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 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 is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) 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 ratios (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 it 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 requirement 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:

Worker exposure

1. A higher tier exposure assessment 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), PROC 10 (roller application or brushing) and PROC 19 (hand-mixing with intimate contact and only Personal Protective Equipment (PPE) available);

2. Combined inhalation exposure estimations for different sources of exposures (time weighted average of a similar exposed group of 8 hours) when a time reduction factor is used (e.g. ES2-F1 and ES4-IW1).

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[1], including robust study summaries and, where relevant, an update of the Chemical Safety Report (CSR).

III. Statement of reasons

1. **Higher tier exposure assessment 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), PROC 10 (roller application or brushing) and PROC 19 (hand-mixing with intimate contact and only** Personal Protective Equipment **PPE available)**

Establishing the concern
Several exposure scenarios describe processes where workers have to spray TCP. These processes are PROC 7 (industrial spraying) and/or PROC11 (non-industrial spraying). Inhalation 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) or where there is intimate and intentional contact with TCP without any exposure controls other than personal protective equipment (PPE, PROC 19). 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 exposure to the registered substance using the Tier 1 model ECETOC TRA v3 and the Tier 2 model ART, using factors that deviate from the ECHA Guidance (R.14, Version 2.1, November 2012, p.41). However, in case of aerosol formation all estimations shall be performed by Tier 2 models (ART). For dermal exposure, the Registrant used ECETOC TRA v3 to estimate dermal exposure concentrations during non-industrial spraying (PROC 11). In addition, the feasibility of the combination of

[1] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

risk management measures can be questioned since a general ventilation of 10 ACH (Air Changes per Hour) in combination with a large room size were used as input variables in ART (the modelling software). This is difficult to achieve in the workplace, the Registrant should provide adequate justification to demonstrate these RMMs can be implemented in the workplace.

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), PROC 10 (roller application or brushing) and PROC 19 (hand-mixing with intimate contact and only PPE available). Higher tier testing shall be performed for both inhalation exposure (ART) and dermal exposure (RISKOFDERM, only PROC 11), 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 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
ECHA acknowledges that in his comment the Registrant has noted the request and stated that "*Dependent on the outcome of the in vitro dermal absorption study, revisions to the DNEL's may be made. The above can be conducted as part of the revised Chemical Safety Assessment. A revised Chemical Safety Assessment will be presented for inspection.*"

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant shall submit, in the form of an updated CSR using the specified approaches where applicable, a higher tier exposure assessment 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), PROC 10 (roller application or brushing) and PROC 19 (hand-mixing with intimate contact and only PPE available).

2. Combined exposure estimations for different sources of exposures

Establishing the concern
There is a concern on the inhalation exposure assessment for aggregated exposure of workers. The inhalation exposure may be underestimated and based on the current information it is difficult to assess whether worker exposure to TCP is adequately controlled.

Justification why new information is needed
In the registration dossier, inhalation exposure estimates are provided for each contributing exposure scenario and related process category. The estimations for dermal exposure and inhalation are combined for each process category and a RCR for all routes combined is calculated for each PROC.

No combined inhalation exposure estimate is provided for all sources of inhalation exposures of a worker (time weighted average of 8 hours). Several inhalation exposure estimations are calculated using a reduction factor for exposure duration (e.g. ES2-F1 (PROC 15 and PROC19) and ES4- IW1 (PROC7 indoors)). Workers may be involved in

multiple processes during a day. For these workers, a combination of inhalation exposure estimates for different process categories shall be taken into account. Taking combined inhalation exposures not into account may have led to an underestimation of the inhalation exposure estimates of the worker.

What is the request
To perform an adequate exposure assessment on the registered substance, each relevant route of human exposure shall be addressed and combined through all sources of exposure (all PROCs during 8 hour working day because a worker often performs work described by more than one PROC).

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.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant is required to submit for the registered substance subject to the present decision combined inhalation exposure estimations for different sources of exposures (time weighted average of a similar exposed group of 8 hours).

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[2] by Claudio Carlon, Head of Unit, Evaluation 2, on behalf of Leena Ylä-Mononen, Director of Evaluation

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.