EUROPEAN CHEMICALS AGENCY

Helsinki, 25 April 2018

Addressee: [redacted]

Decision number: CCH-D-2114407671-55-01/F
Substance name: 3-(dichloroacetyl)-5-(2-furyl)-2,2-dimethyloxazolidine, 2,2-dichloro-1-[5-(2-furyl)-2,2-dimethyl-oxazolidin-3-yl]ethanone
EC number: 434-800-1
CAS number: 121776-33-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 26/03/2013
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:[1]

1. **Composition of the substance (Annex VI, Section 2.3.) of the registered substance;**

2. **Description of the analytical methods (Annex VI, Section 2.3.7.) of the registered substance;**

3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

4. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

5. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.): generate a quantitative exposure assessment for all the exposure scenarios and revise the risk characterisation accordingly.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

[1] No testing for endpoints listed in Annexes IX or X to the REACH Regulation may be started or performed at this moment: A decision only becomes legally effective and binding for you after it has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

You have to submit the requested information in an updated registration dossier by **2 November 2019**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[2] by Kevin Pollard, Head of Unit, Evaluation E1

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

INFORMATION ON THE IDENTITY OF THE SUBSTANCE

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

1. Composition of the substance (Annex VI, Section 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

A substance is completely identified by its chemical composition i.e. the chemical identity and the content of each constituent in the substance. As outlined in chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) – referred to as the "SID Guidance" from here on, the reporting of the composition of well-defined substances shall include the following:

- Each main constituent (i.e. the constituent that contributes to composition at ≥80% for a mono-constituent substance or each constituent that contributes at ≥10% and 80% for a multi-constituent substance) is identified and reported individually; and

- Each impurity that contributes to composition at ≥1% or relevant for the classification and/or PBT assessment of the registered substance ise identified and reported individually.

- For each constituent, its typical, minimum and maximum concentration values are reported regardless of the substance type.

As a general rule, the compositional information should be completed up to 100%.

You reported a 95 % (w/w) as the minimum degree of purity and typical concentration value for the main constituent in your legal entity composition record in section 1.2. You did not report impurity(ies) in the composition record. The analytical data provided in section 1.4 reports several impurities.

Based on the above, 5 % (w/w) of your compositional information is not reported in section 1.2 of your IUCLID dossier which may indicate the presence of impurities that contribute to composition at ≥1% and must therefore be identified and quantified. You did not report the identities of impurities or their contribution to the composition of the substance.

You are accordingly requested to revise the compositional information reported in your composition record such that 100 % of its compositional profile is accounted for. You are requested to report any impurity present in compositions covered by your registration following the principles outlined in the guidance.

Specifically, you are requested to report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula. Furthermore, the minimum, maximum and typical concentration need to be reported in the appropriate fields in the composition record in Section 1.2 of the IUCLID dossier. The information reported must be verifiable and consistent with information reported in sections 1.1 and 1.4 of your dossier.

Technical instructions on how to report the compositional information for well-defined substances in IUCLID 6 are available in the Manual "How to prepare registration and PPORD dossiers" (version: 1.0, April 2016) on the ECHA website.

2. Description of the analytical methods and the results thereof (Annex VI, Section 2.3.7.)

According to Annex VI Section 2.3.7, description of the analytical methods used for the identification of the substance and, when appropriate, for the identification of impurities and additives is required be reported in a registration dossier. This information shall be sufficient to allow the methods to be reproduced.

The description of the chromatographic method was not provided in your registration dossier and the "analytical profile summary table" shows several listed impurities with the respective concentrations but the peak table with retention times and peak areas corresponding to the relevant chromatograms were not provided. Furthermore, the impurities identified in the analytical report are not reported in section 1.2.

Additionally, no description of the methods used to record the infra-red spectrum, the ultra violet spectrum, the nuclear magnetic resonance spectrum and the mass spectrum were provided. No justification for the non-inclusion of this information was included in your dossier.

Without a description of the analytical methods or a proper justification for its absence, the information requirements described in Annex VI section 2.3.7 are not fulfilled.

You are accordingly requested to provide the description and results of spectral and chromatographic methods used to verify the identity and composition of the registered substance as reported in section 1.1.and 1.2 of your dossier. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

In particular, for chromatographic methods the following information is expected to be provided:

- Results of analysis: chromatogram and corresponding peak table including peak identification, retention times, peak area and area % for main constituent and impurities
- Description of the method: details of sample/standard preparation, column specification, and identity of carrier gas/eluent and detector type

You shall ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in section 1.4 of the IUCLID dossier.

Further technical details on how to report the requested information are available in the Manual "How to prepare registration and PPORD dossiers" (version: 1.0, April 2016) on the ECHA website.

TOXICOLOGICAL INFORMATION

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2) in a second species

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Annex IX, Section 8.7.2., column 2 provides that the decision on the need to perform a pre-natal developmental toxicity study on a second species at a tonnage level of 100 to 1000 tonnes per year should be based on the outcome of the first test and all other relevant and available data. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet these information requirements.

The technical dossier contains a pre-natal developmental toxicity study with rats by the oral route. This study fulfils the standard information requirement for a pre-natal developmental toxicity study in a first species (Annex IX, Section 8.7.2.). In that study, developmental toxicity was observed at 175 mg/kg bw/day by decreased fetal weights, an equivocal increase in post-implantation loss, an equivocal increase in the incidence of total (external, visceral and skeletal) malformations and an increase in one skeletal variation. The substance has not been classified for reproductive or developmental toxicity. As explained in the *Guidance on information requirements and chemical safety assessment Chapter R.7a, Section R.7.6.2.3.2 (version 6.0, July 2017),* there is inconclusive evidence of developmental toxicity caused by the registered substance, when tested with the first species. Accordingly, ECHA considers that there is a need to proceed to the testing of prenatal developmental toxicity with the second species, in order to characterise the toxicity of the substance, and to conclude on the necessary classification of the registered substance.

Therefore, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out with rats. According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species rabbit by the oral route.

Notes for your consideration

ECHA notes that a revised version of OECD TG 414 may be adopted later on this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. After the adoption of the revised version of the OECD TG 408 you should test in accordance with that version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788.

Even if you start testing before the guideline is published, it is appropriate to consider including these endocrine-sensitive parameters in your testing protocol in accordance with the proposed revised version of the draft guideline (see http://www.oecd.org/env/ehs/testing/section4-health-effects.htm).

ECOTOXICOLOGICAL INFORMATION

4. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided information on the residues of the registered substance "*The residue levels of MON 13900 (furilazole) was found in 0-10 cm layer up to 0.01 mg/kg dry weight just after the application and reached a maximum of 0.001 mg/kg after 14 d. In the 10-20 cm soil layer, the concentration of furilazole was always below the* [redacted] *mg/kg, except once at* [redacted] *mg/kg at 0 d after application.*" However, the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement. "

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable (OECD 301F provided 1.5% degradation in 28 days, [redacted] 1997).

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide

information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You will need to provide a scientifically valid justification for the chosen method.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. This guidance document explains that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the requirement detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

INFORMATION ON RISK ASSESSMENT

5. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.).

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

In the CSR you provided, the quantitative exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that "*risk to the environment is expected to be low and a quantitative environmental exposure and risk assessment was therefore not carried out*".

ECHA notes that you have classified the substance as Acute Tox. 4, Skin Sens. 1 and Aquatic Chronic 2. This classification fulfills the criteria set out in Article 14(4) of the REACH Regulation for the requirement of an exposure assessment and a risk characterisation in the chemical safety assessment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate a quantitative exposure assessment for all the exposure scenarios and revise the risk characterisation accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 10 July 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment. As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.