ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114310860-60-01/F Helsinki, 17 November 2015

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, EC No 271-867-2 (CAS No 68610-51-5), 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 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, EC No 271-867-2 (CAS No 68610-51-5), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirement[s] of Annex I, sections 5 and 6, Annex VII, Section 7.14, Annex X, Section 8.7.2. of the REACH Regulation.

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 after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016. ECHA notes, in particular, that the information requirement of Annex IX/ X, Section 8.7.3 has not been addressed in this decision.

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 16 April 2015.

On 9 June 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. That draft decision was based on submission number [redacted].

On 6 July 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision for the requests relating to granulometry and human health exposure assessment

and risk characterisation and commenting on the request relating to pre-natal developmental toxicity in rabbits.

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 3 September 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VII, X 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. Granulometry (Annex VII, Section 7.14.; test method: OECD 110 "Particle Size Distribution/Fibre Length and Diameter Distributions" Method A: Particle Size Distribution);
2. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD 414) in 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. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

3. Human health exposure assessment and risk characterisation (Annex I, sections 5 and 6), as specified under section III.B below.

4. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **24 November 2016** an update of the registration dossier containing the information required by this decision.

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.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Granulometry (Annex VII, Section 7.14.)

"Granulometry" is a standard information requirement as laid down in Annex VII, Section 7.14. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The registration dossier contains one experimental study on the registered substance which is assigned reliability 2 by the Registrant and used dry sieve measurements to determine particle size distribution. The majority of the ground substance ([redacted]%) had particles of size <45 micron which are therefore in the inhalable fraction and the result cannot exclude the presence of smaller particles in the thoracic and/or respirable fractions.

According to REACH guidance, dry sieving is not suitable for determining the fraction of inhalable/respirable particles. The REACH Guidance on information requirements and Chemical Safety Assessment Chapter R.7a: Endpoint specific guidance, Version 3.0, August 2014, Table R.7.1-11 Methods to determine particle size distribution of a material states "*Sieving using wire-mesh sieves and perforated sheet metal sieves is not suitable to determine the distribution of particles of respirable and inhalable size since their range is only 100-10,000 microns. Micro mesh sieves (range 5-100 micron) may give better results. However, since these sieves are generally operated in combination with mechanicalor ultrasonic vibration, modification of median size and form may result.*
Sieving not suitable to determine distribution of particles of respirable size, but might be suitable to determine particles of inhalable size."

ECHA therefore concludes that the information provided is not sufficient to determine the fraction of inhalable/respirable particles and therefore does not meet the requirements of Article 13(3) of the REACH regulation.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. The

Registrant submitted comments agreeing to conduct testing on granulometry as required by the present decision.

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: Granulometry (Annex VII, Section 7.14.; test method: OECD 110 "Particle Size Distribution/Fibre Length and Diameter Distributions" Method A: Particle Size Distribution)

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

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material.

However, there is no information available for a pre-natal developmental toxicity study in a second species. Moreover, the technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7. or with the general rules of Annex XI for this standard information requirement.

The Registrant submitted comments on this information request that sought to waive the standard information requirement of pre-natal developmental toxicity (PNDT) study in the second species. The Registrant approach is mainly based on the lack of effects in the 90 day repeated dose study, genotoxicity study, and prenatal developmental toxicity study in rats. More specifically the Registrant pointed out that "*no effects on the gonads in the repeated dose studies and developmental toxicity available were noted*" and concluded that "*considering the above mentioned data, and the low NOAEL in the 90day tox study (32 mg/kg bw/d), possible reproduction effects are expected to occur only at maternal toxicity levels. Therefore, the repeated dose toxicity level stays critical for DNEL derivation*".

ECHA is of the opinion that the argumentation presented by the Registrant is not suitable to waive the PNDT study in the second species, rabbit.

The Registrant wrongly referred to the legal text which is a requirement at Annex IX. The current registration is at Annex X and PNDT on a second species is a default requirement.

The result from the repeated dose toxicity study (e.g. lack of effect in the reproductive organs) cannot be used to exempt the PNDT study since they do not cover the key aspects/elements and the same life stage (e.g. fetal development) as in the PNDT study.

Neither the PNDT in rats nor the investigations of reproductive organs in the repeated dose studies lead to classification which would have been a waiving argument as stated in Annex X, Section 8.7.2.

The legal text, Annex X, 8.7., column 2 states that toxicity to reproduction need not be conducted if the substance is "*known to be a germ cell mutagen and appropriate risk management measures are implemented" and* thus the negative effects observed in the genotoxicity studies is not considered as a valid argument.

As outlined on page 374 of the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance, Version 4.0, July 2015 (http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf) *"Availability of information on two species allows a more comprehensive evaluation of prenatal developmental toxicity."*

Furthermore, the Registrant stated that the NOAEL from the 90 day toxicity study is critical for DNEL derivation. Indeed this is true; however REACH Annex I, Section 1.0.2 and 1.0.4 indicates that the CSR shall address both repeated dose toxicity studies and toxicity to reproduction. Since the dossier has a data gap for the PNDT study in the second species, the developmental toxicity cannot be fully assessed. The results from this study could change the NOAEL value used for the overall DNEL derivation.

Therefore ECHA is currently of the opinion that this adaptation does not meet the specific rules for adaptation according to Annex X, 8.7., column 2 or the general rules for adaptations according to Annex XI section 1.2.

Therefore ECHA has not amended section II of the draft decision.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. The additional argumentation provided by the Registrant in his comment is not considered as a valid waiver. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is 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 rabbit as a second species to be used.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

B. Information related to the chemical safety assessment and chemical safety report

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.

3. Human health exposure assessment and risk characterisation (Annex I, section 5 and 6)

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation. In accordance with Article 14(4), the CSR must include an exposure assessment

and risk characterisation, due to the substance being classified as hazard class category 1, PBT or vPvB.

ECHA notes that the Registrant has classified the substance as Aquatic Chronic 4 and thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and a risk characterisation in the chemical safety assessment.

Additionally, ECHA notes that effects were observed in some human health toxicity studies. In particular, in the 90-Day Repeated Dose Oral Toxicity study with rats, performed in accordance with OECD Guideline 408, a NOAEL of 500ppm (32 mg/kg bw/day) was obtained for the registered substance based on the increased activated partial thromoboplastin time and increased liver weights in male rats.

Annex I section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

In the CSR provided by the Registrant the exposure assessment for human health is missing. The Registrant claims that no exposure assessment is necessary for human health by stating that "*The submission substance does not meet the criteria to be classified dangerous for physical and human health hazards. Therefore, this exposure assessment will only focus on the environmental exposure. Indirect exposure of humans via the environment will neither be taken into account.*"

ECHA notes that effects were observed in some human health toxicity studies as indicated above.

The Registrant submitted comments agreeing to perform a human health risk assessment and risk characterisation as required by the present decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk characterisation for human health. The chemical safety report shall be amended accordingly.

IV. Adequate identification of the composition of the tested material

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://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 Claudio Carlon, Head of Unit, Evaluation E2

[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.