Decision number: CCH-D-2114295281-48-01/F Helsinki, 9 March 2015

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

For diethyl 1-(2,4-dichlorophenyl)-5-methyl-4,5-dihydro-1H-pyrazole-3,5-dicarboxylate, CAS No 135590-91-9 (EC No 603-923-2), 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 for diethyl 1-(2,4-dichlorophenyl)-5-methyl-4,5-dihydro-1H-pyrazole-3,5-dicarboxylate, CAS No 135590-91-9 (EC No 603-923-2), 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 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 30 October 2014, 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 20 September 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.

On 20 December 2013 ECHA received comments from the Registrant on the draft decision.

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

On 30 October 2014 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.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 5 December 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 15 December 2014 ECHA referred the draft decision to the Member State Committee.

By 5 January 2015, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant on the proposal for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 19 January 2015 in a written procedure launched on 9 January 2015.

ECHA took the decision pursuant to Article 51(6) 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 chronic aquatic toxicity based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and 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), 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 **16 June 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 their comments on the intial draft decision the Registrant indicated that, as the substance is rapidly degradable, classification as Aquatic Chronic Hazard Category 3 is required instead of Category 1 initially requested by ECHA.

ECHA notes that in the technical dossier under the endpoint study record of 5.2.2. 'Biodegradation in water and sediment: simulation tests' the Registrant has provided results of a simulation study carried out according to BBA Part IV, 5-1 (1990)/ EPA Subdivision N Pesticide Guideline 162-4 (Aerobic Aquatic Metabolism). As the half life the Registrant has provided a DT50-value of 2 to 3 days. The Registrant has provided a degradation pathway identifying the metabolites as [redacted] (substance names only available in CSR). The Registrant has also in his comments provided a summary of aquatic toxicity data on the degradation products.

ECHA agrees with the Registrant that the simulation data in the technical dossier shows that the registered substance fulfills the criteria of being rapidly biodegradable as defined in the CLP guidance since even when no proper half life based on Deg50 is given, the Registrant has provided the individual degradation rates of the total biodegradation pathway which indicates that the criteria of half life of less than 16 days would be met. ECHA notes further that according to the Guidance on the application of the CLP criteria the Registrant would furthermore need to demonstrate that the degradation products do not fulfill the classification as hazardous to the aquatic environment.

In his comments the Registrant also discussed the use of the Maximal Acceptable Toxicant Concentration (MATC) instead of the NOEC as the basis for classification. The use of this approach was questioned by a MSCA in their proposal for amendment. The MATC for the fish study based on which classification is needed is reported to be 0.18 mg/L, the geometric mean of the NOEC 0.1 and the LOEC 0.32 mg/L. The Guidance on the Application of the CLP Criteria (Version 4.0., November 2013) establishes that "*for determining chronic aquatic toxicity for classification purposes data generated according to the standardised test methods referred to in Article 8(3) shall be accepted, as well as results obtained from other validated and internationally accepted test methods. The NOECs or other equivalent ECx (e.g. EC10) shall be used*". Hence, MATC or LOEC values should not be used as basis of environmental classification.

In their comments to the proposal for amendment the Registrant raised the possibility of applying the same approach used for STOT classification, i.e. the reference to an interpolation between a NOAEC and an effect dose, also for environmental hazard classification. ECHA notes that the current approach in Regulation (EC) No 1272/2008 (CLP Regulation) and its Guidance for chronic aquatic hazard classification is to base the classification on the chronic NOEC when adequate toxicity data are available (Table 4.1.0, Annex I, CLP Regulation).
Therefore, based on rapid degradation of the substance ECHA agrees with the Registrant that classification as Aquatic Chronic Hazard category 1 seems unwarranted. However, for the reasons outlined in the previous paragraph, ECHA does not consider the classification as Aquatic Chronic Hazard category 3 proposed by the Registrant to be fully justified based on the available information.

In their proposal for amendment a MSCA considered that according to the information provided by the Registrant in the technical dossier and in the comments to the initial draft decision, the substance would meet the criteria for classification as Aquatic Chronic Hazard Category 2. ECHA notes that as the technical dossier includes an aquatic chronic toxicity study indicating a NOEC or equivalent value equal to or lower than 0.1 mg/l which is considered reliable by the Registrant (Klimisch score 1 or 2) a classification in line with the criteria set out in Part 4 of Annex 1 of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. (b) and 4.1.4 of the CLP Regulation) with a full justification is required. However, in the technical dossier the Registrant has not classified the substance nor provided the according justification.

Furthermore, the technical dossier does not contain scientifically justified reasons relating to why the substance has not been classified in accordance with the available study/studies.

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 as specified above 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.

Notes for consideration by the Registrant

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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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