EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288615-38-01/F Helsinki, 12 December 2014

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

For Magnesium, bis(2-hydroxybenzoato-o1,o2)-, ar,ar'-di-c14-18alkyl derivs., CAS No 171171-80-5 (EC No 931-371-5), 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 Magnesium, bis(2-hydroxybenzoato-o1,o2)-, ar,ar'-di-c14-18alkyl derivs., CAS No 171171-80-5 (EC No 931-371-5), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 8.6.2. and 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 submitted after 12 June 2014, 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 3 July 2013.

On 30 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 29 August 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting an extension of the deadline to provide the updated registration. The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III.3) whereas no amendments to the Information Required (Section II) were made.

On 12 June 2014 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, proposals for amendment to the draft decision were submitted.

On 18 July 2014 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 the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

The draft decision was split into two draft decision documents: one relating to the request for a two-generation reproductive toxicity study and one relating to the request for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study.

The present decision relates solely to compliance checks for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study. The other compliance check requirement of a two-generation reproductive toxicity study (Annex X, 8.7.3) is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision relating to the sub-chronic toxicity study (90-day) and the pre-natal developmental toxicity study was reached on 1 September 2014 in a written procedure launched on 21 August 2014.

ECHA took the decision pursuant to Article 51(6) 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. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route.

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 **19 December 2016**. The timeline has been set to allow for sequential testing as appropriate.

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.

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.

Pursuant to Articles 10(a)(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 IX and X of the REACH Regulation.

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

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided a study record of a 28-day oral toxicity study according to OECD 407 with an analogue substance. The Registrant has not provided any study record of a sub-chronic repeated dose toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2. Instead, the Registrant has sought to adapt the information requirement for a sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.). The Registrant has justified the proposal for adaptation with the following "exposure considerations": "*Results from short term studies on this material, and 28-day repeated dose oral toxicity and reproductive/developmental screening studies on a very similar material, all show no evidence of hazard. Furthermore, the substance is handled only in an industrial setting where correct training and strict application of PPE and risk management measures are expected. With no likely exposure, and no evidence of any likely hazard, and no justification from a chemical safety assessment, it is considered unnecessary to conduct further repeated-dose (e.g. 90-day) testing on vertebrate animals taking into account animal welfare considerations.*"

First, ECHA notes that results of a short-term repeated dose toxicity study (28-day) and results of a reproductive/developmental screening studies are appropriate to fulfil the information requirements of Annex VIII, Sections 8.6.1 and 8.7.1, respectively, but not that of a sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.) because the exposure duration is not sufficiently long and the numbers of animals used in the 28-day study is not sufficiently high. Furthermore, the Registrant did not provide any justification for the read-across approach according to Annex XI, 1.5.

Second, the information on this endpoint can be adapted according to Annex IX, 8.6.2., column 2 if there is no evidence of toxicity in a 28-day "limit test", particular if such a pattern is coupled with limited human exposure. However, this adaptation can be applied only if in addition the substance is unreactive, insoluble and not inhalable and there is evidence of no absorption. The Registrant described that the available information with the analogue substance are providing no evidence of toxicity. However, the Registrant did not demonstrate that the further abovementioned criteria are also met.

Third, the arguments that "*the substance is handled only in an industrial setting where correct training and strict application of PPE and risk management measures are expected*" is not an appropriate justification to adapt the information requirement according to general adaptation possibilities of Annex XI, Section 3. According to Annex XI, Section 3.2., the Registrant has to demonstrate and document based on a thorough and rigorous exposure assessment either the absence or no significant human exposure in all scenarios combined with an appropriate DNEL and exposure assessment showing that exposures are always well below the derived DNEL. The Registrant did not provide an exposure assessment that could demonstrate "no likely exposure".

Fourth, for some of the uses specified as identified industrial uses in the dossier, exposure is to be expected; for instance PROC 2, PROC 4, PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 15. Furthermore, in the dossier professional and consumer use of lubricants and grease in vehicles or machinery is indicated. However, correct training and strict application of PPE and risk management measures are not compatible with consumer uses.

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.

In light of the properties of the substance (sticky solid with low vapour pressure not classified as corrosive or irritating to the skin or eyes), ECHA considers that testing by the oral route is most appropriate.

According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

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

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2. Instead, the Registrant has proposed to adapt the information requirement for a prenatal developmental toxicity study (Annex IX, 8.7.2.). The Registrant has justified the proposal for adaptation with the following "exposure considerations": "*Regulation (EC) 1907/2006 states that a pre-natal developmental toxicity study should be conducted using the most appropriate route of administration. However, the substance is used under industrial conditions where correct training and strict application of PPE and risk management measures is expected and enforced. Hence the potential of the substance to influence pre-natal development in humans is minimal. This combined with the lack of evidence of any hazard potential to neonates seen in the OECD 421 conducted on a very similar material supports a lack of further investigative testing as it is unlikely that further hazard evaluation/information will be gained.*"

First, ECHA notes that results of a OECD 421 screening study does not provide information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations.

Second, ECHA notes the arguments that "*the substance is used under industrial conditions where correct training and strict application of PPE and risk management measures is expected and enforced*" is not an appropriate justification to adapt the information requirement according to the general adaptation possibilities of Annex XI, Section 3. According to Annex XI, Section 3.2., the Registrant has to demonstrate and document based on a thorough and rigorous exposure assessment either the absence or no significant human exposure in all scenarios combined with an appropriate DNEL and exposure assessment showing that exposures are always well below the derived DNEL. However, the Registrant did not provide an exposure assessment that could demonstrate "no likely exposure".

Third, as indicated in the dossier, the substance is not only used under industrial conditions, but has also professional and consumer use of lubricants and grease in vehicles or machinery are indicated. However, correct training and strict application of PPE and risk management measures are not to be expected and enforced especially for consumer uses.

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.

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

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 rats or rabbits by the oral route.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for these adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2. of the REACH Regulation.

3. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. In his comments on the draft decision of 29 August 2013, the Registrant requested an extension of the timeline without specifying the additional time required. He sought to justify this request by performance of the required tests in a step-wise manner, to account for the time required for communication of early study findings and a judgment to be made on whether the two-generation study is necessary, and to account for the availability of laboratory space for completing a two-generation reproduction toxicity study.

However, ECHA notes that the 36 months' time period for submission of the required information already takes into account sequential testing. Furthermore, the Registrant did not specify the additional time required and did not provide any confirmation from testing laboratories on limited availability of laboratory space. Therefore, ECHA has not modified the deadline of the decision.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also addressed a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted 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.

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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.

Furthermore, 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.

[redacted]

Leena Ylä-Mononen
Director of Evaluation