EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114328640-56-01/F Helsinki, 03 May 2016

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

For A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives, EC No 421-820-9 (CAS No 192268-65-8), 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 A mixture of: triphenylthiophosphate and tertiary butylated phenyl derivatives, EC No 421-820-9 (CAS No 192268-65-8), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 12 June 2015.

On 21 August 2015 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 25 September 2015 ECHA received comments from the Registrant on the draft decision.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 3 March 2016 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, Section 2.1.) as further specified under section III.A.1.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(d), 13 and Annexes VII, VIII, 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:

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD 408) in rats;
3. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216);

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial study is available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

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.

C. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **10 November 2017** an update of the registration dossier containing the information required by this decision including, where relevant, an update of the Chemical Safety Report.

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.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the Registrant identified the registered substance as a multi constituent substance in section 1.1 of the IUCLID dossier. 'Guidance for identification and naming of substances under REACH and CLP', referred thereafter as the Guidance, clarifies the difference between well-defined substances and UVCB substances. As specified in the Guidance, page 14, Chapter 4.1: *substances can be divided into two main groups:*

1. "Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2.
2. "UVCB substances": Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified by the above parameters.

Variability of composition for well defined substances is specified by upper and lower limit of the concentration range(s) of the main constituent(s). For UVCB substances the variability is relatively large and/or poorly predictable.

ECHA points out that due to the variability of the position of the alkyl chains on the aromatic rings, the registered substance should be regarded as a UVCB substance. The naming of UVCB substances shall consist of two parts: (1) the chemical name and (2) a detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance. ECHA observes that the Registrant did not provide sufficient information on the description of the manufacturing process for the proper identification of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, ECHA observes that the description of the manufacturing process provided in IUCLID section 3.1 is not sufficiently detailed to identify the registered substance. The registrant reported only the following information: "[redacted]" ECHA notes that the identities of the starting materials and the relevant process parameters used for the manufacturing of the registered substance have not been specified.

ECHA points out that the identity of the starting materials is one of the factors determining the composition of the registered substance, therefore the identity and compositional information of starting materials is a necessary element for the identification of the registered substance itself.

Other elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. In particular, the type and ratio of reactants used and specifications of any other manufacturing process parameters have not been indicated.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered UVCB substance. The Registrant is accordingly requested to clarify the identity of the registered UVCB substance. For this purpose, the Registrant shall provide the missing information on the description of the process used for the manufacturing of the substance registered.

ECHA acknowledges the Registrant's comments agreeing with the UVCB nature of the substance and his intention to update the registration dossier.

As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description" fields in IUCLID section 1.1.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 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 sought to adapt this information requirement by means of a read-across from supporting substance structural analogue according to REACH Annex XI, section 1.5. The justification of the adaptation given by the Registrant is: "*Considering its technical function as an antioxidant in lubricants, both enzymatic and non-enzymatic rapid oxidation of the thiophosphate to the phosphate is expected. In addition, phosphate esters are known to be susceptible to enzymatic hydrolysis. This may be slowed for the fraction with a tertiary butyl group in o-position to the ester bond, but in principle, all components of the test substance are expected to undergo hydrolysis.The resulting alkylated phenols should be readily conjugated by UDP-glucuronosyltransferases or sulfotransferases. The conjugates are sufficiently small and water soluble for renal elimination.*" ECHA notes that the registrant has provided a read across study conducted with a mixture of tert-butylphenyl phosphates ([redacted]%) and triphenyl phosphate ([redacted]%). The registered substance contains [redacted]% O,O,O-triphenyl thiophosphate, [redacted]% mono-tert-butyl O,O',O''-triphenylphosphorothioate, [redacted]% di-tert-butyl O,O',O''-triphenylphosphorothioate and various impurities up to about [redacted]% in total. According to the the Registrant's claim the substance in the read-across study is the oxidation product to which the registered substance is expected to metabolise very rapidly.

However, ECHA considers that this adaptation does not meet the general rules for adaptation of Annex XI, 1.5. because the existing evidence contradicts the hypothesis that the registered substance rapidly breaks down to the read-across substance. In particular, the results of the rate of hydrolysis (non-enzymatic) provided in the registration dossier indicate that at pH 4, 7 and 9 after 5 days the decomposition was less than [redacted]%. In addition, the half-life period (t1/2) for the hydrolytic degradation is > 8760 h (pH 7, 25 °C). In relation to the enzymatic hydrolysis, the Registrant has provided no information to support this statement. Accordingly, ECHA concludes that it is not possible that the human health properties of the registered substance may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach), on the basis that the properties of the registered substance may be predicted from the properties of the source substance on a hypothesis of rapid oxidation and/ or enzymatic hydrolysis. The proposed adaptation thus fails to meet the requirements of Annex XI, 1.5.

With his comments, the Registrant submitted a read-across justification document which was not present in the initial registration dossier. According to the Registrant the analogue approach is based on the structural similarities and the similar toxicological properties of the two substances and not on the enzymatic (or non-enzymatic) ester-hydrolysis.

ECHA notes the following:

a) Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural similarity *per se* is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties.
b) ECHA considers that "*similar toxicological properties*" are not in themselves a robust basis for predicting the properties of a substance, since there are many substances which share a number of toxicological properties, but then differ in other toxicological properties. ECHA also notes that in this case, the amount of information for the target substance which is in common and is comparable to the source substances is limited. The only tests that obtained comparable results are acute toxicity, irritation and genotoxicity tests. The results of the screening study for reproduction toxicity are quite different: a NOAEL of 250 mg/kg was obtained for the target substance while for the source substance the calculated NOAEL was 1000mg/kg. The sub-acute toxicity study for the source substance is missing hence by only having results of the sub-acute toxicity study (for the target substance) and the sub-chronic toxicity study (for the source substance) it cannot be determined whether there is a correlation between the two substances.

   From the data matrix provided it cannot be concluded that there is a "*strong correlation*" in the repeated-dose toxicity studies, as claimed by the registrant. The differences in composition of the two substances can be expected to indeed have an influence on their toxicological properties. ECHA notes that the missing data and the differences noted, as explained above, show that the hypothesis advanced by the registrant has not been sufficiently justified. This further undermines the use of similar toxicological profile as a basis for predicting the properties of the registered substance.

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

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 physical-chemical properties of the substance, a liquid with low vapour pressure and high viscosity, the information provided on the uses and human exposure, i.e., no uses with spray application and as there is evidence of absorption from the gastro-intestinal tract demonstrated by the toxicity in the 28d sub-acute oral study, 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 species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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.

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The Registrant has waived the standard information requirements of Annex IX, section 9.4. using the following justification: *"In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms. An environmental exposure assessment was performed in order to determine possible risks of the test substance to the environment. According to the results of the exposure assessment, all the relevant uses of the test substance are considered to be safe with a Risk Characterization Ratio below 1. However, additionally a study according to OECD 222 is currently running to investigate terrestrial toxicity."*

The Registrant refers to Column 2 of Annex IX and X indicating that toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms. This statement applies to Annex X, Section 9.4., Column 2, but it is not valid for Annex IX, Section 9.4., Column 2, which states the following: "*These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.*"

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only. In this regard, the Registrant indicated in the registration dossier that a long-term toxicity testing to macroorganisms (OECD 222 Earthworm Reproduction test) is currently ongoing.

Based on the agreement in the Member State Committee meeting MSC29, ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

In his comments to the draft decision the Registrant brought forward the argumentation that "*according to ECHA Guidance on information requirements and chemical safety assessment Chapter R7c, p.136 (version 2.0, November 2014) the integrated test strategy for effects on terrestrial organisms depends amongst others on the aquatic hazard, physical chemical properties of the substance and the tonnage band. The ECHA guidance clearly specifies that one terrestrial test is suitable to meet Annex IX requirements if there is no chronic aquatic toxicity at the limit of water solubility*". The Registrant has then argued how this scenario applies to the registered substance and concluded that "*a study with micro-organisms is not recommended in the ECHA guidance as stated above and not necessary. To perform a study on earthworm reproduction is also not contradictory to the agreement of Member State Committee meeting MSC29 on adaption possibilities to Annex IX Section 9.4 as with the result of the earthworm study a PNEC can be derived without using EPM. Additionally, the registrant wants to inform ECHA that the dossier is currently being updated. However, as soon as the Earthworm reproduction test is completed the available information will be evaluated, a PNECsoil will be derived and the chemical safety assessment according to Annex I revised.*"

ECHA acknowledges the Registrant's comments to the draft decision and his intention to update the registration dossier.

The Registrant claims that the use of the EPM method is not needed and that the information requirement can be adapted on the basis that no toxicity has been observed in chronic aquatic toxicity at the limit of water solubility. ECHA notes that currently the dossier contains one study for long-term toxicity to invertebrates and one on long-term toxicity to fish, both of which have been assigned reliability 3 from the Registrant due to major flaws related to the preparation of the test solutions. ECHA agrees with the score assigned by the Registrant. In addition, the Registrant has conducted a new long-term toxicity testing on aquatic invertebrates, for which no effects were observed up to the highest loading rate of 5.5 mg/L (WAF); however, the study is currently not present in the dossier and the Registrant indicated that it will be submitted in the next update. Therefore, although the argument of the Registrant appears to be plausible, the adaptation based on the lack of toxicity in chronic aquatic tests cannot be accepted at this stage.

As a consequence, in the context of an integrated testing strategy for soil toxicity, ECHA considers that the substance would fall into soil hazard category 3. In this case the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. In this regard, the Registrant indicated in the registration dossier that a long-term toxicity testing to macroorganisms (OECD 222 Earthworm Reproduction test) is currently ongoing.

However, a PNEC derived solely on the Equilibrium Partitioning Method (EPM) and a long-term test on terrestrial invertebrates might not reflect the hazard to the soil microbial communities, since their intrinsic properties are not addressed through the EPM extrapolation. Therefore, soil microorganisms may still be the most sensitive, and appropriate testing is necessary for soil PNEC calculation. In respect to this, the ongoing earthworm study cannot be used on its own to derive the PNECsoil, as stated in the comments by the registrant.

ECHA notes that the current Guidance on information requirements and chemical safety assessment Chapter R7c (version 2.0, November 2014) does not yet reflect the MSC29 agreement on adaptation possibilities to Annex IX, Section 9.4., and the requirement to perform the soil microorganisms testing in addition to the one long-term confirmatory test for the soil hazard category 3.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally 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://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 Ofelia BERCARU, Head of Unit, Evaluation E3

[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.