SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

1,1,1,3,3,3-hexamethyldisilazane

EC No 213-668-5

CAS No 999-97-3

Evaluating Member State(s): Spain

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process, the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

1,1,1,3,3,3-hexamethyldisilazane (HMDZ) was originally selected for substance evaluation in order to clarify suspected risks about:

- exposure,
- high RCRs for the terrestrial compartment and,
- aggregated tonnage.

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	
No need for regulatory follow-up action	X

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

Not applicable.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

3.1.3. Need for restrictions

Not applicable.

3.1.4. Proposal for other Community-wide regulatory risk management measures

Not applicable.

3.2. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	Tick box
Hazard and /or exposure was verified to be not relevant and/or	***X***
Hazard and /or exposure was verified to be under appropriate control and/or	
The registrant modified the applied risk management measures.	
other: <Please specify>	

Conclusions

After the registrant's clarifications, the eMSCA carried out an assessment which resulted in RCRs quite well below 1. According to this assessment, no additional information is considered to be needed for further refinement of the assessment or to remove any additional concern for the environment.

The following exposure scenarios are presented for the manufacture of 1,1,1,3,3,3-hexamethyldisilazane (HMDZ):

ES1: Use as an intermediate in the production of other organic chemicals
ES2: Use as a processing aid in polymerisation processes
ES3: Use as a non-metal surface treatment agent
ES4: Use in the electronic industry in the manufacture of semiconductors
ES5: Use as a laboratory chemical/reagent– as a small-scale derivatising agent in analytical laboratories

In contact with water, HMDZ reacts very rapidly (half-life << 1 minute at 25ºC and pH 4, 7 and 9) to produce trimethylsilanol (TMS) and ammonia and therefore, it is considered appropriate to carry out environmental exposure assessment and risk characterisation based on the properties of the two hydrolysis products of HMDZ. Based on the above, all release amounts for environmental exposure calculations are therefore corrected for the molecular weight of:

(i) two moles of the silanol hydrolysis product (90.2 g/mol) compared to the parent (161.4 g/mol).

(ii) 1 mole of the ammonia hydrolysis product (17.03 g/mol) compared to the parent (161.4 g/mol).

In all cases, RCRs for the expected moles of TMS and ammonia formed after the hydrolysis of HMDZ are below 1. According to these results no follow-up action is considered to be needed.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.