ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 13 June 2012

Decision number: TPE-D-0000002002-94-05/F

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

For Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol (List No 911-254-5), 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 testing proposals set out in the registration dossier for Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol (List No 911-254-5) submitted by [redacted] (Registrant), latest submission number [redacted], for 100 - 1000 tonnes per year.

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

- Annex IX, 7.17: Viscosity
- Annex IX, 8.7.2: Pre-natal developmental toxicity study

The examination of the testing proposals was initiated on 19 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 16 June 2011 until 1 August 2011. ECHA did not receive comments from third parties.

On 13 October 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.

On 14 November 2011 the Registrant provided to ECHA comments on the draft decision requesting the extension of a deadline to submit an updated IUCLID dossier.
ECHA reviewed the further information received but did not amend the draft decision.

On 20 January 2012 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 of the receipt of the notification.

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

On 23 February 2012 ECHA notified the Registrant of 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.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 5 March 2012, the draft decision was referred to the Member State Committee.

On 23 March 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 11 April 2012 in a written procedure launched on 28 March 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 tests using the indicated test method:

- Viscosity (Annex IX, 7.17, OECD 114)
- Pre-natal developmental toxicity study (Annex IX, 8.7.2, EU Method B 31 or OECD 414) in rat by the oral route

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 13 June 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 proposals of the Registrant for the registered substance.

Pursuant to Article 40(3)(a) ECHA may take a decision requiring the Registrant to carry out the proposed test and setting a deadline for submission of the study summary or robust study summary.

A viscosity study is required under Annex IX, 7.17 and a pre-natal developmental toxicity study in one species under Annex IX, 8.7.2. The studies are subject to all appropriate column 2 or Annex XI data adaptations. Since information on these endpoints is missing in the registration dossier, and since no acceptable adaptations to omit these information requirements have been received, ECHA accepts the proposed tests. The tests shall be

carried out using the test methods indicated in section II above. ECHA notes that the Registrant did not specify the species and route of exposure to be used in the pre-natal developmental toxicity study. The test guidelines mentioned in section II recommend the rat and the oral route unless otherwise justified. No evidence was found in the registration dossier to justify deviating from this recommendation. Therefore ECHA has specified that the rat and the oral route shall be used.

The Registrant should ensure that the study is planned in a way that takes into consideration the worst-case scenario with regard to the composition of the tested substance, since it is clear that the registered substance is manufactured in two different compositions of the two main constituents. The choice of the test substance shall take into consideration the two main constituents of the test substance, 2-tert-butyl-4,6-dimethylphenol (EC number 217-533-1) and 4-tert-butyl-2,5-dimethylphenol (EC number 241-696-8) and shall be duly justified with evidence supporting the choice. This will ensure that the results obtained are meaningful and relevant to the substance properties. As such, the Registrant is reminded that the use of tools including Structure-Activity Relationship (SAR) models and screening tests for each of the individual constituents may provide valuable information on the substance to be tested and may help ensure that an adequate representative for the substance is chosen.

In his official comments on the draft decision the Registrant requested an extension of the deadline to provide an updated IUCLID dossier. ECHA notes that the Registrant did not specify how much more time would be needed and did not justify the request with arguments specific to the registered substance or the tests requested. Therefore ECHA did not amend the deadline.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted by the Registrant in the technical dossier was sufficient to determine the composition of this substance for the purpose of assessing 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.

V. 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.

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VI. 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.

[redacted]

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