Helsinki, 9 September 2016

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For Reaction product of ammonium molybdate and C12-C24-diethoxylated alkylamine (1:5-1:3), EC No 412-780-3 (no assigned CAS number)

Addressee: [redacted]

Based on an evaluation by the French Agency for Food, Environmental and Occupational Health Safety (ANSES) as the Mandated National Institute of the Competent Authority of France (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier on 19 December 2014, i.e. the day on which the draft decision was notified to the Registrant pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in the registration is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier of the Registrant at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

The Registrant notified Reaction product of ammonium molybdate and C12-C24-diethoxylated alkylamine (1:5-1:3) (referred to as [redacted] hereinafter) pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the Competent Authority of France in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was 93-01-299. Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The Competent Authority of France requested additional information on the substance with a deadline that reached beyond the entry into force of the REACH Regulation and the dossiers are therefore subject to transitional measures described in Article 135 of the REACH Regulation. According to Article 135, requests to the notifier to provide further information on a substance in accordance with Article 16(1) of Directive 67/548/EEC shall be considered to be decisions adopted in accordance with Article 52 of the REACH Regulation, which relates to Substance Evaluation. Such substances are regarded as being

included in the Community rolling action plan (CoRAP) in accordance with Article 44(2) of the REACH Regulation.

Under Directive 67/548/EEC the French Competent Authority started evaluation targeted on the PBT properties based on the dossier and the SNIF files available from the notification and issued a decision to the notifier on 31 July 2008 with reference [redacted].

In the course of this follow up transitional evaluation, the registrant/notifier provided other information and documents than requested in the decision from 31 July 2008 (reference [redacted]), including more information on substance identification and several registration dossier updates. Considering this new information on substance identity and taking into account that the substance's composition is much better specified than the one previously notified and on which the previous decisions were based, the evaluating MSCA considered that the testing strategy formerly required in 2008 is no more relevant.

Consequently, the Competent Authority of France has carried out a substance evaluation taking into account information that the Registrant has submitted directly to France. The same information was also subsequently officially submitted by the Registrant as a dossier update via REACH-IT on 22 May 2014. Thus the Competent Authority of France considered all relevant and available information and concluded that still further information is necessary to clarify the PBT and vPvB concern posed by the substance. It prepared the present decision in accordance with Article 46(1) of the REACH Regulation and submitted the draft decision to ECHA on 23 May 2014.

On 19 December 2014 ECHA sent the draft decision to the Registrant and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 45 days of the receipt of the draft decision.

Registrant commenting phase

By 9 February 2015 ECHA received comments from the Registrant of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant. The statement of reasons (section III) was amended following these comments.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 04 March 2016 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 8 April 2016 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the

draft decision. Initial requests for information concerning the fulfilment of P (persistency) and B (bioaccumulation) criterion for relevant constituents of [redacted] as well as for robust study summaries for aquatic toxicity studies were thus removed.

Referral to Member State Committee

On 18 April 2016 ECHA referred the draft decision to the Member State Committee.

By 10 May 2016, the Registrant did not provide comments on the proposals for amendment, in accordance to Article 51(5) and on the draft decision.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 May 2016 in a written procedure launched on 13 May 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant shall submit the following information using the indicated test method and instructions (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

Hydrolysis as a function of pH of [redacted] (test method: Hydrolysis as a function of pH, EU C.7/OECD 111).

Pursuant to Article 46(2) of the REACH Regulation, the Registrant shall submit to ECHA by **18 September 2017** an update of the registration containing the information required by this decision, including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

[redacted]

According to the Registrant, the production method used today is the same as described in the 1993 new substance notification, indicating that the identity and quantity of the constituents of [redacted] have not been modified. This statement is supported by comparisons of RMN spectra from 1993 and from 2011. In the new substance notification in 1993, an identification of the final constituents of [redacted] was attempted. However, a recent detailed analysis of [redacted] has allowed to better identify and quantify these constituents.

This new identification could allow a new block approach to assess the PBT criteria of [redacted], leading to an assessment of PBT criteria for each of the identified constituents. Besides, bibliographical information indicates that the stability of [redacted] in the environment could be questionable and assessment could focus on relevant constituents of [redacted] which will enter in the environment and/or relevant degradation products. Due to these recently provided data, further information is considered necessary to solve the raised PBT issues of [redacted]. It should be kept in mind that physico-chemical properties of the identified constituents make the assessment difficult, because of analytical and

experimental limitations (for instance low solubility) and because constituents are often outside the domain of applicability of the available models. Therefore, it is proposed to first solve the stability issue of [redacted] in the environment, in order to determine which constituents and/or degradation products are expected to enter in the environment. Further works on this substance will take place once this issue will besolved.

Hydrolysis as a function of pH of [redacted] (test method: Hydrolysis as a function of pH, EU C.7/OECD 111)

The component [redacted] is hydrophobic and acts as a moisture protectant and a stabilizer. However, when released in the environment, the [redacted] and other constituents of [redacted] can be separated and these other constituents will be in contact with moisture. According to the literature on metal alkoxides[1], including molybdenum alkoxides[2], it is expected that, when exposed to water, the [redacted] identified [redacted] structures will completely dissociate leading to the release of [redacted] and inorganic molybdenum. However, no information about the kinetics of the reaction is available. If this hydrolysis occurs, it should nonetheless be determined whether this hydrolysis can occur sufficiently rapidly in the environment to support the PBT analysis of only the hydrolysis products or whether both [redacted] and the hydrolysis products still need to be assessed. Additionally, the exact identity of the hydrolysis products should be confirmed and better defined. This information is necessary to determine which chemical structures are the most relevant for further PBT assessments.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to provide a hydrolysis study of the registered substance [redacted] (test method: Hydrolysis as a function of pH, EU C.7./OECD 111). Due to the properties of the substance (low solubility, high adsorption capacities), the test could be adapted from the EU C.7/OECD 111 guideline and in this case the adaptation should be justified. Particularly, the test material should be specially prepared to remove as much oil as possible prior to testing to avoid an oil protection of the constituents of [redacted] against the hydrolysis. Moreover, relevant containers (e.g. stainless steel) shall be used to minimise adsorption. This study shall be carried out with well specified experimental conditions and should allow the determination of the kinetics of the reaction, the identification, the quantification and the stability of each relevant hydrolysis product.

In his comments, the Registrant reminds that [redacted] is an UVCB with low solubility and high adsorption properties, and several technical and analytical issues can be expected for the hydrolysis test. The Registrant particularly worries about the determination of the kinetic parameters. As previously explained, it is considered that information on the kinetics of the reaction is necessary to ascertain whether hydrolysis in the environment is sufficiently rapid to support a PBT assessment of only the hydrolysis products, or if a PBT assessment of both [redacted] and the hydrolysis products is required.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental study, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by the Registrant. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

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[1] Turova, N. Y. (Ed.). (2002). *The chemistry of metal alkoxides*. Springer.
[2] Yanovskaya, M. I., et al. "Hydrolysis of molybdenum and tungsten alkoxides: sols, powders and films." *Journal of Non-Crystalline Solids* 124.2 (1990): 155-166.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 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 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.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[redacted]

[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.

[redacted]