ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114360471-55-01/F Helsinki, 30 May 2017

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

For fatty acids, C16 and C18 unsatd., polymers with bisphenol A, Bu glycidyl ether, epichlorohydrin and triethylenetetramine, EC No 600-687-2 (CAS No 105839-18-7), 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)(d) thereof for fatty acids, C16 and C18 unsatd., polymers with bisphenol A, Bu glycidyl ether, epichlorohydrin and triethylenetetramine, (EC No 600-687-2; CAS No 105839-18-7; ARADUR 460 J90 BD), submitted by [redacted] (Registrant).

- Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; OECD 408) conducted with the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; OECD 414) conducted with the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8).

This decision is based on the updated registration dossier as submitted on 14 April 2015, with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision takes into account only updates submitted within the deadline for updating the dossier (17 May 2015), i.e. within 30 calendar days after the end of the commenting period.

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 from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 8 July 2014.

On 8 July 2014 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 18 September 2014 until 3 November 2014. ECHA did not receive information from third parties.

On 11 March 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of receipt of the drat decision.

On 14 April 2015 the Registrant updated the dossier as submitted with submission number [redacted].

On 15 April 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat has considered the Registrant's comments and update.

On the basis of this information the Section II was amended. The Statement for reasons (Section III) was changed accordingly.

On 9 March 2017 ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD 408) in rats, with the registered substance;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in a first species (rat or rabbit), oral route, using the registered substance;

while the originally proposed tests for

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

  and both studies proposed to be carried out using an analogue substance (Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8; EUREDUR 450 BD) are rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Note for consideration by the Registrant:

The Registrant 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 of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **6 June 2019** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

The decision of ECHA is based on the examination of the updated testing proposals submitted by the Registrant in his comments to the draft decision and in the updated dossier with the submission number [redacted].

In his comments to the draft decision, the Registrant indicates that he reviewed the registration dossier and updated the dossier with the following elements:

- an updated testing strategy is proposed i.e. instead of testing the registered substance, tests with an analogue substance for read-across purposes are proposed for both endpoints under consideration;
- reflection on the actual uses and application of the registered substance;
- an updated manufacturing process, by change in the starting material as described in section 3.1 of the technical dossier.

Grouping of substances and read-across approach

ECHA based its decision on the evaluation of the updated registration dossier with the submission number [redacted] that contains adaptation arguments in form of a grouping and read-across approach under Annex XI, 1.5. of the REACH Regulation, for certain toxicological endpoints which are addressed in the current decision. ECHA has assessed first the scientific and regulatory validity of the read-across approach in general before assessing the individual endpoints (sections 1-2). The proposed read-across is discussed in the following section of this decision. The corresponding sections 1-2 refer back to this section.

According to Annex XI, Section 1.5. there needs to be structural similarity among the substances within a group or category and furthermore, 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 (read-across approach). Furthermore, Annex XI, Section 1.5. lists several additional requirements, including that adequate and reliable documentation of the applied method have to be provided.

Description of the grouping and read-across approach proposed by the Registrant

In the registration dossier the Registrant intends to adapt the following standard human health information requirements subject to the current decision:

- Sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2).

The Registrant has proposed to read-across between the substance subject to this decision, fatty acids, C16 and C18 unsatd., polymers with bisphenol A, Bu glycidyl ether, epichlorohydrin and triethylenetetramine, (EC No 600-687-2; CAS No 105839-18-7; ARADUR 460 J90 BD) as target substance and the structurally similar substance, Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine, (EC No 606-078-8; CAS No 186321-96-0; EUREDUR 450 BD) as source substance for both the sub-chronic toxicity (90-day) study (Annex IX, 8.6.2.) and the pre-natal developmental toxicity study (Annex IX, Section 8.7.2).

The Registrant uses the following arguments to support the prediction of properties of the registered (target) substance from data for source substances:

"Read across with /EUREDUR 450 BD is claimed because of the following similarities of the chemical structures and manufacturing process:"

"The basis for the read-across approach for /ARADUR 460 J90 BD is the chemical analogy with /EUREDUR 450 BD, as well as similar physical, toxicological and ecotoxicological properties."

"Based on their chemical similarity, comparable properties are expected for /Euredur 450 BD and /ARADUR 460 J90 BD in both human and the environment."

ECHA understands that according to the Registrant the source and target substances have similar properties for both information requirements addressed in this draft decision; i.e. the sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.) and the pre-natal developmental toxicity study (Annex IX, Section 8.7.2).

Information submitted to support the grouping and read-across approach

In the updated dossier with the submission number [redacted], the Registrant provided the following information.

The updated registration dossier contains a read-across document as a separate attachment, in IUCLID Section 13. The same document has been submitted during the commenting period as an attachment to the Registrant's comments.

The document contains the read-across hypothesis, the identification of the source and target substances; comparison of the structural features, physico-chemical properties, available toxicological and eco-toxicological data on the target and source substances and conclusion on the read-across approach. The following analysis presents the read-across hypothesis and justification together with ECHA's analysis concerning the above listed elements of the hypothesis and justification.

ECHA's analysis of the grouping and read-across approach in light of the requirements of Annex XI, 1.5, Submission number: [redacted]

According to ECHA's understanding the Registrant claims that based on their similarities in the chemical structure and the manufacturing process, target and source substances have similar physico-chemical, environmental fate and pathways, eco-toxicological and toxicological properties and hence the toxicological properties of the substances related to sub-chronic toxicity (90-day) and pre-natal developmental toxicity study would be similar.

(i) **Substance characterisation** of source and target substances

The substance characterisation of the source substance(s) needs to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the Chapter 4.4 of ECHA's practical guide" How to use alternatives to animal testing to fulfil your information requirements for REACH registration" (Version 2.0, July 2016) it is recommended to follow the ECHA "Guidance for identification and naming of substances under REACH and CLP (version 2.0, December 2016) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

In chapter *"1. Hypothesis for the analogue approach"* of the read-across document both target and source substances are identified by their name, CAS and EC number.

ECHA notes the followings:

- Both target and substances are complex, UVCB (Unknown or Variable composition, Complex reaction products or Biological materials) substances.
- The structure and the composition of the source substances is not provided.
- The provided information related to the manufacturing process of the source substance does not contain data on the staring material, which is essential for the identification of a UVCB substance. (Please refer to the above mentioned ECHA "Guidance for identification and naming of substances under REACH and CLP; version 2.0, December 2016.)
- In the updated dossier with submission number [redacted] there is a change in relation to the substance identification of the target substance, compared to the dossier (submission number [redacted]) which was the basis for the initial DD. The change is to the starting material described in section 3.1. In the updated dossier it is described as "[redacted] *(EU No.* [redacted] *, CASRN* [redacted] *)"*. In the previous dossier (submission number [redacted] it was described as "[redacted] *(EU No.* [redacted] *, CASRN* [redacted] *)"*. Neither of these starting materials is reflected in the overall identification of the substance, which is *fatty acids, C16 and C18 unsatd., polymers with bisphenol A, Bu glycidyl ether, epichlorohydrin and triethylenetetramine;* this is because in the latest dossier C18 saturated fatty acids and branched and linear fatty acids do not appear in the final product.
  Similarly [redacted] contains very small amounts of C16 fatty acids. Therefore the starting material identification is inconsistent with the final product identification.

Thus, currently the identity of the target substance, and the composition of the source substance cannot be assessed and compared using the information provided in the registration dossier. Consequently, the suitability of the substances for predictions based on read-across cannot be verified.

In view of the issues outlined above, ECHA is not in the position to verify which substance is intended to be used as a target substance. Additionally, ECHA cannot be certain that the Registrant's read-across justification is intended to justify read-across to the registered substance. Consequently, ECHA is unable to verify that there is an adequate basis for predicting the properties of the registered substance.

(ii) **Structural** (dis)similarities and their impact on prediction

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural similarity *per se* is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

The Registrant describes the structural similarities between target and source substances as *"Both hardeners contain comparable constituents as* [redacted] *, and common functional groups as* [redacted] *.".* ECHA notes that in addition to the structural similarities, structural differences might be present in the chain length distribution, saturation, number and position of the double bound.

ECHA notes that the Registrant does not provide any information on how the structural differences may impact the toxicity of the substances and thus affect the possibility to predict properties of the target substance from the data obtained with the source substances.

The provided explanation is therefore not sufficient to establish a scientifically credible link between the structural similarity and the prediction.

(iii) Similar **properties** or regular pattern as a result of structural similarity

Annex XI, Section 1.5. provides that *"substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances"*. One prerequisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

In the following, ECHA examines to which extent similar patterns are indeed demonstrated for physico-chemical properties, toxicological and eco-toxicological properties.

In the read-across justification the Registrant states that *"Both the source and target chemicals have the same* ***physico-chemicals*** *properties."* Based on the comparison of the physico-chemical properties, the Registrant concludes that *"EUREDUR 450 BD and /ARADUR 460 J90 BD have comparable physico-chemical properties and are therefore supposed to behave similarly in biological systems hence supporting the approach for read-across from the source chemical /EUREDUR 450 BD to the target chemical /ARADUR 460 J90 BD. "*

ECHA observes that the presented physico-chemical properties of target and source substances are in the same range.
ECHA considers that the fact that physico-chemical parameters are similar may support the structural similarity, but cannot be used alone to justify a prediction on properties related to human health.

The Registrant claims that "***Toxicological data*** *was considered as suitable information since this provides relevant evidence on whether the source and target chemicals behave similarly as expected from read-across."*

ECHA notes that the dossier contains for the **target** substance *in vitro* data such as results of an *in vitro* Ames test (key study, OECD 471, RL1, [redacted] 2012), an *in vitro* mammalian chromosome aberration test (key study, OECD 473, RL1, [redacted], 2013), an *in vitro* mammalian cell gene mutation assay (key study, OECD 476, RL1, [redacted], 2013) and *in vitro* skin and eye irritation studies (key study, OECD 439, RL1, [redacted] 2013c and key study, OECD 405, RL1, [redacted] 2013d). Furthermore, *in vivo* data, such as acute dose toxicity studies (an oral and a dermal study: key study, OECD 423, RL1, [redacted] 2013a and key study, OECD 402, RL1, [redacted] 2013b), and a skin sensitisation study (key study, OECD 429, RL1, [redacted] 2013e) are provided in the technical dossier.

In addition the dossier contains an OECD 422 (key study, RL1, [redacted], 2013) Combined repeated dose toxicity study with the reproduction / developmental toxicity screening test with a surrogate substance, Fatty acids, C18-unsatd., dimers, oligomeric reaction products with tall-oil fatty acids and triethylenetetramine (EC 500-191-5).
The Registrant explains that this surrogate substance is a precursor of the target substance, has a lower molecular weight compared to the crosslinked reaction product (i.e. the target substance), and therefore it is considered by the Registrant that it is more bioavailable and represents a worst case approach.

ECHA notes that neither the read-across justification nor the technical dossier contains an explanation, justification and/or adaptation argument why the results of this latest study, conducted on a surrogate substance, are appropriate to fulfil the requirement for Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; OECD 408).

ECHA observes that for the **source** substance results of *in vitro* data such as results of an *in vitro* Ames test, an *in vitro* mammalian chromosome aberration test, an *in vitro* mammalian cell gene mutation assay and an *in vitro* skin irritation study are presented in the read-across justification document. Furthermore, results of *in vivo* data, such as acute dose toxicity studies (an oral and a dermal study), skin and eye corrosion studies are available in the same document.

In addition, in the read-across justification document the Registrant states *"that* ***environmental fate*** *data was considered as suitable information since this provides relevant evidence on whether the source and target chemicals behave similarly as expected from read-across"* and *"the similar* ***ecotoxicological*** *results provide the relevant information to support the rationale for read-across from the source chemical to the target chemical. As indicated in ECHA's guidance on QSARs and grouping of chemicals (ECHA Chapter R.6, 2008), other supporting information can be used to support the read across strategy, including similarity in toxicological data.*

ECHA observes that results of ready biodegradability and toxicity to activated sludge studies are presented in the read-across document and the results are in the same range for the target and source substances.

The results of the eco-toxicological studies (Acute toxicity to Zebra fish; Acute toxicity to daphnia; Toxicity to green algae) as presented in the read-across document are indeed in the same range for the target and source substances.

ECHA notes that the presented toxicological and eco-toxicological data alone is not sufficient to establish the toxicological profile of a substance with regard to repeated dose and/or developmental toxicity reproductive toxicity. On this basis, ECHA does not accept that the Registrant has shown toxicological similarity, and the basis for predicting toxicological properties fails.

Further, the proposed adaptation argument is that the toxicological similarity between the source and target substance is a sufficient basis for predicting the properties of the substance. This argument is limited and is in principle not capable of being sufficient. Toxicological similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that toxicological similarity per se is sufficient to enable the prediction of human health properties of a substance. This is because toxicological similarity does not always lead to predictable or similar human health properties. Further elements are needed[1], such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s), to allow a prediction of human health properties that does not underestimate risks. The Registrant has not provided such elements in the dossier.

Therefore, ECHA concludes that based on the presented information it is not possible to confirm that the substances would have similar properties or they would follow a regular pattern in their properties. In the absence of such information there is not an adequate basis for predicting the properties of the target substance from the data obtained with the source substances.

Conclusion on the read-across approach

The adaptation of the standard information requirements (*Sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.)* and *Pre-natal developmental toxicity study (Annex IX, Section 8.7.2*)) in the technical dossier is based on the proposed read-across approach examined above. ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the registered substance for the reasons set out above and taking into account data available in the updated registration dossier.

Thus, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, 1.5. Therefore, ECHA rejects the above mentioned adaptations in the technical dossier that are based on Annex XI, 1.5.

A. Tests required pursuant to Article 40(3)

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

1Please see for further information ECHA Guidance on information requirements and chemical safety assessment (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals and ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

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 provide information for this endpoint.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) via the oral route (EU B.26/OECD 408) to be performed with the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8).

ECHA has evaluated the Registrant's proposal to perform the test with the analogue substance. As explained in section *'Grouping of substances and read-across approach'* of this decision, the adaptation of the information requirements cannot be accepted. Hence there is a need to test the registered substance.

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

The Registrant proposed testing by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure (0.0003626 Pa at 25 °C). Uses with industrial/professional spray application are reported in the chemical safety report. However, the reported concentrations are low (7.583 mg/m3). Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26./OECD TG 408) while the originally proposed test a Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) using the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8) is rejected according to Article 40(3)(d) of the REACH Regulation.

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

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. 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 provide information for this endpoint.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414 to be performed with the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8).

ECHA has evaluated the Registrant's proposal to perform the test with the analogue substance. As explained in section *'Grouping of substances and read-across approach'* of this decision, the adaptation of the information requirements cannot be accepted. Hence there is a need to test the registered substance.

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with the rat or rabbit 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 4.1, October 2015) R.7a, chapter 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.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31./OECD TG 414) while the originally proposed test for a Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) route using the analogue substance Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine (CAS 186321-96-0; EC 606-078-8) is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015), Chapter R.7a, section R.7.6.2.3.2.

IV. Adequate identification of the composition of the tested material

The process of examination 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 examination of the testing proposal.

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Finally, 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 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[2] by Ofelia Bercaru, Head of Unit, Evaluation E3

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.