ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114310696-49-01/F Helsinki, 24 November 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline), EC No 407-560-9 (CAS No 107934-68-9), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(c) thereof for 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline), EC No 407-560-9 (CAS No 107934-68-9), submitted by [redacted] (Registrant).

- Bioaccumulation test according to OECD Guideline 305 (Bioconcentration: Flow-through Fish Test).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes per year. This decision does not take into account any updates submitted after the deadline for updating (15 March 2015) communicated to the Registrant by ECHA on 6 February 2015.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 15 July 2014.

ECHA held a third party consultation for the testing proposal from 16 October 2014 until 1 December 2014. ECHA did not receive information from third parties.

On 8 January 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 16 February 2015 the Registrant did not provide any comments on the draft decision to ECHA.

The Registrant updated his registration after the expiry of the deadline for updating mentioned above, and therefore too late in the decision making process for being considered. If still relevant, the dossier update will be considered by ECHA in line with its follow up process after the deadline established in the present decision has passed.

On 11 June 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.

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

On 17 July 2015 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 27 July 2015 ECHA referred the draft decision to the Member State Committee.

By 17 August 2015 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

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

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

- Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305).

Note for consideration by the Registrant:

The Registrant 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 of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **31 August 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance and scientific information submitted by third parties.

A. Tests required pursuant to Article 40(3)

Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

The substance is registered for 10-100 tonnes per year. For such a registration dossier the information requirements in Annex VII and Annex VIII apply in accordance with Article 12(1)(c) of the REACH Regulation. Therefore, "Bioaccumulation in aquatic species, preferably fish" is not a standard information requirement at this tonnage.

However, the Registrant has submitted a testing proposal for testing the registered substance for bioaccumulation in aquatic species (Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305) with the following justification: "*4,4´-(9H-fluoren-9-ylidene)bis(2-chloroaniline) (CAS No. 107934-68-9) has a high log Kow (6.49 calculated) indicating a potential to accumulate in biota. An extensive screening was performed as to whether a weight of evidence approach can be applied for this substance (see attached document in IUCLID chapter 5.3.1). A screening based on molecular structure data and relevant physical properties, QSARs using various QSAR tools such as (BCFBAF v3.01; VegaNIC v1.0.8, T.E.S.T v4.1) resulted inconclusively. A further screening using the ratio of n-octane solubility (Co) and critical body burden (CBB) indicated 4,4´-(9H-fluoren-9-ylidene)bis(2-chloroaniline) to be bioaccumulative. The Biota-to soil/sediment accumulation factor (BSAF) however indicated no bioaccumulation potential. Due to the contrasting results in the bioaccumulation screening a weight of evidence was disregarded. The Guidance on Information Requirements and Chemical Safety Assessment R.11 PBT-assessment (ECHA 2012) states: "If the tonnage produced or imported is below 100 t/y, normally a bioaccumulation test is not required and therefore a BCF value may not be available. In that case it should be considered if the available testing and non-testing data are sufficient to conclude on the B-properties for those substances < 100 t/y or if bioaccumulation testing is required to draw a reliable conclusion. If the weight of evidence approach described under "Conclusions on the Endpoint" is not sufficient to draw a conclusion, the performance of an experimental bioaccumulation test must be considered." Therefore, for 4,4´-(9H-fluoren-9-ylidene)bis(2-chloroaniline) (CAS No. 107934-68-9) a bioaccumulation test according to OECD 305 is being proposed.*"

ECHA notes that according to the Guidance note on fulfilling the requirements of Annexes VI to XI provided at the beginning of Annex VI to the REACH Regulation, for each registration the precise information requirements differ, according to tonnage, use and exposure. They

should thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

With regards to the PBT assessment, the Registrant indicates the substance fulfils the very persistent (vP) criterion (0% ready biodegradation in an OECD 301D ready biodegradability test and half-lives of 360 days for soil and 1620 days for sediment with Level III fugacity model) and the very toxic (T) criterion (based on a NOEC of 6.8 ng/l in an OECD 211 long-term toxicity test on invertebrates, 2014). ECHA notes that based on the available screening biodegradation information in the technical dossier indicate that the registered substance may have P or vP properties.

ECHA has considered the available information submitted in the technical dossier and agrees with the Registrant that the available information does not meet the conditions set out in Annex XI, 1.2. of the REACH Regulation. I.e. the contrasting results obtained from the bioaccumulation screening do not allow an assumption/conclusion that the registered substance subject to the present decision has or has not bioaccumulation potential in aquatic species. Hence, the available data are not adequate for the purpose of classification and labelling and/or risk assessment.

Due to the fact that the considered weight of evidence approach based on the currently available information does not allow to draw a conclusion, although the proposed test is not a standard information requirement at the registered tonnage band, ECHA considers that the proposed study is appropriate and necessary to clarify the concerns on the bioaccumulation properties for the registered substance and to conclude on the PBT assessment.

The Registrant is reminded that this decision does not take into account any updates submitted after 15 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.; test method: Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305).

c) Notes for consideration by the Registrant

Before conducting testing, the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11. PBT/vPvB assessment, in particular to first conclude on whether the registered substance is not persistent and not very persistent or whether it may fulfil Annex XIII of the REACH Regulation criteria of being persistent or very persistent and to consult the PBT assessment for Weight-of-Evidence determination and the integrated testing strategy for bioaccumulation assessment.

In addition, the Registrant is advised to consult the ECHA Guidance on the information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.4, 5, 6, R.7b and R.7c. Where the Registrant decides to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to the general rules

contained in Annex XI of the REACH Regulation, ECHA refers him to the advice provided in practical Guides 4, 5 and 6.

For the selection of the appropriate exposure route for the test, the Registrant is advised to consult the OECD 305 Test Guideline and the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), Chapter R7c, (Section R.7.10.3).

In addition, due to the low solubility of the substance in water and high octanol-water partition coefficient, OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, 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 proposed test, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the test proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. 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 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[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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