EUROPEAN CHEMICALS AGENCY

Helsinki, 08 March 2016

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

For N,N'-dithiodi-o-phenylenedibenzamide, CAS No 135-57-9 (EC No 205-201-9)

Addressees: Registrant(s)[1] of N,N'-dithiodi-o-phenylenedibenzamide (Registrant(s))

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent for comment, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants holding active registrations on the day the draft decision was sent are *not* addressees of this decision if they are: i) Registrant(s) who had on that day registered the above substance exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Belgian Federal Public Service Health, Food Chain Safety and Environment, Risk Management Service as the Competent Authority of Belgium (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 is based on the registration dossier(s) on 5 May 2015 , i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or 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 Belgium has

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

initiated substance evaluation for N,N'-dithiodi-o-phenylenedibenzamide, CAS No 135-57-9 (EC No 205-201-9) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Environment/Suspected PBT/vPvB; Exposure of environment, N,N'-dithiodi-o-phenylenedibenzamide, CAS No 135-57-9 (EC No 205-201-9) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of Belgium was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the abovementioned: Suspected PBT/vPvB. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 18 March 2015.

On 5 May 2015 ECHA sent the draft decision to the Registrant(s) 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.

On 11 June 2015 ECHA received comments from the Registrant(s)of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s).
On the basis of this information, there was no need to amend the Information Required (Section II). The Statement of Reasons (Section III) was changed in order to reflect the comment of the Registrant(s).

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 3 September 2015 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 of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted three proposals for amendment to the draft decision.

On 9 October 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment (PfA) received and amended the draft decision. One of the PfAs suggested further tiered bioaccumulation testing. The evaluating MSCA did not amend the draft decision in this regard as the possible need for further testing to clarify the PBT concern will be considered in the follow-up evaluation.

Referral to Member State Committee

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015, the Registrant(s) provided comments on the proposals for amendment, in accordance to Article 51(5). The Member State Committee took the comments on the proposals for amendment of the Registrant(s) into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 November 2015 in a written procedure launched on 12 November 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. Aerobic mineralisation in surface water – Simulation biodegradation test (EU C.25, OECD 309), at a temperature of 12° C. This test shall include both the part concerning derivation of the degradation kinetics and the part concerning identification of transformation products / pathways.

2. In case the test under 1. does not allow to conclude that N,N'-dithiodi-o-phenylenedibenzamide is persistent (P) or very persistent (vP) according to Annex XIII, 1.1.1. / 1.2.1. of the REACH Regulation, soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/ OECD 307 as specified in section III. 2) is needed.

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA an update of the registration(s) containing the information required by this decision, including robust study summaries and, where relevant, an update of the Chemical Safety Report, by **15 June 2018** if both studies at point 1 (OECD 309) and 2 (OECD 307) are conducted, or by **15 December 2017** if only the study at point 1 (OECD 309) is conducted.

III. Statement of reasons

1. Aerobic transformation in surface water, including a kinetic and a degradation pathway study.

N,N'-dithiodi-o-phenylenedibenzamide is a potential PBT substance. Information on biodegradation is needed to determine whether the persistency (P) criterion is fulfilled.

In order to clarify the PBT concern of this substance, evaluating MSCA applied a tiered approach. Due to animal welfare reasons, this draft decision only addresses the P property of PBT. The possible additional need for information on the bioaccumulation (B) and toxicity (T) properties will only be considered later on in the procedure if it is shown that N,N'-dithiodi-o-phenylenedibenzamide, CAS No 135-57-9 (EC No 205-201-9) or any of its degradation products are P.

In a ready biodegradability test (OECD 301C: modified MITI test) no biodegradation was seen. Furthermore in two other ready biodegradability tests (OECD 301B: CO_2 evolution test and OECD 301D closed bottle test) 24% and 17% degradation respectively after 28 days was seen. These results clearly indicate that the substance is not readily biodegradable. It is possible that the substance degrades by abiotic or biotic degradation processes into smaller, stable compounds. In order to examine this degradation pathway further, the Registrant(s)s identified (some of) the degradation products and quantified the amount of the mother compound in the extended closed bottle test. In samples taken on day 42, two metabolites were found, namely N-((1E)-4-oxo-2-sulfanylcyclohexa-2,5-dien-1-ylidene)benzamide and N-(2-((2-aminophenyl)disulfanyl)phenyl)benzamide. The first metabolite is formed by cleavage of the disulfide bond with subsequent hydroxylation and oxidation. The second metabolite is formed by biotic or abiotic cleavage of one amide function and release of benzoic acid. Benzoic acid is readily biodegradable and could explain the oxygen consumption during the test.

The metabolites were however not quantified. The mother compound was quantified on day 0, 35 and 42. Concentrations of 21 µg/L, 0.8 µg/L and 3.4 µg/L respectively were found. In view of the water solubility of 4.8 µg/l and missing quantification of the metabolites, it is not possible to assess in a reliable way to what extent the substance degrades, what the metabolites are and the amount of degradation products formed.

Therefore, ECHA concluded that the substance is not readily biodegradable and that further data on degradation is needed.

Since the identification of the pathway and the rate of transformation (with identification and quantification of the degradation products) is one of the main targets and the water solubility still allows for a test in water, ECHA concludes that an aerobic mineralisation study in surface water is most appropriate. This is also supported by the environmental fate properties of the substance which affect the environmental distribution. According to the Mackay environmental fugacity model III (EPIWIN 4.1) the substance distributes to water (9%), sediment (24%) and soil (67%), if equal emission to water, sediment and soil is assumed. If emission is only expected to go to surface water, the relative mass distribution changes to water (28%) and sediment (71%). However, due to a likely significant formation of Non Extractable residues (NER) in sediments, the dependency of NER with extraction methods, the debated relationship between extraction method and the amount and nature of NER and the uncertainty as to whether all NER is irreversibly bound to sediment, preference is to measure the persistency in a test system with a minimum possibility of NER formation, i.e. the OECD 309 test with clean water (i.e. not the turbid water version). This is also supported by the Registrant(s) in their comments to the relevant PfA who stated that if the decision would still include the requirement for an OECD 309 study, they agree that this should be carried out with clean water to minimise the possibility of non extractable residues.

It is further clarified to the Registrant(s) that if the substance is eventually identified as PBT or vPvB, the evaluating MSCA would then assess the need for appropriately revised risk management measures under REACH or any other relevant legislation.

Moreover, it is considered that for PBT/vPvB assessment the most appropriate temperature to test is 12°C since it is the environmentally relevant temperature in the EU (ECHA guidance on information requirements and chemical safety assessment: PBT/vPvB assessment, Section R.11.4.1.1, November 2014). Avoidance of temperature correction with the Arrhenius equation will allow obtaining more accurate results reducing uncertainties.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: Aerobic transformation in surface water, including a kinetic and a degradation pathway study (Simulation biodegradation test: EU C.25/ OECD 309) at 12°C.

On 17 June 2015, the Registrant(s) confirmed that they will comply with the request to provide the study as stated above.

2. Aerobic and anaerobic transformation in soil

If the aerobic transformation test in surface water does not allow to conclude that the substance is persistent (P) or very persistent (vP) according to Annex XII, 1.1.1/1.2.1 of the REACH regulation, it does not exclude that it is persistent in other compartments. Therefore ECHA proposes a tiered approach, where testing on soil is only to be initiated if the result of the OECD 309 test does not allow to conclude that the registered substance subject to this decision is persistent (P) or very persistent (vP).

As seen in the Mackay environmental fugacity model III, the substance distributes mainly to soil when equal emissions to the three compartments is assumed. The registered substance has a high adsorption tendency and therefore soil (via STP sludge deposition) can be considered as a compartment of concern. Also the use of the substance in rubber and mainly tyre production can lead to emission to the soil compartment.

It is considered that for PBT/vPvB assessment the most appropriate temperature to test is 12°C since it is the environmentally relevant temperature in the EU (ECHA guidance on information requirements and chemical safety assessment: PBT/vPvB assessment, Section R.11.4.1.1, November 2014). Avoidance of temperature correction with the Arrhenius equation will allow obtaining more accurate results reducing uncertainties.

It is important to identify and quantify the metabolites with a concentration of ≥1% w/w, (unless it can be demonstrated that this is technically not feasible). In addition the rate and course of kinetics of the parent and metabolites shall be evaluated.

The Registrant(s) in their comments on one of the PfAs suggesting a tiered approach (adding a soil study (OECD 307)) stated that with the request of a soil study (OECD 307), they question whether the OECD 309 is still appropriate. Instead, degradation should concentrate on the soil study. They commented that the statement made in one of the other PfAs (requesting to minimise NER formation) is valid in that if the water study would be attempted in sediment laden water, adsorption to particulates would make the analysis even more difficult. The Registrant(s) stated that this statement does agree with their observations that exposure to water will be exceptionally low and if there is any contamination of surface water under natural conditions, the substance will quickly adsorb to sediments and will effectively not 'persist' in water. The Registrant(s) also stated that testing of soils or sediments are a lot more relevant for risk assessment and therefore proposes to start with a soil study and will consider radio-labelling. The Registrant(s) also considered that 21 months is appropriate for a soil simulation test.

In addition, the Registrant(s) considered that a tiered approach as suggested in one of the PfAs seems appropriate, but contrary to the proposal made, they prefered to first perform the soil study (OECD 307).

ECHA considered these comments by the Registrant(s) but still finds it more appropriate for the PBT assessment to first assess whether the substance is P/vP in surface water and only

continue with soil testing if no conclusion can be made based on the pelagic version of the water test. The pelagic water test will allow to provide information on degradation and not on removal (no NER formation) as is needed for the PBT/vPvB assessment of the substance. Even though the share of the substance released to water will be small compared to the other compartments, it still remains a compartment of concern.

It is further clarified to the Registrant(s) that if the substance is eventually identified as PBT or vPvB, the evaluating MSCA would then assess the need for appropriately revised risk management measures under REACH or any other relevant legislation.

The Registrant(s) also claimed that the proposed timescale of 27 months for tiered testing is insufficient and proposes an extension of 6 months (33 months in total). ECHA considers that no justification is provided by the Registrant(s) and therefore maintains the proposed 27 months deadline.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: Aerobic and anaerobic transformation in soil, EU C.23/ OECD 307 at 12°C.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental stud(y/ies), the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
http://echa.europa.eu/regulations/reach/registration/data-sharing

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.

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

Authorised[2] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[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.