ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 26.02.2014

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For 1,3-diphenylguanidine, CAS No 102-06-7 (EC No 203-002-1)

Addressee: [redacted], registrant of 1,3-diphenylguanidine (concerned registrant)

The present decision is exclusively addressed to [redacted] and it contains information requests that are additional to the information requests included in the decision addressed to all concerned registrants of 1,3-diphenylguanidine.

Based on an evaluation by French Agency for Food, Environmental and Occupational Health Safety (ANSES) on behalf of the French Competent Authority (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registration of the concerned registrant after 5 September 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

This decision does not imply that the information provided by the concerned registrant in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the concerned registrant at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of France has initiated substance evaluation for 1,3-diphenylguanidine, CAS No 102-06-7 (EC No 203-002-1) submitted by the addressees (concerned registrants) and prepared decisions in accordance with Article 46(1) of the REACH Regulation. The present decision is exclusively addressed to the registrant of [redacted] and it contains information requests that are additional to the information required in decision number in format SEV-D-000000XXX-XX-XX/F addressed to all registrants of 1,3-diphenylguanidine.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health/CMR, exposure/high tonnage, risk characterisation ratio>1 (human health) 1,3-diphenylguanidine was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of France was appointed to carry out the evaluation. In the course of the evaluation MSCA noted additional concerns regarding environmental fate of the substance and composition of the substance.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared draft decisions pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft of the present decision to ECHA on 28 February 2013.

On 4th April 2013 ECHA sent the draft decision to the Registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision. The Registrants provided comments on the draft decision by the given timeline. Having taken the comments into account, the Competent Authority of France modified Section III of the draft decision.

In accordance with Article 52(1) of the REACH Regulation, on 5 September 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information:

Composition of 1,3-diphenylguanidine:

- **maximum content of [redacted] in the substance,**
- **origin of [redacted],**
- **further information (regarding the other impurities ([redacted]).**

Pursuant to Articles 46(2) of the REACH Regulation, the concerned registrant shall submit to ECHA by 26 May 2015 an update of the registration dossiers containing the information required by this decision.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on 1,3-diphenylguanidine and other relevant and available information ECHA concludes that further information is required. In order to lead a better assessment of the substance regarding the CMR and human health initial concerns, the evaluating MSCA needs more information regarding the impurity profile of 1,3-diphenylguanidine.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is requested to provide specifications of [redacted], classified Carc 1B, [redacted] present as impurity in 1,3-diphenylguanidine. The Registrant is also requested to provide further information (identity, maximum content (specifications), origin and potential toxicological relevance) about the [redacted] impurities and the [redacted] impurities. In particular the registrant is requested to clarify if these impurities contain substances which could be classified as Carc. 1A or 1B such as aromatic amines or polycyclic aromatic hydrocarbons.

Concerning the Registrant's comments, it is acknowledged that the Registrant agrees with this requirement.

Clarifications from the Registrant about the formation of [redacted] are acceptable and should be added to the dossier.

Analytical data provided in the IUCLID dossier cannot be used to assess the amount of any impurity <1% and proposed additional characterization would answer this requirement. Consequently, no amendment of the draft decision has been done following Registrant's comments.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 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 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
Deputy Executive Director