ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000001989-55-03/F Helsinki, 8 March 2012

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

For dodecamethylcyclohexasiloxane, CAS No 540-97-6 (EC No 208-762-8), registration number: [redacted]

Addressee: [redacted]

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

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined a testing proposal set out in the registration dossier for Dodecamethylcyclohexasiloxane, CAS No 540-97-6 (EC No 208-762-8) submitted by [redacted] (Registrant), latest submission number [redacted], for over 1000 tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex X:

Annex IX, 8.6.2: Sub-chronic toxicity study (90-day) by inhalation route.

The examination of the testing proposal was initiated on 8 November 2010.

ECHA opened a third party consultation from 31 May 2011 until 15 July 2011 as the testing proposal included testing on vertebrate animals. ECHA received comments only from [redacted] (see section III).

On 4 October 2011 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 3 November ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 20 January 2012 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, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his

registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

- Subchronic inhalation toxicity study (90-day) (Annex IX, 8.6.2., EU method B.29.) in rat.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **9 September 2013** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance and scientific information submitted by third parties.

Examination of the testing proposals

1. Subchronic inhalation toxicity study (90-day)

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

According to section 8.6.2. of Annex IX, subchronic toxicity study (90-day) is a standard information requirement. The most appropriate route of administration should be chosen, having regard to the likely route of human exposure. For dodecamethylcyclohexasiloxane, the inhalation and dermal routes are relevant for workers. According to Column *2 of* section 8.6.2 of Annex IX, the inhalation route is regarded appropriate if exposure via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of inhalable size.

The substance has a low vapour pressure (5 Pa in 20-25° C). There is no information of size of droplets or aerosol particles. However, the substance is used in spraying in both industrial and in professional settings. In addition, in the exposure assessment, inhalation exposure was rather high in some of the exposure scenarios, the highest inhalation exposure being [redacted].Testing by dermal route is less appropriate, since in an *in vitro* skin absorption test using human skin, the absorption through the skin was negligible.

Therefore, testing for repeated dose toxicity (90-day) by the inhalation route is regarded appropriate. Consequently, the testing proposal for subchronic toxicity study (90-day) by the inhalation route is accepted.

Consideration of information received during third party consultation

ECHA always examines the information submitted by third parties following the consultation in order to determine whether there is already scientifically valid information that addresses the relevant substance and hazard endpoints.

[redacted] submitted comments during third party consultation.

[redacted] noted that category approach could possibly be used for all endpoints of several silanes and siloxanes. However, no assessment using the category approach was submitted by [redacted] to cover the missing data in accordance with Annex XI, 1.5 and as further detailed in ECHA's Guidance on information requirements and on chemical safety assessment, R 6.2 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1315205631#r6).

ECHA concludes that [redacted] has therefore not provided any scientifically valid information which could form a basis for ECHA to reject the testing proposal.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in your dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. You must note, however, that this information, or the information submitted by other registrants of the same 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 proposed tests, 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 the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.

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

ECHA always 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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://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.

[redacted]

Jukka Malm
Director of Regulatory Affairs