

Helsinki, 24 November 2015

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 phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased, CAS No 68784-26-9 (EC No 272-234-3)****Addressees: Registrant(s)<sup>1</sup> of phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased (Registrant(s))**

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who cease manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by Bureau REACH on behalf of the Dutch 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(s) on 23 July 2015, i.e. the day on which the draft decision the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent 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 phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased (PDSC-Ca), CAS No 68784-26-9 (EC No 272-234-3) based on registration(s) 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.

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<sup>1</sup> The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health/CMR, exposure/wide dispersive use, consumer use, and aggregated tonnage, phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of the Netherlands was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the human health/CMR, exposure/wide dispersive use, consumer use, and aggregated tonnage. 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 13 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) 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 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. The evaluating MSCA considered the comments received from the Registrant(s) and the dossier updates. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

In accordance with Article 52(1) of the REACH Regulation, on 23 July 2015 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, ECHA submitted proposals for amendment to the draft decision.

On 29 August 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them 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.

On 7 September 2015 ECHA referred the draft decision to the Member State Committee.

On 25 September 2015, in accordance to Article 52(2) and Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant(s) on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 13 October 2015 in a written procedure launched on 1 October 2015.

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(s) shall submit the following information regarding the registered substance subject to the present decision:

### 1. **Dermal exposure information, following a tiered approach:**

**a) Dermal exposure modelling using the RISKofDERM Model, including aggregate exposure calculations in case time reduction factors are applied.** In case the RISKofDERM Model indicates that the exposure estimation is outside the validity range of the model, or in case RCRs > 1 are obtained for aggregated (8h) exposures, it is requested to perform (next tier):

**b) Dermal exposure measurements of workers in ES-1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime), ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A) and ES 4 Professional use of lubricants and greases in vehicles or machinery (████████████████████).** Dermal exposure shall be measured according to the absorbent glove method by OECD (OECD, 1997), by analyzing tetrapropenyl phenol (TPP) contamination of cotton gloves that are worn under the chemically protective gloves used. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDCS-CA overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated dermal exposure. Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition.

2. **Inhalation exposure measurements for similar exposure groups of workers in ES 1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime) and in ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A).** Inhalation measurements shall be measured according to the internationally accepted guidelines, such as EN 689 and EN 482, or according to 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, analysing TPP. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDCS-CA overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated inhalation exposure. Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition.

This information is requested unless the Registrant(s) proves with adequate and documented justification that for technical or scientific reasons this information cannot be provided.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **3 March 2017** an update of the registration(s) containing the information required by this decision<sup>2</sup>, including robust study summaries and, where relevant, an update of the Chemical Safety Report.

### III. Statement of reasons

Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased (further referred to as PDSC-Ca overbased) is registered as a UVCB, a substance of unknown or variable composition, complex reaction products or biological materials. The substance is composed of a series of alkylated phenol species of variable composition and a highly refined, lubricant base oil necessary to act as a solvent for the synthetic reaction and to optimize the reaction kinetics used in the substance's manufacture. One of the constituents of PDSC-Ca overbased is phenol, dodecyl-, branched (also named 'tetrapropenyl phenol' (TPP) and

<sup>2</sup> 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).

'phenol, alkylation products with C10-C15 branched olefins derived from oligomerisation'). Comparison of reproductive toxicity studies with PDSC-Ca overbased itself, with PDSC-Ca overbased stripped of TPP and with TPP alone show that TPP is the only constituent in PDSC-Ca overbased causing reproductive toxicity. The concentration of TPP varies considerably within and between registration dossiers.

## **1. Dermal exposure information, following a tiered approach**

### *Link to the concern*

The initial concerns were Human health/CMR; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage. There is a concern for health risks in workers caused by the estimated dermal exposure. The dermal exposures estimations are not considered acceptable, and could be underestimated, hence risks from dermal exposure may not be sufficiently controlled.

### *What relevant data is available*

The Registrant(s) estimated dermal exposures using ECETOC TRA v3, RISKofDERM Model and RISKofDERM Toolkit, HEEG opinions and UK POEM.

### *Justification why new information is needed*

Regarding the exposure assessments of PDSC-Ca overbased, three exposure scenarios were considered: ES-1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime), ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A) and ES 4 Professional use of lubricants and greases in vehicles or machinery (████████████████████). There is a concern on the dermal exposure estimations of PROCs that were evaluated with RISKofDERM Toolkit, HEEG opinions or UK POEM. These are discussed below.

The Registrant(s)' estimation of dermal exposure during ES-1 and ES 2 is partly based on the second tier models RISKofDERM Toolkit and HEEG Opinion (TM I08). The RISKofDERM Toolkit is not the same as the RISKofDERM Model and should be avoided since it is a semi-quantitative model (see HEEG Opinion (TM I08)). In addition, the Registrant(s)' choice for 'automated transfer/pumping' according to the HEEG Opinion (TM I08) for non-dedicated facilities (PROC 8a) is questioned. Based on the information in the CSR, a semi-automated transfer/pumping would be a more realistic choice for PROC8a. In case of semi-automated transfer/pumping, HEEG recommends to use the RISKofDERM Model. The dermal exposure with this model could not be assessed because of lack of input variables (such as use rate). In addition, for transfer of chemicals or waste collection with dedicated facilities (PROC8b), measures other than personal protective equipment to control dermal exposure are not specified. Finally, applying a time reduction factor in calculating dermal exposure for contributing scenarios leads to underestimation of the aggregated dermal exposure, and consequently of the aggregated total (both inhalation and dermal) exposure.

The Registrant(s)' estimation of dermal exposure in ES 4 is based on a best case basis during maintenance work and disposal of waste product (PROC 8b). For both contributing scenarios the UK POEM model is used to estimate dermal exposure during loading/unloading of the engine oil into/out of the automobile engine and transferring waste product to a container via hand pouring. According to the Registrant(s), a 10 or 20 L container with a wide opening is used to fill the engine of an automobile. This is not a realistic situation. Oil will be spilled using 10-20 L vessels with a large opening, and will come into contact with the skin during handling. The oil will be poured through a funnel, which will be

contaminated, resulting in dermal exposure. Furthermore, dermal exposure may occur during the replacement of the old oil filter. UK POEM only estimates dermal exposure during mixing and loading, which means that the unloading of used oil from the engine into a vessel, the replacement of the oil filter, and pouring the old motor oil from the pan into a used oil container, is not estimated. The dermal contact area equal to both hands can be assumed. This leads to a dermal exposure estimate of about 9 ml per pouring operation (860 cm<sup>2</sup> hand x layer of 0.01 cm), instead of 0.05 ml per pouring operation estimated by UK POEM.

Therefore, the current dermal exposure estimations could be an underestimation of the exposure and further information on the dermal exposure levels is required. In addition, time reduction was applied in the second tier exposure assessment models, but the exposures were not consequently summed, thus the aggregated exposure is unknown.

In conclusion, the provided update of the registration dossier(s) does not remove the concern on a health risk for workers during ES 1 (manufacture of lubricant additives, lubricants and greases), ES 2 (industrial formulation of lubricant additive, lubricants and greases) and ES 4 (professional use of lubricants and greases in vehicles or machinery) of PDSC-Ca overbased. The performed second tier dermal exposure estimations for PROC 8a and 8b in ES1 (Manufacture) and in ES2 (Formulation and blending) and for PROC 8b in ES4 (Professional use) are not acceptable, thus these need to be replaced by estimations using the accepted RISKofDERM Model, including aggregated exposure calculations in case time reduction factors are applied. In case the RISKofDERM Model indicates that the exposure estimation is outside the validity range of the model, or in case RCRs>1 are obtained for aggregated (8h) exposures, dermal exposure measurements are necessary for the similar exposure groups (SEGs) working within these exposure scenarios. Aggregated exposure is measured in case 8 hour exposure measurements are performed.

#### *What is the request*

It is requested to provide dermal exposure estimations from the RISKofDERM Model for the PROCs where the RISKofDERM Toolkit, the HEEG opinion or UKPOEM were used. Aggregated exposure estimations for similar exposure groups (SEG) should be included in case time reduction factors are applied.

In case the RISKofDERM Model indicates that the exposure estimation is outside the validity range of the model, or in case RCRs>1 are obtained for aggregated (8h) exposures, it is requested to provide dermal exposure measurements for SEGs of workers in manufacturing, in formulation and blending, and in professional use. Dermal exposure shall be measured according to the absorbent glove method by OECD (OECD, 1997), by analyzing TPP contamination of cotton gloves that are worn under the chemically protective gloves used. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDSC-Ca overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated dermal exposure.

Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition. Other important aspects of this analysis are:

- Substances similar to constituents of TPP are reported to be analysable with liquid chromatography with a variety of detectors (e.g. Environment Agency, 2007);
- The main constituents, forming 95% of the UVCB composition, should be analysed, and this choice of constituents should be documented. This will result in constituents with a range of different chain lengths, so possible different glove penetrations for these different chain lengths can be covered;

- Standards for these main constituents should be included, to allow quantitative analysis of these constituents while also allowing distinction from other substances that will be present on the cotton glove (which is not possible when using only peak areas);
- The whole of a cotton glove should be extracted with an appropriate solvent (as recommended in the OECD guideline (OECD, 1997)), where the extraction efficiency is determined with spiked gloves;
- The recovery of the whole procedure should be determined with the standards and corrected for in the quantitative exposure determinations.

#### *Further consideration of comments and Proposals of Amendment*

In the dossier of 29 July 2013, the Registrant(s) estimated dermal exposure of workers using ECETOC TRA v3, lacking aggregated exposure estimations. In the first draft decision, as was drafted in March 2014, the Registrant(s) were requested to provide these aggregated exposure estimations. In addition, more appropriate worker exposure modelling was requested, with adaptations of certain modelling input, such as the effect of local exhaust ventilation and of the use of gloves when working with rotating parts.

In response, the Registrant(s) adapted the modelling accordingly and explained no work was performed with rotating parts. When evaluating the resulting exposure and risk assessment, RCRs >1 were found for several process categories (PROCs), using the Registrant(s)'s estimated exposure concentrations according to ECETOC TRA v3 and using DNELs following ECHA Guidance. This was communicated to the Registrant(s), with the suggestions to apply second tier models for the exposure assessment. For dermal exposure this would be the RISKofDERM Model.

In the updated dossier of 26 January 2015, the Registrant(s) indeed applied second tier modelling for critical PROCs, and used adapted DNELs, but applied the RISKofDERM Toolkit, HEEG opinions or UK POEM in some cases. Based on the updated registration dossier there was still a concern on the dermal exposure estimation and the control of risks, as described above. Therefore, the Draft Decision was amended and dermal exposure measurements (i.e. 3<sup>d</sup> tier exposure assessment) were requested because 2<sup>nd</sup> tier exposure assessment (modelling) had appeared not to remove the concern.

One proposal for amendment, which was also supported by the Registrant(s) in their comments, proposed to provide the opportunity to the Registrant(s) to apply appropriate 2<sup>nd</sup> tier models first, to see whether RCRs <1 can be achieved this way without having to resort to measurements. This proposal was accepted, resulting in a request with a tiered approach in the Decision.

#### *Conclusion*

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide dermal exposure information, following a tiered approach:

- a. Dermal exposure modelling using the RISKofDERM Model, including aggregate exposure calculations in case time reduction factors are applied. In case the RISKofDERM Model indicates that the exposure estimation is outside the validity range of the model, or in case RCRs>1 are obtained for aggregated (8h) exposures, it is requested to perform (next tier):
- b. Dermal exposure measurements of workers in ES-1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime), ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A) and ES 4 Professional use of lubricants and greases in vehicles or machinery (██████████). Dermal exposure shall be measured according

to the absorbent glove method by OECD (OECD, 1997), by analyzing TPP contamination of cotton gloves that are worn under the chemically protective gloves used. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDSC-Ca overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated dermal exposure. Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition.

## **2. Measurement of inhalation exposure of workers in ES-1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime) and ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A)**

### *Link to the concern*

The initial concerns were Human health/CMR; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage. There is a concern for health risks in workers caused by the estimated inhalation exposure. The exposure by inhalation leads to a health risk (RCRs >1) when following ECHA Guidance in the risk assessment and aggregated exposure has not been determined and considered.

### *What relevant data is available*

The registration dossier includes a two-generation reproduction toxicity study, a combined repeated dose toxicity study with the reproduction / developmental toxicity screening test and two prenatal developmental toxicity studies, all oral studies. All studies were performed with a commercial sample of the registered substance, all with the same concentration of TPP.

In the current dossier, the Registrant(s) have applied first- and second-tier exposure modelling for the inhalation route using ECETOC TRA v3.3 and the Advanced REACH Tool (ART). The Registrant(s) find RCRs < 1 based on these exposure estimations and based on, among others, a long-term DNEL for PDSC-Ca overbased of 3.5 mg/m<sup>3</sup> (0.13 ppm) for inhalation exposure of workers. This DNEL was derived from studies testing PDSC-Ca overbased with a certain percentage of TPP, while some registration dossiers cover a composition of PDSC-Ca overbased with higher levels of TPP. To verify whether PDSC-Ca overbased with higher levels of TPP results in an RCR > 1, the Registrant(s) have compared the DNELs derived for constituent TPP with the expected exposure to TPP, covering the manufacture and use of PDSC-Ca overbased with the highest % of TPP. The Registrant(s) come to RCRs <1 using a long-term DNEL for TPP of 1.05 mg/m<sup>3</sup> (0.10 ppm) for inhalation exposure of workers.

### *Justification why new information is needed*

Regarding the exposure assessments of PDSC-Ca overbased, three exposure scenarios were considered: ES 1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime), ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A) and ES 4 Professional use of lubricants and greases in vehicles or machinery (████████████████████).

In ES 1 and ES 2, RCRs > 1 are found for PDSC-Ca overbased. The difference with the calculations performed by the Registrant(s) lies in the applied long-term DNEL for inhalation by workers. Following the ECHA Guidance, a value of 50% should be applied for the

(unknown) oral absorption in the route-to-route extrapolation from an oral to an inhalation NOAEL for PDSC-CA overbased, while the Registrant(s) use a value of 100%.

A risk assessment based on PDSC-Ca overbased was considered first. This risk assessment is preferred as the underlying data are based on tests with PDSC-Ca overbased itself. RCRs >1 were obtained for several PROCs. The inhalation exposure estimations for these scenarios were estimated with ECETOC TRA, a first tier model. In the other ESs, no RCRs >1 are obtained. It is noted that risk assessment was based on PDSC-Ca overbased as tested in the animal studies, which is not the PDSC-Ca overbased with the highest level of TPP.

When linearly extrapolating the DNEL for the PDSC-Ca overbased as tested to PDSC-Ca overbased with the highest level of TPP, nearly all PROCs in ES1 (Manufacture) result in an RCR >1 and some PROCs in ES2 (blending and formulation) do, too. The exceedance of the value of 1 for these PROCs are all mainly due to inhalation exposure, which have been estimated either with ECETOC TRA or ART.

As time reduction was applied in the second tier exposure assessment models, but the exposures were not consequently summed, the aggregated exposure is unknown. This could lead to even higher RCRs.

A risk assessment based on the TPP constituent was then considered, as was also proposed by the Registrant(s). The inhalation DNEL according to ECHA Guidance for TPP would be a 32-fold lower than the DNEL for PDSC-Ca overbased, while the exposure to TPP is < 10-fold lower than the exposure to PDSC-Ca overbased (as the maximum level of TPP is >10%). Therefore, such a risk assessment is not expected to produce lower RCRs, but in fact higher RCRs than the risk assessment with PDSC-Ca overbased.

In conclusion, the provided update of the registration dossiers does not remove the concern on a health risk for workers during ES 1 (manufacture of lubricant additives, lubricants and greases) and ES 2 (industrial formulation of lubricant additive, lubricants and greases), using DNELs following ECHA Guidance. The inhalation RCRs (and total RCRs) are above 1 in ES1 and ES2 based on DNELs derived according to the ECHA guidance, even when second tier inhalation exposure estimations have been performed. Thus, inhalation exposure measurements are necessary for the SEGs working within these exposure scenarios to verify whether the concern can be alleviated. Aggregated exposure is measured in case 8 hour exposure measurements are performed.

#### *What is the request*

It is requested to provide inhalation exposure measurements for SEGs of workers in ES 1 and in ES 2. Inhalation measurements shall be measured according to the internationally accepted guidelines, such as EN 689 and EN 482, or according to 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, analysing TPP. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDSC-CA overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated inhalation exposure. With these measured TPP data, the risk assessment will have to be based on TPP, using the DNELs for TPP.

Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition. Other important aspects of this analysis are:

- Substances similar to constituents of TPP are reported to be analysable with liquid chromatography with a variety of detectors (e.g. Environment Agency, 2007);
- The main constituents, forming 95% of the UVCB composition, should be analysed, and this choice of constituents should be documented. This will result in constituents with a range of different chain lengths, so possible different evaporation levels of the constituents are covered;
- Standards for these main constituents should be included, to allow quantitative analysis of these constituents while also allowing distinction from other substances that will be present in the sampling material (which is not possible when using only peak areas);
- The sampling material should be extracted with an appropriate solvent, where the extraction efficiency is determined with spiked sampling material;
- The recovery of the whole procedure should be determined with the standards and corrected for in the quantitative exposure determinations.

This information is requested unless the Registrant(s) prove with adequate and documented justification that for technical or scientific reasons this information cannot be provided.

#### *Further consideration of comments and Proposals of Amendment*

In the dossier of 29 July 2013, the Registrant(s) estimated inhalation exposure using ECETOC TRA. In the first draft decision, the Registrant(s) were requested to recalculate the inhalation exposure after making adaptations for processes performed at temperature higher than 25°C. In addition, the Registrant(s) were asked to provide aggregated exposure estimations, to clarify the contribution of other constituents than TPP to the toxic effects of PDSC-Ca overbased, and to show that registered PDSC-Ca overbased with higher levels of TPP does not cause health risks.

In response, the Registrant(s) adapted the inhalation exposure calculations accordingly. In addition, the Registrant(s) added a one-generation reproduction toxicity study with PDSC-Ca overbased, stripped of TPP to show TPP is the only constituent responsible for the toxic effects of PDSC-Ca overbased. To show that registered PDSC-Ca overbased with higher levels of TPP does not cause health risks, the Registrant(s) added a risk assessment based on TPP, using the highest percentage of TPP present in registered PDSC-Ca overbased. When evaluating the resulting exposure and risk assessment, RCRs >1 were found for several process categories (PROCs), using the ECETOC TRA exposure estimations and using DNELs following ECHA Guidance. This was communicated to the Registrant(s), with the suggestions to apply second tier models for the exposure assessment. For inhalation exposure this would be ART.

In response, the Registrant(s) updated the dossier, including ART estimations for exposure by inhalation for some critical PROCs. Based on the updated registration dossier there is still a concern on the control of risks via inhalation, as described above. Therefore, the draft decision was amended and inhalation exposure measurements (i.e. 3<sup>rd</sup> tier exposure assessment) were requested because 2<sup>nd</sup> tier exposure assessment (modelling) had appeared not to remove the concern.

One proposal for amendment, which was also supported by the Registrant(s) in their comments, proposed to provide the opportunity to the Registrant(s) to apply appropriate 2<sup>nd</sup> tier models first, to see whether RCRs <1 can be achieved this way, without having to resort to measurements. However, as appropriate 2<sup>nd</sup> tier models have already been applied by the Registrant for inhalation exposure, further modelling is therefore not expected to decrease the RCRs to <1. The next tier in exposure assessment (i.e. measurements) should therefore be performed.

### *Conclusion*

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide inhalation exposure measurements for SEGs of workers in ES 1 Manufacture of lubricant additives, lubricants and greases (ATIEL-ATC Group A Prime) and in ES 2 Industrial formulation of lubricant additive, lubricant and greases (ATIEL/ATC Use Group A). Inhalation measurements shall be measured according to the internationally accepted guidelines, such as EN 689 and EN 482 or according to 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, analysing TPP. Reasonable worst case situations shall be tested regarding both the TPP concentration in PDCS-CA overbased used for a typical exposure scenario, and the work performed during an 8 hour shift, to account for aggregated inhalation exposure. Considering TPP is a UVCB, the analysis of TPP should be performed through the analysis of its main constituents, forming 95% of the UVCB composition. This information is requested unless the Registrant(s) proves with adequate and documented justification that for technical or scientific reasons this information cannot be provided.

#### 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://echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised<sup>[3]</sup> by Leena Ylä-Mononen, Director of Evaluation

Annex 1: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

Annex 2: References

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<sup>[3]</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

## **Annex 2: References**

Environment Agency (2007) Environmental risk evaluation report: *para*-C12-alkylphenols (dodecylphenol and tetrapropenylphenol), SCHO0607BMVN-E-P. Available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/290856/sc\\_ho0607bmvn-e-e.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290856/sc_ho0607bmvn-e-e.pdf) . Accessed 29 September 2015.

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.