Decision number: TPE-D-2114300116-69-01/F Helsinki, 20 May 2015

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

For 2-[methyl[(nonafluorobutyl)sulphonyl]amino]ethyl acrylate, CAS No 67584-55-8 (EC No 266-733-5), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 2-[methyl[(nonafluorobutyl)sulphonyl]amino]ethyl acrylate, CAS No 67584-55-8 (EC No 266-733-5), submitted by [redacted] (Registrant).

- 90-day oral toxicity study (OECD 408)
- Pre-natal developmental toxicity study (OECD 414)
- Extended one-generation reproductive toxicity study (OECD 443) as an alternative to OECD 416.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 15 January 2015, 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 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.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 25 March 2013.

ECHA held a third party consultation for the testing proposals from 16 May 2014 until 30 June 2014. ECHA received information from third parties (see section III below).

On 6 November 2014 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 15 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 15 January 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 20 February 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 did amend the draft decision.

On 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 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 7 April 2015 in a written procedure launched on 26 March 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 tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

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. Test(s) rejected pursuant to Article 40(3)

Pursuant to Article 40(3)(d) of the REACH Regulation the following proposed test is rejected:

Extended-one generation reproductive toxicity study (test method: OECD 443).

C. 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 **29 May 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

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

A. Tests required pursuant to Article 40(3)

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) via the oral route (EU B.26/OECD 408). ECHA considers that the proposed study via the oral route is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation. The substance is a waxy solid with a melting point of 54.7°C, a very low vapour pressure and the dossier includes only uses without relevant inhalation exposure. Therefore, ECHA considers that testing by the oral route is most appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408).

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2)

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.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be

present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used for testing. He did not specify the route for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

B. Tests rejected pursuant to Article 40(3)

Two-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

The Registrant has submitted a testing proposal for an extended one-generation reproduction toxicity study according to OECD 443 with the following justification: *"This dossier is for a substance manufactured or imported at > 100 t/a and therefore we include a testing proposal for a prenatal developmental toxicity study and a testing proposal for a 2-generation reproductive toxicity study rather than the screening for reproductive/developmental toxicty study required by Annex VIII section 8.7.1. . Registrants note that Annex I, 0.5 last paragraph applies."*

According to Annex IX, Section 8.7.3., a two-generation reproductive toxicity study is an information requirement if adverse effects on reproductive organs or tissues have been observed in a 28-day or 90-day repeated dose toxicity study. ECHA notes that there is no 28-day or 90-day repeated dose toxicity study and no screening study for reproductive/developmental toxicity available in the registration dossier, while the Registrant has proposed to perform a 90-day study.

ECHA observes that while the Registrant refered correctly to Annex I, 0.5. last paragraph, the testing proposal was motivated only with a reference to omit the screening study for reproductive/developmental toxicity. However, the Registrant did not provide scientific arguments explaining why he proposes to perform an extended one-generation reproduction toxicity study at a tonnage level of 100 – 1000 tonnes per year.

In the absence of repeated dose toxicity studies and of a screening study for reproductive/developmental toxicity showing adverse effects on reproductive organs or

tissues and without an explanation for exceeding the standard information requirements applying to this substance, ECHA concludes that the proposed study is at this stage not tailored to real information needs. A decision on the need to perform further testing to fulfil the information requirement of Annex IX, Section 8.7.3. should be based on the outcome of the 90-day study.

b) Consideration of the information received during third party consultation

A third party has indicated that the substance subject to this decision would be registered for the tonnage band of 10 to 100 tonnes per year and that consequently the information requirements of Annexes VII and VIII apply. The third party referred to Annex VIII, Section 8.7.1, column 2 according to which a two-generation reproductive toxicity study may only be proposed by the Registrant instead of a screening study "in cases where there are serious concerns about the potential for adverse effects on fertility".
ECHA observes that the substance subject to the present decision has been registered for the tonnage band of 100 to 1000 tonnes per year. Consequently, according to Article 12(1)(d) of the REACH Regulation, the information requirements specified in Annexes VII to IX apply to this substance and the respective testing proposal has been rejected by ECHA.

c) Outcome

ECHA concludes that there is at this stage no information gap for the standard information requirement of Annex IX, Section 8.7.3. Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, the proposed test for an extended one-generation reproduction toxicity study (OECD 443) is rejected.

d) Notes for consideration by the Registrant

Once the results from the sub-chronic toxicity study (Section II, 1. above) are available, the Registrant should reconsider the information requirement of Annex IX, Section 8.7.3. If the sub-chronic toxicity study or other information available to the Registrant indicates adverse effects on reproductive organs or tissues a new testing proposal for the present endpoint would – in accordance with the REACH Regulation – have to be submitted, unless compliance with this information requirement is scientifically justified and documented by means of specific or general rules of adaptation.

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 studies meet 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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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

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

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Guilhem de Seze
Head of Unit, Evaluation