EUROPEAN CHEMICALS AGENCY

Helsinki, 26 July 2016

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

For Tris(methylphenyl) phosphate, CAS No 1330-78-5 (EC No 809-930-9)(previously registered with EC No 215-548-8)

Addressee: [redacted]

Based on an evaluation by Bureau REACH on behalf of the Ministry of Infrastructure and the Environment as the Competent Authority of The Netherlands (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 4 May 2015, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

For the substance specified above, ECHA has issued different decisions depending on the type of information requested and the Registrant(s) in question. One decision is addressed individually to all Registrant(s) which are jointly responsible to provide the information required. It contains requests to provide information on the toxicity of the substance, derived no effect levels (DNEL) and on worker exposure. ECHA has issued separate decisions to individual Registrants requesting information on worker exposure and related exposure scenarios that is specific to those operators.

This decision does not imply that the information provided by the Registrant in the registration(s) 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 subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of The Netherlands has initiated substance evaluation for Tris(methylphenyl) phosphate, CAS No 1330-78-5 (EC No 809-930-9)(previously registered with EC No 215-548-8) based on registrations submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to (suspected) PBT, wide dispersive use, aggregated tonnage and other (potential neurotoxic effects of the substance in aviation uses), Tris(methylphenyl) phosphate (here after referred to as TCP) was included in the Community rolling action plan

(CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of The Netherlands was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding high risk characterisation rations (RCRs).

The evaluating MSCA considered that further information was required to clarify the following concerns: potential neurotoxic effects of the substance in aviation uses and high RCR. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 25 March 2015.

On 4 May 2015 ECHA sent the draft decision to the Registrant and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 10 June 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.

On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 3 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, the Competent Authorities of the Member States and ECHA did not submit proposals for amendment to the information requirements set out below, however, other proposals for amendment were submitted.

Referral to Member State Committee

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

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 also submit the following information regarding the registered substance subject to the present decision:

1. A higher tier exposure assessment using realistic input variables, or perform exposure measurements, for dermal and inhalation exposure in accordance with the procedure laid down in the 'ECHA Guidance on Information Requirements and Chemical Safety

Assessment', Chapter R.14 Version 2.1, November 2012, and a risk assessment in accordance with the procedure laid down in Part E for exposure scenarios with process category PROC 7 (industrial spraying), PROC 11 (non-industrial spraying) and PROC 10 (roller application or brushing);

2. Re-assessment of the professional worker exposure estimation for the use of photochemicals containing TCP using a model that is specifically made for worker exposure estimation (ES 11).

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant shall submit to ECHA by **2 August 2018** an update of the registration containing the information required by this decision including an update of the Chemical Safety Report.

III. Statement of reasons

1. Higher tier exposure assessment using realistic input variables, or perform exposure measurements, for dermal and inhalation exposure, in accordance with the procedure laid down in the 'ECHA Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.14 Version 2.1, November 2012, and subsequent risk assessment in accordance with the procedure laid down in Part E for exposure scenarios with process category PROC 7 (industrial spraying), PROC 11 (non-industrial spraying) and PROC 10 (roller application or brushing)

Establishing the concern
Several exposure scenarios describe processes where workers have to spray TCP. These processes are process category PROC7 (industrial spraying) and/or PROC11 (non-industrial spraying). Inhalation and dermal exposure may occur due to aerosols formed during spraying. Further, several scenarios describe processes where workers have to perform low energy spreading of e.g. coatings, including cleaning of surfaces (PROC 10). Inhalation of the substance may occur due to aerosols forming in these processes; skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.

There is a concern that inhalation exposure to aerosols and dermal exposure are not sufficiently assessed by the current registration dossier and risks may not be adequately controlled.

Justification why new information is needed
The Registrant has estimated workplace inhalation and dermal exposure to the registered substance using the Tier 1 model ECETOC TRA v3. However, in case of aerosol formation all assessments shall be performed by Tier 2 models using realistic input variables, or by performing exposure measurements. Therefore, the current risk assessment based on ECETOC TRA v3 may be an underestimation of the risk.

What is the request
The Registrant shall perform a higher tier exposure assessment on the registered substance for exposure scenarios that include PROC 7 (industrial spraying), PROC 11 (non-industrial spraying) and PROC 10 (roller application or brushing), using Tier 2 models with realistic input variables, or by performing exposure measurements. When models are used, higher tier testing shall be performed for both inhalation exposure (ART) and dermal exposure (RISKOFDERM), using the 90th percentile as indicated in the ECHA Guidance (R.14, Version

2.1, November 2012, p.41). Default values shall be used for input parameters and protection factors. The use of protection factors higher than the default parameters is only valid when an acceptable justification is provided (see also request 6 in the decision addressed to all Registrants). In case the assessments are not within the applicability domain of the second tier models, or when the estimated outcomes are not realistic according to the Registrant, inhalation and dermal exposure measurements shall be performed. Exposure measurements shall be performed according to internationally accepted guidelines. Inhalation measurements shall be performed according to both EN 689:1995 "workplace atmospheres: guidance for the assessment of exposure to inhalation to chemicals for comparison with limit values and measurement strategy", or the guidance "Testing Compliance with Occupational Exposure Limits for Airborne Substances" (http://www.arbeidshygiene.nl/~uploads/text/file/2011-12%20BOHS-NVvA%20Sampling%20Strategy%20Guidance.pdf) or similar, and EN 482:2012+A1 2015 "workplace exposure; general requirements for the performance of procedures for the measurements of chemical agents". Dermal exposure measurements shall be performed through generation of measured data according to, for example, the absorbent glove method by OECD (OECD, 1997), by analysing TCP contamination of cotton gloves that are worn under the chemically protective gloves used.

In case of inhalation and dermal measurements, reasonable worst case situations shall form part of the distribution to be tested for a typical exposure scenario. Aggregated exposure shall be assessed by measuring during an 8 hour shift; a relevant guidance for that assessment is e.g. *"OECD (1997) Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application, Series on Testing and Assessment No. 9, OCDE/GD(97)148"*

In case the data asked in this request give rise to RCRs > 1, more stringent regulatory risk management measures might be needed to ensure safe use of the substance.

Consideration of Registrant's comments
The Registrant used ART 1.5 to estimate inhalation exposure for PROC7 (industrial spraying) and PROC10 (roller application or brushing) and agrees that ART 1.5 is a useful tool for the modelling of spraying and brushing applications. ECHA has concerns regarding the underpinning of several input variables used in the estimation (e.g. what is meant by 'other LEV systems' when secondary RMMs are claimed (PROC7), how realistic is use of a fixed capturing hood of surfaces 1-3 m2 (PROC10)). No inhalation exposure was estimated for PROC11 (non-industrial spraying). According to ECHA, there are serious omissions in the underpinning of the input variables used by the registrant in ART1.5. This may lead to significantly higher inhalation exposure estimations. In case the registrant has the opinion that the inhalation exposure estimations are not realistic using realistic input variables in ART1.5, exposure measurements should be performed. These exposure measurements shall meet internationally accepted guidelines.

The Registrant used RiskofDerm to estimate dermal exposure for PROC 7 (industrial spraying) and PROC10 (roller application or brushing) and concludes that RiskofDerm is not considered reliable and therefore ECETOC TRA shall be used. No dermal exposure was estimated for PROC11 (non-industrial spraying). It is ECHA's opinion that ECETOC TRA is not valid for estimating dermal exposure when aerosols may be produced. In that case a higher tier tool like RiskofDerm should be used or dermal exposure measurements shall be performed. Dermal exposure measurements shall meet internationally accepted guidelines.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant shall submit, in the form of an updated Chemical Safety Report (CSR) and using the specified approaches where applicable, a higher tier exposure assessment using realistic input variables or exposure measurements for dermal and inhalation exposure, in accordance with the procedure laid down in the 'ECHA Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.14 Version2.1, November 2012, and a risk assessment in accordance with the procedure laid down in Part E for exposure scenarios with process category PROC 7 (industrial spraying) PROC 11 (non-industrial spraying) and PROC 10 (roller application or brushing).

2. Re-assessment of the professional worker exposure during the use of photochemicals containing TCP

Establishing the concern
There is a concern on the exposure assessment for professional users during the use of photochemicals containing TCP. The input variables may not be representative for worker exposure and risks may be underestimated. Based on the current exposure estimation it cannot be determined if risks are sufficiently controlled.

Justification why new information is needed
Exposure scenario 11 estimates the professional worker exposure to TCP by referring to exposure scenario 12, which estimates the consumer exposure using a consumer exposure model. It is common knowledge that exposure of workers (especially during professional use) is higher than consumer exposure. In addition, the input variables used for the consumer exposure estimation are not realistic for professional workers (exposure every other day, duration of exposure 6 h/d). The RCR for the consumer exposure estimation is [redacted], which makes it plausible that the RCR for professional workers might be higher than 1.

What is the request
It is requested to perform an exposure assessment on the registered substance for professional workers during the use of photochemicals containing TCP by using exposure model for workers. Based on this assessment, it can be determined if the risk for humans is controlled.

In case the data asked in this request give rise to RCRs > 1, more stringent regulatory risk management measures might be needed to ensure safe use of the substance.

Consideration of Registrant's comments
The Registrant did not provide comments on this information requirement.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to reassess the professional worker exposure estimation in exposure scenario 11 using a model that is specifically made for worker exposure estimation.

IV. 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://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 2, on behalf of Leena Ylä-Mononen, Director of Evaluation

[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.