EUROPEAN CHEMICALS AGENCY

~~CONFIDENTIAL~~

Decision number: CCH-D-0000003873-68-05/F Helsinki, 28 May 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene, CAS No 68610-51-5 (EC No 271-867-2), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene, CAS No 68610-51-5 (EC No 271-867-2, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 9.1.5. and 9.1.6. relating to aquatic toxicity, of the REACH Regulation and related environmental hazard assessment. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 31 October 2013, 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 9 May 2013.

On 29 July 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 15 August 2013 ECHA received comments from the Registrant agreeing to address the issues raised in ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 31 October 2013 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD 211);

2. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210).

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including the derivation of the aquatic PNECs.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **7 December 2015**.

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

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements. The scope of the present decision covers Annex IX, 9.1.5. and 9.1.6. as well as related environmental hazard assessment. In accordance with Articles 10(a)(vii), (b), 12(1) and 14(1) of the REACH Regulation, the registration is required to contain this information.

1. and 2. Long-term aquatic toxicity testing on invertebrates and fish

According to column 1 of Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and on fish is required to fulfil the standard information requirements. Regarding long-term toxicity testing on fish, the information shall be provided for one of the following: Fish early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1), fish short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2), or Fish, juvenile growth test (Annex IX, 9.1.6.3).

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I, Section 3.3. of the REACH Regulation requires the registrant to establish, based on the available information, predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere, including the aquatic compartment.

ECHA notes that the Registrant has waived the long-term testing on fish using the following justification: "In view of its insolubility in water, its low bioaccumulating potential, its high molecular weight and the lack of any effects in the acute aquatic studies, the substance is concluded not be bioavailable to fish to such an extent that it will cause adverse effects. In addition, in view of animal welfare, no long-term testing in fish is proposed." ECHA further notes that the Registrant has waived the long-term toxicity on aquatic invertebrates using the following justification: "In view of its insolubility in water, its low bioaccumulating potential, its high molecular weight and the lack of any effects in the acute aquatic studies, the substance is concluded not be bioavailable to aquatic invertebrates to such an extent that it will cause adverse effects. Therefore, no long-term testing is proposed."

ECHA points out these justifications for waiving provided by the Registrant do not meet the criteria of the general adaptation rules of Annex XI to the REACH Regulation.

The ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having a low water solubility can, therefore, not be used as an argument for adaptation of long-term tests.

In addition to the justifications addressed above, the Registrant has further justified the waiving of long-term aquatic studies by the low bioaccumulation potential and high molecular weight of the substance. ECHA notes that these are not valid adaptations according to Column 2 of Sections 9.1.5. and 9.1.6. of Annex IX and do not meet the criteria of the general adaptation rules of Annex XI of REACH Regulation.

Therefore, for the reasons stated above the adaptation proposed by the Registrant cannot be accepted.

As the submitted information does not fulfil the above information requirements, there are information gaps and it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with the relevant information requirements.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 1.2., November 2012, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.
As for the test method for the long-term toxicity testing on aquatic invertebrates, ECHA considers the standard recommended test method EU C.20./OECD 211 to be the most appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

- Daphnia magna reproduction test (test method: EU C.20./OECD 211); and
- Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation including the derivation of the aquatic PNECs.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (pages 32-57, including Figure R.7.8-4 page 56) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the low solubility of the substance in water 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.

In the comments of 15 August 2013 submitted to ECHA draft decision, the Registrant stated that they "are strongly of the opinion that the substance does not demonstrate any effects to aquatic organisms at the limit of solubility in water, in both acute and chronic tests". Nevertheless, the Registrant agreed that the justifications brought forward were not valid adaptations according to Column 2 of sections 9.1.5. and 9.1.6. of Annex IX to the REACH Regulation. Furthermore, the Registrant agreed to address the concerns raised by ECHA. As highlighted above, ECHA does not consider that absence of toxicity observed in the short-term tests with a substance having a low water solubility can be used as an argument for adaptation of the long-term tests concerned.

In the comments the Registrant also discussed the possibility of a new test resulting in the substance no longer being classified. ECHA points out that any new data will need to be taken into account for also classification purposes.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies 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 who manufacture or import the same substance to agree on the appropriate composition of the test material 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 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies 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 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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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