ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004000-96-04/F Helsinki, 19 March 2014

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

For triclosan, CAS No 3380-34-5 (EC No 222-182-2), 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 dossier for triclosan, CAS No 3380-34-5 (EC No 222-182-2) submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band 1000 tonnes or more per year. This decision does not take into account any updates after 1 August 2013, 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.

The compliance check was initiated on 9 March 2012.

On 28 August 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 20 September 2012 ECHA received comments from the Registrant.
On 27 September 2012 and 23 April 2013 the Registrant updated his registration dossier.

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

On 1 August 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the

notification.

ECHA reviewed the proposals for amendment received and modified the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

On 7 October 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 25 October 2013 in a written procedure launched on 15 October 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(a) and 13 as well as Annex VII of the REACH Regulation, the Registrant shall submit the following information using the test method as indicated below:

> In vitro gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one E. coli WP2 uvrA strain or S. typhimurium TA102, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

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

> Further information on exposure as specified in Section III., 2) below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **19 March 2015.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more tonnes per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10 and 12 and with Annexes I and VII thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to mutagenicity

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance manufactured or imported in quantities of more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII-X of the REACH Regulation.

Pursuant to Annex VII 8.4.1 of the REACH Regulation, "*in vitro* gene mutation study in

bacteria shall be provided. Further mutagenicity studies shall be considered in case of positive results".

The Registrant has provided in his dossier data from an *in vitro* gene mutation study in bacteria performed in 1988 according to OECD Test Guideline (TG) 471 in force at that time and in accordance with the OECD good laboratory practice (GLP) principles.

The Registrant has also provided four other *in vitro* studies (mammalian cell gene mutation study, negative; chromosome aberration assay, positive; mouse lymphoma TK locus assay, negative; an unscheduled DNA synthesis (UDS) in mammalian cell study, negative). Further, the Registrant reported a negative outcome from the *in vivo* chromosome aberration study. The Registrant did not provide any *in vivo* test on gene mutation.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the European Commission or ECHA. Other international test methods recognised as being appropriate may be used if the conditions of Annex XI are met.

In the present case, the required *in vitro* gene mutation study in bacteria was carried out according to GLP and to OECD TG 471. However, since the test was conducted, significant changes have been made to OECD 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.

The version of the EU Test Method B. 13/14 OECD TG 471 in force since 1997 introduced the need for performing the test in at least 5 strains of bacteria whereas the OECD TG 471 in force in 1989 only required testing in a minimum of 4 bacterial strains. The required 5th bacterial strain, i.e. *E. coli* WP2 uvrA strains or *S. typhimurium* TA102, has the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which the 4 bacterial strains recommended in the former version of the OECD TG 471 may not detect. The other genotoxicity studies submitted are not sufficient to conclude on the genotoxic activity of the substance through a gene mutation mechanism. Therefore, the data set submitted does not provide data for the required 5th bacterial strain.

In its comments, the Registrant consented to perform an *in vitro* gene mutation study as required.

Consequently, the Registrant is required to complete the data set on mutagenicity by performing an *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. one *E. coli* WP2 strain or *S. typhimurium* TA102, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

2) Missing information on exposure related to Chemical Safety Report

Annex I of the REACH Regulation sets out the general provisions for assessing substances and preparing chemical safety reports (CSR). ECHA has observed omissions and inconsistencies in the CSR. In response to ECHA's draft decision sent on 28 August 2012, the Registrant provided comments on 20 September 2012 and updated the dossier on 29 September 2012 and 23 April 2013. ECHA considered these and amended the draft decision by removing a number of requests while observing still the following omissions and inconsistencies:

a. The Registrant consented to clarifying the inconsistencies between the CSR and IUCLID in the updated dossier. However, some uncertainty remains and the exposure scenario for wide dispersive use in the CSR (section 9.4) should address Human Health while this is not currently the case.

b. The Registrant clarified in his updated dossier that in his opinion only inhalation and dermal systemic long-term DNELs for workers are relevant and references to other DNELs have been deleted from the dossier.

However, a description of established work practices, air exposure limits and manufacturing process practices to justify such waiving, as required by Annex I, 1.4.2., is not available in the updated dossier. Further, some risk characterisation ratios (RCRs) for workers are [redacted] (CSR table 84, 85, 88) and the combined RCR was not calculated correctly (it is the sum of RCRs and not the average). Therefore, actual RCRs (combined) might be >1. The Registrant shall consequently correct the combined RCR.

c. Personal protective equipment (PPE: gloves, goggles and protection) are mentioned, but no characteristics are provided in the updated dossier. In IUCLID Section 11 gloves were considered but type, breakthrough time and material were not described. PPE specification is a requirement of Annex II, 8.2.1. and the efficacy is needed to assess residual exposure occurring to workers when PPE are used. In Annex I, 5.2.4. it is written that "the estimation of the exposure level (...) shall take into account (...) implemented and recommended RMM including the degree of containment."

d. The Registrant did not provide a "hazard conclusion" for the general population but waived it with the following justification in the updated dossier: "We do not expect that the General Population will have direct exposure to triclosan as a raw material because it is only sold to commercial formulators of consumer products. The exposure to cosmetics is covered elsewhere and Triclosan is not marketed into the home care sector." Consequently, the Registrant did not perform an exposure assessment and risk characterisation for the general population. In his comments on the Member State Competent Authority proposal for amendment from Germany, the Registrant clarified that all supported uses are either covered by the Cosmetics Regulation (1223/2009/EU) or the Biocidal Product Regulation (528/2012/EU) and therefore no exposure assessment for human health is needed for the cosmetics and personal care product category (PC 39). The Registrant states in his comments "*Triclosan is an active molecule and is only used in regulated markets. The use of triclosan in cosmetics and personal care products is defined according to the cosmetic regulation (1223/2009/EU) and the use concentration is only allowable to a maximum of 0.3%. The use of triclosan in professional applications is supported by the registrant, and is regulated by the Biocidal Products Regulation (528/2012/EU). The relevant use and exposure scenarios for this type of product (Product Type 1) are addressed and so it is not necessary to cover the use and exposure in the CSR. Other typical consumer products may be surface disinfectants (Product Type 2), which is also regulated by the Biocidal Products Regulation (523/2012/EU) in Europe. The registrant is not supporting the use of Triclosan in this application and so the production volumes are not provided as relevant for this possible exposure. Within the scope of the REACH regulation text, cosmetic products are referred to as those products, which fall within the definition according to the cosmetics directive (76/768/EEC) and now the cosmetics regulation (1223/2009/EU) as the directive has since been repealed. A cosmetic is defined as 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair*

system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.' The term personal care product is not specifically defined either within the REACH legal text or the cosmetic regulation, however, it is generally understood to mean consumer products for use in personal hygiene and beautification. The term 'cosmetics' is often used generically as a subgroup of the personal care market.
With reference to Article 14 (5) (b) of the REACH regulation it states that the risk assessment for cosmetic products does not need to be addressed. As written above, the description of what a cosmetic product is, also covers personal care products. Hence, the use of product category (PC) 39 is adequate to cover the use of Triclosan in consumer products. The only relevant REACH market use of Triclosan is the cosmetic market. All other potential uses are either exempt (human medicines use) or classed as already registered (biocidal use). There are no other consumer products to be assessed."

ECHA considers the justification provided by the Registrant in his comments to the proposals for amendment as a valid waiver. However, this statement is currently not included in the registration dossier. The Registrant should therefore update his dossier and include a detailed statement that justifies the lack of hazard conclusion for the general population.

e. The maximum allowed dilution factor for the receiving river water in the environmental exposure modelling for production is 1000 (Guidance R.16, version May 2008, p. 68, local concentrations in site-specific assessment). The factor used by the registrant (exposure scenarios (ES) 1 and 2) is 9848. If a dilution factor of 1000 was used this would have resulted in a RCRfreshwater >1 for production instead of [redacted] as reported in the registration dossier (ES 1).

f. In the exposure scenarios not all information on waste treatment is provided. Recycling of sulphuric acid should be covered in the scenario related to manufacturing of the substance. The waste life cycle stage is missing for:
   - waste generated during formulation at customer site (ES 3); the Registrant should indicate in ES 3 how waste is to be treated;
   - waste generated from consumer use (end of life of the substance in cosmetics and personal care products, ES 4); the Registrant should indicate in the ES 4 how waste is to be treated; in section 10.5.2 the Registrant states that consumer waste is supposed to be incinerated or recycled. This assumption/advice is not acceptable as it is not possible control how waste from consumer use is treated in the EU. Finally, the Registrant has indicated in section 10.5.2 of the updated dossier that the concentration of triclosan in consumer products is low. However, the Registrant did not specify the *fraction* of triclosan going to waste for this ES Annex I, 5.2.2. requires the Registrant to provide such information.

Therefore, pursuant to Articles 41(1)(c), 14 and Annex I of the REACH Regulation, the Registrant shall submit an update of the Chemical Safety Report addressing the further information on exposure requested as described.

IV. Adequate identification of the composition of the tested material

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

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

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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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