EUROPEAN CHEMICALS AGENCY

Helsinki, 21.02.2014

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 N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine, CAS No 3081-14-9 (EC No 221-375-9)

Addressees: Registrants of N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (concerned registrants)

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, 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 enclosure to this decision.

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants 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 does not take into account any updates of the registrations of the concerned registrants after 1 August 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 registrants 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 registrants 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 Belgium has initiated substance evaluation for N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine, CAS No 3081-14-9 (EC No 221-375-9) based on registration dossiers submitted by the concerned registrants 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 suspected PBT and high aggregated tonnage N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine 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 Belgium was appointed to carry out the evaluation.

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

On 4 April 2013 ECHA sent the draft decision to the concerned 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.

By 3 May 2013 ECHA received comments from concerned registrants of which it informed the evaluating MSCA without delay.

The MSCA considered the registrants' comments received and did amend Section II of the draft decision. The comments were reflected in Section III of the draft decision (Statement of reasons).

In accordance with Article 52(1) of the REACH Regulation, on 1 August 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.

Subsequently, a MSCA and ECHA submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the concerned registrants 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 these proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the MSCA's and ECHA's proposals for amendment and amended the draft decision accordingly.

On 16 September 2013 ECHA referred the amended draft decision to the Member State Committee.

On 4 October 2013 the registrants provided comments on the proposed amendments. The Member State Committee took the comments of the registrants into account.

After discussion in the Member State Committee on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision was reached on 4 November 2013. 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 concerned registrants shall submit the following information using the indicated test method and the analogous substance N,N'-di-sec-butyl-p-phenylenediamine (EC No 202-992-2):

1. Robust study summary of completed hydrolysis test (test method: Hydrolysis as a function of pH, EU C.7/OECD 111).

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information using the indicated test method and the substance under evaluation N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No 221-375-9) or the analogous substance N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3):

2. Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 12 °C.

In view of the new information obtained the concerned registrants shall update the chemical safety report (CSR), including the PBT assessment.

Furthermore, pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit a robust study summary for the information required under 2. of this Section II.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 21 February 2016 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 N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk for the environment.

1. Hydrolysis

The registration dossiers contain a hydrolysis study for the substance under evaluation. However, this study is considered of inadequate quality as the number of examined samples is very small and the study does not allow to establish the degradation pattern in a reliable way.

Preliminary results from an ongoing hydrolysis study for the analogous substance N,N'-di-sec-butyl-p-phenylenediamine (EC No 202-992-2) are available in the registration dataset. The read-across argumentation is available in the registration dossiers and seems plausible. Therefore a grouping approach as described in Annex XI, 1.5. of the REACH Regulation is considered suitable in this case.

The substance under evaluation and the analogous substance N,N'-di-sec-butyl-p-phenylenediamine (EC No 202-992-2) comprise the same functional groups (p-substituted phenylene, amine and secondary alkyl) and the substances are expected to produce the same stable break down products (e.g. p-hydroquinone). As a hydrolysis study on the analogous substance is already ongoing, the results from this study could be accepted instead of requesting a new hydrolysis study on the substance under evaluation. Therefore, further information shall be provided in the registration dossiers completing the preliminary results on hydrolysis with the final findings and conclusions.

Information on hydrolysis is required in order to enable the evaluating MSCA to assess the properties of the substance and its potential degradation products and to decide whether they are persistent. This information is thus needed to establish whether the suspected PBT concern may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.

Degradation products shall be identified and quantified and further investigation might be needed if stable degradation products are formed in the environment.

In their comments to the initial draft decision the concerned registrants consented to provide the required information.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to submit the completed robust study summary for the following study using the analogous substance N,N'-di-sec-butyl-p-phenylenediamine: Hydrolysis as a function of pH (test method: EU C.7/OECD TG 111) to ECHA in the form of an updated IUCLID dossier.

2. Soil simulation testing

In the registration dossiers there are no data regarding the fate of the substance in the soil compartment. The substance is considered to be not readily biodegradable. Furthermore, exposure to soil is likely to occur and available data indicate that the substance shows a high potential for adsorption to soil.

The analogous substance N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3), that is subject to a parallel substance evaluation by the Competent Authority of Austria, shows a similar hydrolysis pattern and this substance has also been subject to the substance evaluation process in 2012. Relevant physico-chemical properties in relation to the fate of these substances in soil (vapour pressure, log K_{ow}, log K_{oc}) are similar and both substances belong to the class of p-substituted phenylene diamines. A read-across argumentation is available in the concerned registrants' comments and seems plausible. Therefore a grouping approach as described in Annex XI, 1.5. of the REACH Regulation is considered a suitable option in this case.

Considering the above read-across argumentation, the comment from the concerned registrants on the initial draft decision, the proposal for amendment on this issue and the concerned registrants' comment on that proposal for amendment, it is appropriate to leave the choice of the substance to be tested to the discretion of the concerned registrants. Consequently, the concerned registrants shall perform the soil simulation test with either the substance under evaluation N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No 221-375-9) or with the analogous substance N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3).

Information on the rate of degradation in soil and on the identity of the potential degradation products formed will provide the information needed to evaluate whether or not the persistency criterion in soil is met.

Information on degradation in soil is required in order to enable the evaluating MSCA to assess the properties of the substance and to decide whether it is persistent in soil. This information is thus needed to establish whether the suspected PBT concern may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.

Furthermore, the concerned registrants shall deliver the robust study summary to ECHA in the form of an updated IUCLID dossier.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to carry out the following study using the substance under evaluation N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No 221-375-9) or the analogous substance N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3): Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307).

Furthermore the concerned registrants are requested to perform the study at 12 °C (285K) as this temperature is accepted in the REACH Guidance (cf. Table R.16-9) to represent the average environmental temperature for the EU.

In their comments on the draft decision that was provided to the concerned registrants on 4 April 2013, the concerned registrants proposed to conduct the simulation test at a temperature of 20 +- 0.2 °C as this temperature is recommended in paragraph 31 of the OECD Guideline 307 for substances that reach the soil in temperate climates. However, the same paragraph in this Guideline also states that "*soils should be incubated at a constant temperature representative of the climatic conditions where use or release will occur*". Further, paragraph 32 of the OECD Guideline 307 mentions that "*chemicals released in colder climates (northern countries) should be incubated at lower temperatures (e.g. 10 +- 2 °C)*". The substance subject to the present decision is used and released within the context of the REACH Regulation in the EU. The temperature of 12°C is a default value used in current risk assessment to reflect the average environmental conditions in the EU. For example, in the EUSES model, the environmental temperature is set by default to 285K (i.e. 12°C). This is also the default environmental temperature recommended in ECHA Guidance R.16. For identification of substances of very high concern, an environmental temperature of 12°C is assumed.

Annex XIII of REACH indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*" ECHA Guidance R.7b further specifies that simulation tests "*attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment*". When only existing results for tests performed at 20°C are available, then ECHA Guidance R7b. indicates that a temperature correction based on the Arrhenius equation is permitted. The Arrhenius equation reflects the fact that the temperature dependence of a chemical reaction depends on the intrinsic activation energy of that reaction. The higher the activation energy is, the slower is the reaction rate at reduced temperature. In practice, temperature dependence of the activation energy is specific for each chemical and reaction. High extrapolation uncertainties can be best avoided by selecting appropriate testing temperatures. Furthermore, this equation was derived originally to illustrate the temperature dependence of chemical reaction rates, not of biological activity. The scientific basis for using the Arrhenius equation for complex biological processes like biodegradation is therefore weak.

So the soil simulation test itself shall be performed at a temperature that represents best the real environmental conditions in the EU, which is 12 °C. Therefore, in order to simulate as much as possible the real environmental conditions in the EU, but avoiding performing the test at multiple temperatures, it is deemed appropriate to conduct this soil simulation test at 12 °C.

Furthermore, in their comment to the proposal for amendment the concerned registrants argued that tests according to OECD 301, A-E, are to be performed between 20 and 25 °C and that a similar approach would be appropriate for the soil simulation test. However, there is a fundamental difference between OECD 301 tests and an OECD 307 test in that the OECD 301 tests are screening tests that are designed to offer the possibility to come to a conclusion for cases that are rather clear-cut. In contrast an OECD 307 test is a simulation test and therefore circumstances in this test should be as similar to real life situations as possible.

The concerned registrants are reminded that the PBT assessment and CSR shall be revised based on the newly available data. According to Annex XIII the PBT assessment shall also cover any stable degradation products.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. In relation to the required tests, the sample of substance used for the new studies shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the tests 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 studies must be shared by the concerned registrants.

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

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants. Since several registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other concerned registrants and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the concerned registrants to perform the tests on behalf of all of them. If a registrant performs a test on behalf of other registrants, they shall share the cost of that study equally and the registrant performing the test shall provide each of the others concerned with copies of the full study reports.

This information should be submitted to ECHA using the following form stating the decision number above at:

https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

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

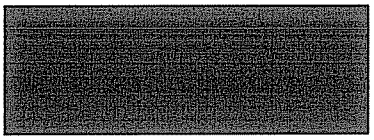
VI. General requirements regarding Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the registrants shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VII. 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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



Jukka Malm
Deputy Executive Director

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.