EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114290271-54-01/F Helsinki, 30 January 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For sodium dodecyl sulphate, CAS No 151-21-3 (EC No 205-788-1), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for sodium dodecyl sulphate, CAS No 151-21-3 (EC No 205-788-1), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted] for the tonnage band of 1000 or more tonnes per year. This decision does not take into account any updates submitted after 24 July 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 2 September 2013.

On 8 November ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 9 December 2013 ECHA received comments from the Registrant on the draft decision.

On 14 January 2014 the Registrant updated his registration dossier with the submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 24 July 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 29 August 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended Section III of the draft decision.

On 8 September 2014 ECHA referred the draft decision to the Member State Committee.

By 29 September 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments on the proposals for amendment of the Registrant into account.

The present decision relates solely to a compliance check requesting information in form of *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.) and Revised Predicted No Effects Levels (PNECs) for the aquatic and marine environmental spheres using assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in PNEC derivation (Annex I, 3.3.1.). The other information requirement for Two-generation reproductive toxicity study (Annex X, 8.7.3.) is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

After discussion in the Member State Committee meeting on 28-29 October 2014, a unanimous agreement of the Member State Committee on this draft decision relating to the information requests for *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.) and Revised Predicted No Effects Levels (PNECs) for the aquatic and marine environmental spheres using assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in PNEC derivation (Annex I, 3.3.1.) was reached on 28 October 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

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

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102, as specified in section III.A.3 below;

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 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.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised Predicted No Effects Levels (PNECs) for the aquatic and marine environmental spheres using assessment factors recommended by ECHA and re-assessment of related risks
   or
   A full justification for not using the recommended assessment factors in PNEC derivation (Annex I, 3.3.1.).

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **6 August 2015**.

III. Statement of reasons

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

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

1. *In vitro* gene mutation study in bacteria

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

The Registrant has provided a test from the year 1988 according OECD 471 and GLP with an assigned reliability score of 2. The test used four different strains of *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100. However, since the test was conducted, significant changes have been made to OECD guideline 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

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

ECHA notes that the Registrant agreed in his comments to the draft decision with this request for *in vitro* gene mutation study in bacteria.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

The chemical safety report in the submitted technical dossier does not provide adequate information for the following elements given below:

1. Revised PNECs for the aquatic environment using the assessment factors (AF) recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in PNEC derivation (Annex I, section 3.3.1.)

Annex I, 3.3.1. of the REACH Regulation requires that an appropriate assessment factor to the effect values be applied when deriving PNECs. Typically an assessment factor of 10 is applied to the lowest of three long-term no observed effect concentration (NOEC) values derived from species representing different trophic levels:

The ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.10, Version 2.1 November 2012 provides further details and specifically provides default factors which should be applied to derive PNECs.

ECHA observes that the Registrant has not followed the recommendations of ECHA's Guidance R.8 for the derivation of PNECs in line with Annex I, 3.1. and 3.3.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose[concentration] response for environment (2008), an AF of 10 is applied for PNEC derivation for freshwater (Table R.10-4) and an AF of 100 for saltwater (Table R10-5) if long-term toxicity values are available from at least three species representing three trophic levels. Only in case a species sensitivity distribution (SSD) method is applied, an AF between 5 and 1 is applied for freshwater. For saltwater, an AF of 50 is applied if two long-term results from freshwater or saltwater species representing two trophic levels (algae and/or crustacean and/or fish) *and* one long-term result from an additional marine taxonomic group (e.g. echinoderms, molluscs) are available.

In particular, ECHA notes that

1) for the derivation of the PNEC aquatic the Registrant applied an assessment factor lower than 10 to the lowest of three long-term NOEC values derived from species representing different trophic levels. The justification refers to "numerous data" which would, according to the Registrant, indicate that aquatic invertebrates were "the most sensitive trophic group".. However, ECHA notes that data given in the dossier indicate that aquatic invertebrates are equally sensitive to the substance subject to this decision as fish (results from key studies: *Ceriodaphnia duba* 48h-LC50=5.55 mg/L and 7d-NOEC=0.88 mg/L compared to *Cyprinodon variegatus* 96h-LC50=4.1 mg/L and *Pimephales promelas* 42d-NOEC=1.4 mg/L). ECHA notes further that indeed the dataset for aquatic invertebrates is more robust than the basic information required by REACH. However, the Registrant's reasoning for lowering the AF only covers one trophic level (aquatic invertebrates) while ECHA does not agree that this trophic level has been proven the most sensitive one. Therefore, ECHA finds that lowering the AF based on elevated data availability on only one trophic level is not acceptable.
2) for the derivation of the PNEC marine the Registrant applied a factor lower than 100 to the the lowest of three long-term NOEC values derived from species representing different trophic levels. The justification is also based on the supposedly higher sensitivity of aquatic invertebrates compared to other throphic groups. As mentioned above, the data presented in the dossier do not support this justification. Furthermore, for derivation of the PNEC saltwater a long-term result from an additional marine taxonomic group (e.g. echinoderms, molluscs) would be required to justify the use of an AF of 50 instead of 100. This precondition is not met.

As explained above, the information provided on PNEC for aquatic and marine environmental spheres for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 3.3.1. Furthermore, the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. or are not justified. Consequently it is necessary to revise the PNECs for microorganisms, aquatic and marine environmental spheres or to provide full justification for the deviation.

The Registrant is given two options: The Registrant shall revise the PNECs for the aquatic and marine environmental spheres by applying the appropriate assessment factors recommended by ECHA. Subsequently, the Registrant shall re-assess related risks.

In the alternative, the Registrant shall, in accordance with Annex I, 3.1.5., provide a full justification for the PNECs derived for the aquatic and marine environmental spheres provided in the chemical safety report by specifying how the difference between effect values derived from a limited number of species from laboratory tests and the potential actual effects for the environmental sphere has been taken into account.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information: Revised PNECs for aquatic and marine environmental spheres using the assessment factors recommended by ECHA and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in PNEC derivation.

The results of the studies requested under section II.A. shall be taken into account when revising the PNECs.

C. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

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

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given 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 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

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

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