EUROPEAN CHEMICALS AGENCY

Helsinki, 9 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114375599-28-01/F
Substance name: ß-Alanine, N-(2-carboxyethyl)-, N-coco alkyl derivs., disodium salts
EC number: 290-476-8
CAS number: 90170-43-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 31/10/2013
Registered tonnage band: 100-1000

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. **Composition of the registered substance (Annex VI, Section 2.3.);**
2. **Description of the analytical methods (Annex VI, Section 2.3.7.);**
3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**
4. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD TG [421/422]) in rats, oral route with the registered substance;**
5. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**
6. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**
7. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) 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 **18 May 2020**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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 Claudio Carlon, Head of Unit, Evaluation E2

[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

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.

1. Composition of the substance (Annex VI, Section 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification.

Annex VI, Section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect according to chapter 4.3 of the 'Guidance for identification and naming of substances under REACH and CLP' (May 2017, Version 2.1), referred thereafter as the Guidance, for UVCB substances, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified as far as possible by a generic description of their chemical nature.
- For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

ECHA notes that in section 1.2 of the IUCLID dossier you have reported in the composition one generic constituent covering about [redacted]% ([redacted]%) "[redacted]". In the "Remarks" field for this constituent, you also report the distribution of the different alkyl chain lengths present in the substance (i.e. [redacted]). However, ECHA notes that in contradiction the analytical reports included in section 1.4 of the IUCLID dossier contain chromatograms indicating the presence of several constituents/group of constituents.

As explained above, all constituents identified in the analytical report included in section 1.4 should be reported individually in section 1.2. Because of the missing reporting of the different constituents/group of constituents in section 1.2 your registration does not contain consistent information for establishing the composition of the registered substance and therefore its identity. ECHA therefore concludes that the compositional information has not been provided to the level of detail required by the Guidance as described above.

You are accordingly requested to revise the compositional information in your registration dossier in order to establish a precise chemical representation of what the substance consists of. Precisely for your substance, we expect you to sub-divide the main constituent in the compositional information "[redacted]" into groups of constituents based on the alkyl disodium salts chain length, i.e. [redacted] alkyl deriv, [redacted] alkyl deriv and [redacted] alkyl deriv. In addition, the [redacted] and [redacted] derivatives identified in the HPLC results should also be reported in the compositional information.

All these groups of constituents must be reported separately with a representative typical concentration and concentration range values.

In general, for each constituent reported individually, IUPAC name, CAS name and CAS number (if available), molecular and structural formula shall be reported in the appropriate fields in IUCLID. For any constituent to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

You shall also ensure that the composition is verifiable and therefore supported by analytical data and a description of the analytical methods used for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7.

2. Description of the analytical methods (Annex VI, Section 2.3.7.)

The description of analytical methods or appropriate bibliographical reference for the identification of the substance is a formal information requirement of Annex VI Section 2.3.7.

ECHA observes that you did not provide sufficient description of the analytical methods used for the identification and quantification of the different constituents present in the composition of the registered substance. More specifically, in the report attached in section 1.4 of the IUCLID dossier [redacted] you provided a HPLC chromatogram with identified peaks and retention times (Appendix 2; Libratteric AA30 [redacted]). However, you did not provide a peak table with peak areas and the corresponding concentrations in percentage for the different identified peaks.

In addition, in the report attached in section 1.4 of the IUCLID dossier "[redacted]", you also provided two GC chromatograms and a peak table reporting identified peaks and retention times (Appendix 4; HAL11-168). However, in the peak table you did not provide the peak areas and corresponding concentrations in percentage for the different identified peaks.

The results from these analyses do not allow the quantification of the different constituents of the substance. ECHA therefore concludes that you did not provide sufficient description of the analytical methods to quantify the constituents and groups of constituents reported in the composition of the registered substance.

In line with Annex VI Section 2.3.7 you are accordingly requested to provide a description of the analytical methods used for the quantification of the constituents/groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. You should note that ECHA will consider any method that is suitable to verify the composition, including any indirect method involving chemical derivatisation of the substance or any analysis involving also considerations on the starting materials and the manufacturing process.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4. You shall ensure that the composition reported in the dossier according to Annex VI section 2.3 is consistent with the analytical results obtained.

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.

Your registration dossier contains for the endpoints sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.), an *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2,), a screening for reproductive/developmental toxicity study (Annex VIII, Section 8.7.1.), a pre-natal developmental toxicity study (Annex IX, Section 8.7.2), and adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation.

Grouping of substances and read-across approach

You have sought to adapt the information requirements for sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2.), *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2,), screening for reproductive/developmental toxicity study (Annex VIII, Section 8.7.1.) and pre-natal developmental toxicity study (Annex IX, Section 8.7.2), by applying a read-across approach in accordance with Annex XI, Section 1.5. 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.
You consider to achieve compliance with the REACH information requirements for the registered substance [reaction products of c12-18-(even numbered)-alkylamines and acrylic acid and sodium hydroxide (EC No 290-476-8)] using data of the following analogue substances:

i. sodium lauriminodipropionate (CAS No 195606-51-1)
ii. disodium N-(2-carboxyethyl)-N-dodecyl-beta-alaninate (EC No 222-899-0)

(hereafter the 'source substances').

However, there is no documentation for the read-across. You only state in your justification that the read-across with source substance (i) is "*valid as this same read-across is used in US EPA review of this class of substance*." While with the source substance (ii) you claim that the "w*ork...approved by the US Environmental Protection Agency Statement in report...covers range of alkylamines; specifically, "sodium and potassium salts of N-alkyl (C8-C18)-beta-iminodipropionic acid where the C8-C18 is linear and may be saturated and/or unsaturated...*"

Therefore, your dossier is lacking a basis for predicting relevant human health properties of the registered substance from data for the source substances.

In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substance.

Hence, you have not established that relevant properties of the registered substance can be predicted from data on the analogue substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected and it is necessary to perform testing on the registered substance. ECHA notes that there are specific considerations for the individual endpoints which also result in a failure to meet the requirement of Annex XI, Section 1.5., and these are set out under the endpoint concerned.

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. 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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for an *in vitro* mammalian chromosome aberration test (EPA OPPTS 870.5375 – *in vitro* mammalian cytogenetics), with the analogue substance sodium lauriminodipropionate (CAS no 195606-51-1). This key study ([redacted], 1990) provided in the technical dossier is GLP compliant with an assigned reliability score of 2 as the study was performed with independent assays over two time points. However, as explained above in Appendix 1, under the Grouping of substances and read-across approach section of this decision, your adaptation of the information requirement is rejected.

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.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

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: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a screening for reproductive/developmental toxicity in the dossier that would meet the information requirement of Annex VIII, Section 8.7.1.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (US EPA, 2009) (OECD TG 422) with the analogue substance disodium N-(2-carboxyethyl)-N-dodecyl-beta-alaninate (EC no 222-899-0). However, as explained above in Appendix 1, under the Grouping of substances and read-across approach section of this decision, your adaptation of the information requirement is rejected.

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 methods OECD TG 421/422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

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 5.0, December 2016) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, 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:

Reproductive/developmental toxicity screening test (test method: OECD TG 421) in rats by the oral route *or*
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

Notes for your considerations

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, Section R.7.5 and 7.6 (version 5.0, December 2016).

You should also carefully consider the order of testing especially the requested screening (OECD TG 421/422) and the developmental toxicity study (OECD TG 414) to ensure unnecessary animal testing is avoided, paying particular attention to ECHA's end point specific guidance document[2].

5. Sub-chronic toxicity study (90-day), oral route (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.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

In the technical dossier you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (US EPA, 2009) (OECD TG 422) with the analogue substance [disodium N-(2-carboxyethyl)-N-dodecyl-beta-alaninate] (EC no 222-899-0)]. However, as explained above in Appendix 1, under the Grouping of substances and read-across approach section of this decision, the adaptation does not comply with the general rules as set out in Annex XI, Section 1.5. Moreover, the screening study (US EPA, 2009) does not provide the information required by Annex IX, Section 8.6.2., because the exposure duration is less than 90 days.

Therefore, your adaptation of the information requirement is rejected.

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.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers 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, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, considering that the substance is used in spray applications by professional users, the vapour pressure indicated in the chemicals safety report is very low (0.00001 Pa). Moreover, there are no available studies with the registered substance that may support that the substance causes respiratory tract effects; according to the toxicokinetics information provided in the dossier there is no concern that the substance might be metabolised in the respiratory tract to reactive metabolites which could lead to local effects. 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.

[2] ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance Version 5.0, December 2016, p 461-2 (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf).

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

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

A "pre-natal developmental toxicity study" (test method EU B.31./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.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

In the technical dossier for the repeated dose and reproductive toxicity endpoints you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (US EPA, 2009) (OECD TG 422) with the analogue substance [disodium N-(2-carboxyethyl)-N-dodecyl-beta-alaninate] (EC no 222-899-0)]. Under this specific endpoint you only provided the following justification, based on the findings of this screening study (US EPA, 2009): "*No effects observed in reproduction study with no adverse effects on young. Further animal testing is not justified*".

ECHA notes that this study (US EPA, 2009) 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 like examinations of foetuses for skeletal and visceral alterations. Hence the justification provided on the basis of the screening study's findings cannot be accepted to waive the developmental toxicity endpoint. Moreover, as explained above in Appendix 1, under the Grouping of substances and read-across approach section, your adaptation of the information requirement is rejected.

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 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 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 5.0, December 2016) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, 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: EU B.31./OECD TG 414) in a first species (rat or rabbit) by the oral route.

7. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

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 IX, Section 9.1.6., column 2. You have provided the following justification for the adaptation *"Substance is considered biodegradable. Daphnia was the most sensitive organism during acute testing and a chronic Daphnia test has been performed"*.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because ECHA considers that the chemical safety assessment indicates a need to investigate further the effects on aquatic organisms.

ECHA Guidance on information requirements and chemical safety assessment Chapter R.10. (Table R.10.4) states that *"An assessment factor of 100 applies to a single long-term result (e.g. EC10 or NOECs) (fish or Daphnia) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests.*

If the only available long-term result (e.g. EC10 or NOECs) is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus the hazard assessment is based on the short-term data with an assessment factor of 1000."

ECHA notes that the PNEC is derived on the basis of the long term Daphnia test (NOEC ca. 10 mg/l) with an assessment factor of 100, however the short term LC100 for fish and the short term EC50 for algae are both lower than that for Daphnia so the PNEC derivation is not appropriate. In this case there is no LC50 available from the short term fish test but the LC100 is 5.6mg/L and the EC50 for algae is 9.4mg/L while the EC50 for short term Daphnia is 29mg/L.

If the most sensitive short term effect values were used together with an assessment factor of 1000 as prescribed by the Guidance many of the RCRs for the ENV would be greater than 1 indicating that further investigations are necessary. Consequently, long term testing on fish is required.

Therefore, your adaptation of the information requirement cannot be accepted.

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 ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 3.0, February 2016).

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Once results of the test on long-term toxicity to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

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.

The compliance check was initiated on 09 June 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 did not receive any comments by the end of the commenting period.

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 relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests 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 by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests 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 tests to be assessed.