EUROPEAN CHEMICALS AGENCY

Helsinki, 6 April 2017

Addressee: [redacted]

Decision number: TPE-D-2114355340-59-01/F
Substance name: 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C12-18(even numbered) acyl) derivs., hydroxides, inner salts
List number: 939-457-4
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08.08.2016
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats using the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3; and**
2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rats), oral route using the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3; and**
3. **Long-term toxicity testing on fish (Annex IX, 9.1.6.1., Fish, early-life stage (FELS) toxicity test, OECD TG 210) using the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3;**

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 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **15 April 2019**. You shall also 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. 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, shall 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

The decision of ECHA is based on the examination of the testing proposals submitted by you for the registered substance (or target substance) 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C12-18(even numbered) acyl) derivs., hydroxides, inner salts and the submitted third party comments.

In relation to the testing proposals subject to the present decision, you propose a testing strategy intending to fulfil the standard information requirements for a:

- Sub-chronic toxicity study (90-day), oral route in rats (Annex IX, Section 8.6.2)
- Pre-natal developmental toxicity study, oral route in rats (Annex IX, Section 8.7.2.) and
- Long-term toxicity testing on fish (Annex IX, 9.1.6.3.)

In your testing strategy you propose to test the following analogue substance hereafter referred to as "source substance": 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3 or *Cocamidopropylhydroxysultaine C8-18 (CAS 68139-30-0 or CAS 70851-08-0* in the endpoints mentioned above.

The results from the structural analogue will then be used to adapt the standard information requirements by using read-across and grouping approach following Annex XI, Section 1.5. of the REACH Regulation.
To the extent that health and environment related proposed testing relies upon an identical read-across justification, ECHA has considered first the scientific validity of the proposed read-across and grouping approach (preliminary considerations; Section 0, below), before assessing the testing proposed (Sections 1., 2. and 3. below).
In a proposal for amendment a Member State competent authority proposes to accept the testing proposed by you on the source substance (C8-18) and delete the additional tests requested in the decision and instead ask for further substance identity information on the compositions particularly the similarities.
In your comments on the proposal for amendment you agree to delete the additional requests but you disagree to provide further information on the substance identity. After a re-evaluation ECHA agrees on your proposed testing strategy.

0. Read-across approach

a. Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by you are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*".

The first Recital and the first Article of the REACH Regulation establish the *"promotion of alternative methods for assessment of hazards of substances"* as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to the present decision by using the results of the proposed tests is plausible based on the information currently available.

b. Description and Information submitted on the proposed grouping and read-across approach

In your original submission ([redacted]) you intended to cover the human health information requirements for a sub-chronic toxicity (90-day) study (Annex IX, 8.6.2.), pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) and a long-term toxicity testing on fish (Annex IX, 9.1.6.3.) with the following source substance: 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3. After receiving ECHA's draft decision, you have provided comment and have updated your registration on 08 August 2016 (submission number: [redacted]). ECHA's analysis is based upon your read-across documentation in the CSR in the updated registration. Furthermore you have provided, in the technical dossier, under the endpoint specific summaries, further information on the tested material for the aquatic toxicity tests.

You use the following arguments to support the prediction of properties of the registered substance from data for reference substance(s) within the group: *"The read-across is based on the hypothesis that the source and target substances have toxicological, ecotoxicological and environmental fate properties likely to be similar as a result of a structural similarity due to a common functional group, common precursors and/or likelihood of common breakdown products, and a constant pattern in the changing of the potency of the properties between substances."* In your comments, you additionally proposed *"that the grouping approach was supported by the similarity of composition between both AAPHS, in association with an expected similarity of mode of action (both substances are amphoteric surfactants) and degradation/ metabolisation pathways."* You propose that the source and registered substances have similar properties for the above-mentioned information requirements.

ECHA considers that this information is your read-across hypothesis.

c. ECHA analysis of the grouping approach and read-across hypothesis in light of the requirements of Annex XI, 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 by interpolation to other substances in 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.

ECHA understands that your read-across approach is based on structurally similar constituents in both the target and source substance. In the read-across justification document you state the following:

"In summary, the source and target substances:

- *are UVCBs with overlapping constituents and close compositions,*
- *share structural similarities with common functional groups and side chains (C-chains) varying in length (between C8 and C18),*
- *differ only by the C-chain length distribution,*
- *have common impurities.*

The side chains are chemically simple structures (alkyl chains) which have no structural alerts for (eco)toxicity and which are closely related to substances of known low toxicity".

ECHA notes that the core structures of the constituents of the target and source substances are identical: both contain [redacted] functional groups. Further, the composition in both substances is very similar: both contain constituents with [redacted] functional groups), [redacted] and same impurities in similar concentration ranges. The difference between the substances are as follows: the source substance contains [redacted] and [redacted] whereas their concentrations in the target substance are [redacted] In addition, the source substance contains [redacted]) which is not present in the target substance. You explain that "*the constituents of the target substance are all included in the source substance composition in very close proportions*", and that "[redacted]*, and corresponding breakdown products) are not expected to display significantly different toxicokinetic or toxicological properties than the main constituents ([redacted]). Should the short C-chain constituents be associated with a significant toxicity, this would be taken into account in the classification and labelling or the risk assessment, as a worst-case for the target substance resulting from the read-across based on the target substance data*". ECHA notes that you consider the substances to have similar toxicity or that the source substance would be the worst-case.

You have based your read-across hypothesis on "*common functional group, common precursors and/or likelihood of common breakdown products*". ECHA notes that both the target and source substance contain structurally similar constituents and thus, similar functional groups. However, you have not provided any data on toxicokinetics, especially on breakdown of the substances.

You further state that both substances have "*an expected similarity of mode of action (both substances are amphoteric surfactants)".* ECHA notes that both substances are indeed amphoteric surfactants and given the similarity in constituents and impurities, a similar mode of action may be expected.

ECHA considers that you have provided information (both the target and source UVCB substance consist of structurally similar constituents in varying concentration ranges) to demonstrate that it may be plausible to predict the human healthand environmental properties of the registered substance from the data obtained from the source substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts, EC 939-455-3.

d. Conclusion on the read-across approach

ECHA therefore concludes that the read-across approach may be considered plausible.

However, in case where the information provided in accordance with the present decision would not confirm the read-across and grouping hypothesis relied upon, this outcome shall not alter your obligation to meet the standard information requirements. Should the read-across approach be inadequate, it is your responsibility to ultimately submit reliable information (or adaptations) which is used in a way that does not underestimate hazards of the registered substance in relation to the relevant endpoints.

In any case, following the update of the dossier submitting the information required in the present decision, ECHA will determine whether the documentation provided is sufficient to address the information requirements of Annex IX. If, upon further consideration, the proposed approach does not satisfy the conditions set out in Annex XI, Section 1.5., ECHA reserves the right to request the information necessary to fulfil the information requirements for the substance subject to the present decision.

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

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

a) Examination of the testing proposal

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.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts (EC No 939-455-3) with the following wording: *"In accordance with Regulation (EC) No. 1907/2006 (REACH), Annex IX, 8.6.2., a 90-day toxicity study in rats by the oral route is proposed, to be conducted according to the OECD No. 408 test guideline. This study is proposed to fulfil the requirements for both Cocamidopropylhydroxysultaine C8-18 and C12-18 substances (distinct dossiers), using the C8-C18 as test substance".*

ECHA has evaluated your proposal to perform the test with the analogue substance - Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts (EC No 939-455-3). ECHA notes that in your original submission you provided a testing proposal for the endpoint sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.) without providing a read-across justification according to Annex XI, Section 1.5. In your updated dossier you provided a read-across justification document. As explained under the section 0. in Appendix 1 of the current decision ECHA considers the proposed test on the analogue substance as plausible.

You 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 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration.

More specifically, the substance is a liquid of low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408. Therefore, ECHA considers that the proposed study performed by the oral route with the analogue substance (1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts) (EC No 939-455-3) is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

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) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation.

A third party has proposed *"For the registration of a very closely related substance, 1-propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivatives, hydroxides,inner salts (EC No. 939-455-3), a sub-chronic toxicity study via the oral route has been proposed, too. Thus an opportunity to read-across to this substance will arise. The similarity of both chemicals can be derived from a range of identical constituents. Furthermore, data of an OECD 422 screening test with the N-coco alkyl analogue (EC No. 268-761-3, CAS No. 68139-30-0) have already been used for the registration of both substances. Furthermore, data of an OECD 422 screening test with the N-coco alkyl analogue (EC No. 268-761-3, CAS No. 68139- 30-0) have already been used for the registration of both substances".*

ECHA acknowledges that the third party has proposed a read across approach for you to consider.

ECHA notes that the information provided by you in your updated dossier is plausible for similar reasons as those described under section 0.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the following study with the analogue substance (1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts): Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD TG 408), for.

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

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

a) Examination of the testing proposal

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.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to EU B.31/OECD TG 414 by the oral route with the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts (EC No 939-455-3).

ECHA has evaluated your proposal to perform the test with the analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts (EC No 939-455-3). In your original submission you did not provide a valid read-across justification for this endpoint. In your updated dossier you provided a read-across justification document. As explained under the section 0. in Appendix 1 of the current decision ECHA considers the proposed test on the analogue substance as plausible.

Therefore, ECHA considers that the proposed study performed by the oral route with the analogue substance (1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts) (EC No 939-455-3) 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 rats or rabbits as a first species.

You proposed testing by the oral route. ECHA agrees 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) Consideration of the information received during third party consultation

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

A third party has proposed *"For the registration of a very closely related substance, 1-propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivatives, hydroxides,inner salts (EC No. 939-455-3), a pre-natal developmental toxicity study has been proposed, too. Thus an opportunity to read-across to this substance will arise. The similarity of both chemicals can be derived from a range of identical constituents. Furthermore, data of an OECD 422 screening test with the N-coco alkyl analogue (EC No. 268-761-3, CAS No. 68139-30-0) have already been used for the registration of both substances".*

ECHA acknowledges that the third party has proposed a read across approach for you to consider.

ECHA notes that the information provided by you in your updated dossier is plausible for similar reasons as those described under section 0.

A third party has provided information on an OECD 422 screening study performed with the analogue substance (*Cocamidopropyl hydroxysultaine, CAS 68139-30-0*).

However, ECHA notes that an OECD 422 screening study is not a test method that corresponds to the standard information requirement of Annex IX, Section 8.7.2 for a pre-natal developmental toxicity study because it does not provide equivalent information. The screening study does not cover the key parameters of a pre-natal developmental toxicity study which are, for example, examinations of the foetuses for skeletal and visceral malformations.
Therefore, as the OECD 422 screening study would not even cover the standard information requirement of Annex IX, Section 8.7.2 for a pre-natal developmental toxicity study for the analogue substance as required byAnnex XI, Section 1.1.2., a read-across on the basis of this information can already for that reason not be justified.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the followingstudy with the analogue substance (1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts): Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31/OECD TG 414),.

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* R.7a, chapter R.7.6.2.3.2 (July 2015).

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

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

a) Examination of the testing proposal

"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. 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.

You have submitted a testing proposal for testing analogue substance 1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts (EC No 939-455-3) for long-term toxicity testing on Fish Juvenile Growth test, OECD TG 215 with the following justification:
"This study is proposed to fulfil the requirements for both Cocamidopropylhydroxysultaine C8-18 and C12-18 substances (distinct dossiers), using the C8-C18 as test substance."

As explained above in Section 0. your justification for the grouping and analogue approach and the test results provided for the analogues were assessed and found as plausible.

ECHA notes that the registered substance is a UVCB and a surfactant and therefore it is justified to study chronic effects on fish as you proposed. Furthermore, the substance has a wide range of uses with high releases to the environment, from industrial use as formulation (formulation of low viscosity liquids, e.g. shampoo, hair conditioner, shower gel, foam bath, herbal hair colorant; large scale), or at industrial sites; but also professional and consumer uses such as personal care products or washing and cleaning products; from closed to open systems. As indicated by you in your Chemical Safety Report for the uses hereby mentioned: *"Releases to the environment for these uses are the same as for all other professionnal and consumer uses."*

In addition, for some exposure scenarios (e.g. formulation of liquid detergents or maintenance products, use at industrial sites) the RCRs are close to 1 for fresh and marine water but also soil.

Therefore the long-term toxicity testing on fish is required.

In your comments on the draft decision and subsequent update, you now agree to perform the long-term toxicity testing according to OECD TG 210 instead of the originally proposed OECD 215 and therefore modified your testing proposal for this test guideline.

ECHA considers that for the endpoint of long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 2.0, November 2014, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as appropriate and suitable.

ECHA notes that there were no indications in the dossier from the short-term toxicity studies on aquatic species that fish would be substantially more sensitive than aquatic invertebrates or algae.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the analogue substance (1-Propanaminium, N-(3-aminopropyl)-2-hydroxy-N,N-dimethyl-3-sulfo-, N-(C8-18(even numbered) acyl) derivs., hydroxides, inner salts): Fish, early-life stage (FELS) toxicity test (test method: Fish, early-life stage toxicity test, OECD TG 210).

Notes for your consideration

You have not discussed the surface activity as a potential challenge in interpretation of the results obtained from the aquatic toxicity studies or for the selection of the test material for the testing proposal in the technical dossier.

As the substance is surface active, it is known that it can form dispersions or emulsions in which the bioavailability is difficult to ascertain, even with careful solution preparation. Moreover, the micelle formation can result in an overestimation of the bioavailable fraction even when a solution seems to be formed. This may present significant problems of interpretation. It is recommended in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b: Endpoint specific guidance, Version 3.0, February 2016, that *"Toxic effect concentrations for dispersions and emulsions should be compared with the dispersibility limit (i.e., the limit at which phase separation takes place) or the critical micelle concentration (CMC) for a substance in water rather than with its water solubility limit. The bioavailable concentration does not change above the CMC, even at higher dosing levels. The highest test concentration should either be 1000 mg active ingredient/litre or the dispersibility limit/CMC, whichever is lower."* Therefore, monitoring the exposure of the test material during the experiment is needed to verify the exposure.

Finally, according to Commission Regulation (EU) 2016/266 of 7 December 2015 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006: *"[...] If the test method is used for the testing of a MCS, UVCB or mixture, sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents."* This means that you should provide sufficient information on the different constituents present in the tested material (analytical monitoring of constituents).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 29 April 2013.

ECHA held a third party consultation for the testing proposal(s) from 18 September 2014 until 3 November 2014. ECHA received information from third parties (see Appendix 1).ECHA received information from third parties (see Appendix 1).

This decision does not take into account any updates after **20 July 2016**, 30 calendar days after the end of the commenting period.

ECHA notified you of the draft decision and invited you to provide comments. You uploaded your registration on 20 July 2016. ECHA took the information in the updated registration into account, and did not amend the draft decision. The updated information is reflected in the Reasons (Appendix 1).

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-52 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your 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.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In carrying out the test(s) 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 test(s) 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 test(s) to be assessed.