EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000001918-64-06/F Helsinki, 29 March 2012

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

For 1-methyl-4-(methylsulfonyl)-2-nitrobenzene, CAS 1671-49-4 (EC No 430-550-0), 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 a testing proposal set out in the registration dossier for 1-methyl-4-(methylsulfonyl)-2-nitrobenzene, CAS No 1671-49-4 (EC No 430-550-0), submitted by [redacted] (Registrant), latest submission number [redacted], for 10-100 tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirement set out in Annex X:

Annex X, 8.4: in vivo genetic toxicity study (According to method OECD 486)

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed, on 28 March 2011.

ECHA opened a third party consultation for the testing proposal involving testing on vertebrate animals that was held from 16 May 2011 until 30 June 2011. ECHA received no comments from third parties.

ECHA examined the testing proposal and drafted a decision in accordance with Article 40 of REACH.

On 9 September 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant did not provide any comments on the draft decision. However, ECHA noticed that the draft decision sent to the Registrant erroneously stated that the registration was for 1000 tonnes or more per year, where in fact the registration is for 10-100 tonnes per year. ECHA modified the draft decision to reflect the correct tonnage, including the necessary changes to Section III of the draft decision.

On 4 November 2011 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 to amend the draft decision within 30 days. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify the draft decision.

On 8 December 2011 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

On 19 December 2011, the draft decision was referred to the Member State Committee.

On 6 January 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-10 February 2012, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 9 February 2012.

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

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

- In vivo genetic toxicity test (Annex X, 8.4, EU Method B 39 or OECD 486)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by 29 March 2013 an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance.

According to Section 8.4 of Annex VIII of the REACH Regulation, an in vivo genetic toxicity study shall be considered in case of a positive result in the genotoxicity studies, as set out in column 2. Specifically, the Registrant identifies positive results in in vitro gene mutation tests in both prokaryotic and eukaryotic systems (the in vitro genotoxicity studies of Annex VII and VIII). Information from a first in vivo somatic cell test (a micronucleus test) is not relevant for the concern identified (i.e. gene mutation). Thus the information sought, which would be a second in vivo somatic cell test, is currently not available in the dossier. Since this is a second in vivo somatic cell test, and it is appropriately triggered, the proposed test

corresponds to the information requirement of Annex X, 8.4. The Registrant's suggestion of the OECD 486 guideline (Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells In Vivo) addresses the appropriate endpoint (i.e. gene mutation), and is an identified option to address this endpoint in the ECHA guidance (R.7.7.6.3).

It is known that there are structurally related substances that are genotoxic carcinogens and therefore there may be some residual uncertainty remaining in the event that a UDS test is negative. There are thus reasons to request the Transgenic Rodent Gene Mutation assay. However, in view of the Registrant's statement that the registered substance is considered to meet the criteria for classification as Reproductive Toxicant Category 1B, H360, May damage fertility, and that the sole use of the substance is as an intermediate in chemical synthesis, in this specific case the UDS test is accepted. ECHA considers that the Fisher 344 rat strain is probably the most appropriate strain of rat in which to conduct the UDS test for this substance.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation the Registrant is requested to carry out the following test: in vivo genetic toxicity test (method B.39 of Regulation (EC) No 440/2008 or OECD test guideline 486).

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always 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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 Registrant 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.

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

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Jukka Malm
Director of Regulatory Affairs