ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114299627-30-01/F Helsinki, 20 May 2015

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

For 1,5-diisocyanatonaphthalene, CAS No 3173-72-6 (EC No 221-641-4), 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 1,5-diisocyanatonaphthalene, CAS No 3173-72-6 (EC No 221-641-4), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI) or those of Annexes VII to IX relating to aquatic toxicity.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 5 March 2015, 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 29 October 2013.

On 22 November 2013 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 19 December 2013 ECHA received comments from the Registrant on the draft decision.

On 28 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 5 March 2015 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.

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 Articles 41(1)(a), 41(3), 10(a)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Title I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- a fully justified hazard classification of the registered substance for aquatic toxicity based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and resulting hazard statement(s) in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (b) and 4.1.4), as specified in section III below, or

- the scientifically justified reasons why no such classification is given in the technical dossier.

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 **27 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 requirement. The scope of the present decision is limited to classification and labelling for aquatic toxicity (Annex VI, Section 4.1. and 4.2 of the REACH Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the dossier:

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In the alternative, for each entry, the scientifically justified reasons for why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes the following:

In his comments to the draft decision the Registrant reasons that as the substance undergoes very rapid hydrolysis (less than 1 hour) and the hydrolysis products are not

classified the substance should be considered as rapidly degradable. The Registrant indicates further that instead of the NOEC value 0.073 mg/L , the ErC10 of 0.512 mg/L for the algae study (triggering classification) should be used for determining the classification. Consequently the Registrant considers the current classification as chronic category 3 as justified.

ECHA agrees that according to the CLP Guidance the ErC10 is preferred over a NOEC. However, the main hydrolysis product 1,5-naphthylene diamine has a harmonised classification as aquatic chronic 1 and acute 1. ECHA considers the hydrolysis study as valid.

According to the Registrant the "*Hydrolysis of 1,5-naphthylene diisocyanate results in formation of the main hydrolysis products 1,5-naphthylene diamine and carbon dioxide. Half-life of the parent compound 1,5-naphthylene diisocyanate is less than 1 hour at pH values between 4 and 9 under ambient conditions. However, formation of hydrolysis products described in this study are assumed to be triggered by laboratory conditions, since stirring of test solution gives dispersed particles of the parent substance. Under environmental relevant conditions 1,5-naphthylene diisocyanate will not be available dispersed but as agglomerates. Hydrolysis would result in formation of 1,5-naphthylene diamine at the surfaces in contact with water and finally in formation of poly-urea. Therefore, poly-urea is expected to be relevant and will be taken forward to risk assessment.*" ECHA notes that in the dossier there is currently no evidence provided that under environmentally relevant conditions hydrolysis would finally result in the formation of poly-urea and only this would be relevant for risk assessment.

ECHA notes further that under IUCLID section 6.1. Aquatic toxicity the Registrant states "*As the parent compound1,5-naphthylene diisocyanate hydrolyses to the main hydrolysis product 1,5-naphthylene diamine within less than 1 hour the parent compound is factually non-existent under environmental or laboratory conditions in aquatic media.*" Also under IUCLID endpoint 6.1.5 Toxicity to aquatic algae and cyanobacteria is it written: "*As 1,5-naphthylene diisocyanate hydrolyses in aquatic media, the main hydrolysis products 1,5-diaminonaphthalene and urethane-dimer were measured by HPLC/MS.*"

ECHA notes that according to the Guidance on the application of the CLP criteria (p. 527-528; version 4.0, November 2013) where rapid degradation occurs, the available test data will frequently define the hazard of the degradation products since it will be these that have been tested. Furthermore, according to the CLP Guidance these data may be used to classify the parent substance in the normal way. As a further note the CLP Guidance states that "*There may be occasions, however, when a substance so tested may degrade to give rise to a more hazardous product. In these circumstances, the classification of the parent compound should take due account of the hazard of the degradation product, and the rate at which it can be formed under normal environmental conditions*".

Therefore, ECHA notes that as it is actually the hydrolysis products that have been tested and measured in the test medium, for purposes of classification the harmonised classification as Aquatic chronic 1 (H410) and Aquatic acute 1 (H400) of the hydrolysis product 1,5-naphthylene diamine (CAS No 2243-62-1, EC No 218-817-8) should be considered also for the parent compound, i.e. the registered substance subject to the present decision.

ECHA notes that the technical dossier does not contain scientifically justified reasons relating to why the harmonised classification of the hydrolysis product is not considered.

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP

Regulation taking into account the harmonised classification of the hydrolysis product 1,5-naphthylene diamine (CAS No 2243-62-1, EC No 218-817-8) and is consistent with the data on aquatic toxicity available in the registration dossier. The Registrant shall also provide a resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (b) and 4.1.4). In the alternative, the Registrant is required to provide the scientifically justified reasons for why no such classification is given.

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

IV. 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.

[redacted]

Guilhem de Seze
Head of Unit, Evaluation