained from a 90-day oral repeated dose toxicity study by assuming comparable systemic availability via intestinal wall and skin. It is however likely that systemic availability via the skin is much less than via the intestinal wall so that the risk characterisation for dermal exposure may be considered as cautious. The exposure assessment for the general public has shown that the identified uses

of AA 15 are likely to result in very low secondary exposure to the substance via the environment. The risk characterisation ratios obtained for oral secondary exposure via the environment are not exceeding [redacted] *for any of the identified uses. In conclusion, the identified uses of AA 15 result in low systemic exposure of workers and the general public. In consideration of the NOAEL of 1000 mg/kg bw/day found in the developmental toxicity screening study it can be concluded that the low exposure of workers and the general public to AA 15 gives no concern for any adverse developmental effects and further testing is deemed not necessary."*

However, your adaptation does not meet the general rule for adaptation of Annex XI; Section 3.2.(a), because criterion ii) is not met:

You argue that "*workers wear appropriate dermal and eye protection in all situations where direct exposure to the substance may occur due to the irritating effects of the substance.*"

ECHA notes that reproduction toxicity is a separate information requirement/hazard class and a different property of a substance than those local effects the substance is already classified for. Thus, skin or eye irritation are not properties that allow an adaptation for information on reproductive toxicity.

Moreover, as already indicated above, in the technical dossier there is no developmental study that fulfils the requirements for this endpoint. Hence, you cannot claim that "*AA 15 gives no concern for any adverse developmental effects*", because the reproductive/developmental screening study does not cover key parameters of a pre-natal developmental toxicity study, as explained above. ECHA notes that the DNEL in the dossier is derived from a sub-chronic toxicity study (OECD TG 408). However, the available OECD TG 408 study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. Hence, ECHA concludes that the condition set out in Annex XI section 3.2(a)(ii) is not met, as DNEL is not relevant and not appropriate both to the information requirement to be omitted and for risk assessment purposes.

Hence, the rules for adaptation set out in Annex XI, Section 3.2.(a) are not fulfilled. Therefore, your adaptation of the information requirement is rejected.

Consideration on uses of the substance in relation to the tests requested in the decision

In your comments on the draft decision you indicated that although the registered substance is manufactured and formulated in the European Economic Area (EEA), it is exclusively further used as an ingredient in cosmetic products.
You further expressed your concerns that performing tests using vertebrate animals on the registered substance, in accordance with the present decision, may eventually lead to a marketing ban under Article 18(1)(b) of the Regulation (EC) No 1223/2009 (the Cosmetics Regulation) in one or several countries of the EEA.
ECHA notes that stages of manufacturing of chemical and formulation of cosmetic products are taking place in the EEA and there is no indication that they are carried out under strictly controlled conditions. As potential worker exposure may exist, testing for human health endpoints is necessary to assess the risks from exposure to workers and therefore in order

to fulfil the relevant REACH requirements. This is in accordance with ECHA's factsheet[2] on the interface between REACH and Cosmetics Regulations, which was developed jointly with the European Commission. It provides that registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints unless such tests are needed to assess the risks from exposure to workers.

As is apparent from the Commission Communication of 11 March 2013 on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics (COM(2013)135)) such testing would not trigger the testing and marketing bans under the Cosmetics Regulation as the testing is to be performed for the purposes of meeting the requirements of the REACH Regulation[3].

As explained above, the information provided 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.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

[2] https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf
[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0135&from=EN

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation. However, following your comments on the draft decision indicating a tonnage band downgrade, only, ECHA has taken into account the updated tonnage band (submission number [redacted] and date 02 February 2018, only). No assessment of the updated registration has occurred. Based on the average production and/or import volumes for the three preceding calendar years, ECHA has changed the tonnage band as basis for the draft decision from 1000+ tonnes per year (submission number: [redacted] from 04 September 2017) to 100-1000 tonnes per year (submission number: [redacted]).

The compliance check was initiated on 1 August 2017.

The decision-making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA took into account your comments and your information about tonnage band downgrade. This has resulted in the removal of the following decision requests: 3. (pre-natal developmental toxicity study in a second species); 4. (extended one-generation reproductive toxicity study) and the amendment of the corresponding sections in Appendix I

As a consequence the deadline for providing the information to meet the requests remaining in the draft decision has been set to 12 months.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In carrying out the tests 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 or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.