EUROPEAN CHEMICALS AGENCY

Helsinki, 18 August 2016

Addressee: [redacted]

Decision number: CCH-D-2114340406-56-01/F
Substance name: dioctyltin oxide
EC number: 212-791-1
CAS number: 870-08-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 05.10.2015

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Description of the analytical methods (Annex VI, Section 2.3.7) for the registered substance;**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

3. **Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3; test method: OECD TG 443) in rats, oral route with the registered substance;**

   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation; and**
   - **Cohort 3 (Developmental immunotoxicity);**

4. **Sediment simulation testing (Annex IX, Section 9.2.1.4; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24 / OECD TG 308) at a temperature of 12 °C with the registered substance;**

5. **Soil simulation testing (Annex IX, Section 9.2.1.3; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307) at a temperature of 12 °C with the registered substance;**

6. **Including the identification of the degradation products (Annex IX, Section 9.2.3.) by means of one of the above test methods under points 4 and 5;**

7. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, dietary exposure) with the registered substance;**

Appendix 1: Reasons

1. Description of the analytical methods (Annex VI, Section 2.3.7.)

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.

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, the information must be sufficient to allow the methods to be reproduced.

ECHA considers the description of the analytical methods as insufficient to allow confirmation of the identity and composition reported in IUCLID section 1.2. More specifically, the chromatogram performed on the substance is almost illegible and it is not possible to attribute the area reported in the peak list to the actual peaks in the chromatogram. In addition, you assigned a peak to the main constituent in the substance but no details of the approach used to carry out this assignment are provided: the unspecific flame ionisation detector (FID) used cannot provide qualitative structural information and therefore information about the standard compound used for the identification of peaks is required. This is relevant as the spectral data provided (IR and NMR) are not adequate to confirm the identity of the main constituent and no other elemental analysis is provided to support such identification. There is a reference to derivatisation with a Grignard reagent but no details of this method are provided. Additionally, the calculations used to obtain the reported composition from the raw chromatographic data are not provided.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the information derived from the registered substance subject to the present decision: correct description of the methods used to identify and quantify the registered substance as specifically explained above while ensuring the information is consistent throughout the dossier.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

Upon receipt of the draft decision you submitted comments explaining that "*Currently an extended OECD TG 414 study (teratogenicity) in the rat is executed in order to meet US-FDA notification requirements.*". You also provided an overview of the study and indicated that the main study will include: Teratogenicity according to OECD TG 414, Immunotoxicity, Toxicokinetics (Mono-, Dioctyltin kation in food, plasma, feces, urine) and Zinc level (plasma, food, water). You also indicated that a side study investigating an osteoporosis marker (e.g. B-CTX, Osteocalcin, P1NP) and an endocrine marker, will also be performed. ECHA acknowledged the comments and information provided. However, as the data for this endpoint are not yet available, the draft decision was not amended. The compliance of the ongoing study will be evaluated during the follow up process.

Therefore, the adaptations of the information requirement cannot be accepted.

You proposed to extend the pre-natal developmental toxicity study by including additional examinations/parameters on immunotoxicity. ECHA notes, that it is at your discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance.

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.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

3. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The basic test design of an extended one-generation reproductive toxicity study (Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex IX of the REACH Regulation if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD TGs 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. If the conditions described in column 2 of Annex IX are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.0, July 2015). The exposure duration is supported also by the lipophilicity of the substance to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

It is recommended that results from a range-finding study (or range finding studies) for the extended one-generation reproductive toxicity study are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Extension of Cohort 1B

If the column 2 conditions of 8.7.3., Annex IX are met, Cohort 1B must be extended, which means that the F2 generation is produced by mating the Cohort 1B animals. This extension provides information also on the sexual function and fertility of the F1 animals.

The use of the registered substance is leading to significant exposure of workers and consumers because the registered substance has industrial and consumer uses such as in adhesive, sealants, coatings and paints, thinners, paint removes, textile dyes. Furthermore, effects indicating endocrine disrupting mode of action such as increase in gestation length were observed in the OECD TG 422 study (see above). Furthermore, the estimated $LogK_{ow}$ of 9.26 of the registered substance indicates a bioaccumulative potential.

Therefore, ECHA concludes that Cohort 1B must be extended to include mating of the animals and production of the F2 generation because the uses of the registered substance is leading to significant exposure of industrial workers and consumers and the internal dose for the registered substance and or any of its metabolites is estimated to reach a steady state in the test animals only after an extended exposure based on the high estimated $LogK_{ow}$ of the registered substance and the OECD TG 422 study indicates modes of action related to endocrine disruption for the registered substance.

Cohort 3

The developmental immunotoxicity Cohort 3 needs to be conducted in case of a particular concern on (developmental) immunotoxicity as described in column 2 of 8.7.3., Annex IX.

ECHA notes that existing information provided in the dossier on the registered substance in the OECD TG 422 study shows evidence of immunotoxicity and severe thymus toxicity (thymus atrophy).

Upon receipt of the draft decision you submitted comments explaining that:

"The registrant agrees to get information concerning reproduction toxicity, on strength of information lack in a further generation.

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default consideration, ECHA considers that testing should be performed in rats.
ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56/ OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation; and
- Cohort 3 (Developmental immunotoxicity).

Notes for your consideration

No triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) were identified. However, you may expand the study by including Cohorts 2A and 2B if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex IX and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.0, July 2015). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

4. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"*Sediment simulation testing (for substances with a high potential for adsorption to sediment)*" is a standard information requirement as laid down in Annex IX, Section 9.2.1.4. 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.

You further state that *"Based on the physical-chemical properties and that the material is completely insoluble in inorganic and organic solvents, it is not possible to extract Dioctyltin oxide from sediment particles. Thus there is no possibility to determine whether or not Dioctyltin oxide was adsorbed. Consequently, the study is scientifically not reasonable"*.

You state that environmental screening data in the registration dossier shows that there are no dioctyltin species detectable in sediment. ECHA notes that the studies referenced refer to dioctyltin species and not to dioctyltin oxide which is the main constituent of the registered substance. The relevance of this information with regard to the distribution of the insoluble constituents of the registered substance has not been explained, therefore no conclusion can be drawn on that basis.

You also argue that the test is technically not possible due to the physicochemical properties of the registered substance. However, on the basis of the information provided ECHA does not consider that testing is technically not possible. ECHA notes that there are studies available in the registration dossier wherein constituents of the substance were detected and quantified e.g. tin analysis via ICP-MS and ICP-AES, which indicate that indirect analysis can be performed.
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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD 308) at a temperature of 12 °C.

Note for your consideration:

ECHA notes that as stated in the ECHA *Guidance on information requirements and chemical safety assessment* R.7b, chapter R.7.9 (version 2.0, November 2014) and R.11, chapter R.11.4 (version 2.0, November 2014) for example lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD 302 series would provide sufficient information to confirm persistence without the need for a further simulation test.

5. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Soil simulation testing (for substances with a high potential for adsorption to soil)" is a standard information requirement as laid down in Annex IX, Section 9.2.1.3. 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.
Column 2 of Annex IX, Section 9.2. specifies that further biotic degradation testing shall be proposed by the Registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment and may include simulation testing in appropriate media.

Note for your consideration:

ECHA notes that as stated in the ECHA *Guidance on information requirements and chemical safety assessment* R.7b, chapter R.7.9 (version 2.0, November 2014) and R.11, chapter R.11.4 (version 2.0, November 2014) for example lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD 302 series would provide sufficient information to confirm persistence without the need for a further simulation test.

6. Identification of the degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

You consider that identification of the degradation products does not need to be conducted using the following justification: "*In accordance with point 9.2.3, column 2 (specific rules for adaptation from column 1) of Annex IX of REACH (Regulation EC 1907/2006), identification of degradation products does not need to be conducted as the chemical safety assessment concludes that the substance is of no immediate concern to the environment. The available data are adequate for classification and labelling purposes and PBT assessment, further testing is therefore considered inappropriate. Also direct and indirect exposure of the soil and sediment is unlikely*".

ECHA considers that exposure of the sediment and soil compartments cannot be excluded because the substance is used in industrial, professional and consumer applications where the environmental release is likely. Wide dispersive outdoor uses are declared with roller/brushing (PROC 10) and non-industrial spraying (PROC 11) applications.
You report minimal environmental release in the chemical safety report for professional and consumer uses as a catalyst process regulator. However, ECHA considers that absence of significant releases to the environment from these uses and also from other industrial and professional uses is not demonstrated.

The substance is not readily biodegradable, is very poorly water soluble (<1.5 x 10-5 g/L) and has a high estimated logK_{ow} >9, therefore it has a high potential for adsorption to sediment and soil.

The justification for waiving provided does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.3, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

Regarding appropriate and suitable test methods, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log K_{ow} and potential toxicity of the metabolite may be investigated.

In your comments on the draft decision you state that "*Based on physico-chemicals properties of Dioctyltin oxide described and discussed in detail in section 7 – bioaccumulation in aquatic species, the expected concentrations of the substance and the degradation products will clearly below the limit of detection in all available analytical methods and devices*" and "*In the recent dossier under section 5.2.2 a study is included (US-Authorities) on the structural analogue Dioctyltin isobutylmaleinate.*

You have provided an adaptation to the standard information requirement in accordance with Annex XI section 1.5 by submitting a Klimisch 2 key study on the analogue substance dioctyltin bis(2-ethylhexyl thioglycolate).

According to Annex XI, section 1.5. of the REACH Regulation "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances*". The similarities may be based on
(1) a common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemical; or
(3) a constant pattern in the changing of the potency of the properties across the category.

You indicate that the analogue substance dioctyltin bis(2-ethylhexyl thioglycolate) will hydrolyse quickly to the registered substance in water and that exposure will be to the registered substance thus employing the adaptation possibility under point (2) of Annex XI, section 1.5. of the REACH Regulation. However, no information on the hydrolysis of the analogue substance has been provided, so similarity based on the likelihood of a common breakdown product is not demonstrated in accordance with Annex XI section 1.5. Furthermore, while there may be some hydrolysis this is not expected to be significant given the limited solubility of both the analogue substance and the registered substance. Consequently, exposure of the registered substance to the organism is expected to be minimal in this test. Finally, there is no direct measurement of dioctyltin oxide concentrations in the test provided, either in the water or in the extracted lipids so significant exposure to the registered substance in the provided test cannot be verified.

You have also provided two Klimisch score 4 QSAR studies. As these QSARs are not validated for organometallics the predictions are deemed unreliable.

Consequently, the justification for adaptation provided does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.3.2., or the general adaptation rules of Annex XI. Therefore, the adaptation 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.

ECHA considers that for substances with very low water solubility in the aquatic environment, exposure via water may be of limited relevance in comparison to the dietary route. Given the very low water solubility of the registered substance and the high estimated log K_{ow} >9 a dietary study is appropriate.

In your comments on the draft decision you state that "*The registered substance is extremely insoluble in water and has a calculated Log Kow > 9. The log KOW of the monomeric Dioctyltin oxide was calculated to be 9.26. In reality it seems, that Dioctyltin oxide occurs only in polymeric form*" and "*Base on the fact Diocyltin occurs in a minimum pentameric polymeric state, the time requirement for reach the steady state are approx 5 years for the minimum acceptable criteria according the guideline. Thus the expected time requirement for reach of the steady state is longer the life span of the fish species according to OECD TG 305 (2012) Annex 3.*

You consider that long-term testing on aquatic invertebrates is not needed using the following justification "*In accordance with point 9.1.5 column 2 (specific rules for adaptation from column 1) of Annex IX of REACH (Regulation EC 1907/2006), longterm testing on aquatic invertebrates does not need to be conducted as the chemical safety assessment concludes that the substance is of no immediate concern to the environment. The available data are adequate for classification and labeling purposes and PBT assessment, so no further testing is required*".

However, ECHA considers that exposure of the water compartment cannot be excluded because the substance is used in industrial, professional and consumer applications where the environmental release is likely. Wide dispersive outdoor uses are declared with roller/brushing (PROC 10) and non-industrial spraying (PROC 11) applications.
You report minimal environmental release in the chemical safety report for professional and consumer uses as a catalyst process regulator. However, ECHA considers that absence of significant releases to the environment from these uses and also from other industrial and professional uses is not demonstrated.

The justification for waiving provided does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.1, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

In your comments on the draft decision you state that "*Dioctyltin oxide occurs only in polymeric form*" and have provided a number of references for evidence of polymeric forms. You further argue that "*This interaction causes a very high partition coefficient and is reasonable for the complete insolubility of the Dioctyltin*" and "*It is to be assumed that the calculated pentameric form is only a "low chain" polymer of the Dioctyltin oxide. In reality higher chains contribute to the substance's properties. This explains the fact that Dioctyltin oxide is not soluble in any known solvent (including organic solvents)*".

You also state that "*Dioctyltin oxide is completely insoluble in water and based on the polarity gradient between water and test vessel, the substance would be move to the less polar medium, e.g. surface of glass or Teflon of magnetic stir bar. The OECD Guidance document 23 for "testing of difficult mixtures and substances" suggest using stock solution in organic solvents. As already discussed, Dioctyltin oxide, is not soluble in any known organic solvent. Another option is the testing of water accommodated fraction via centrifugation or filtration operation. Also this option is not technically feasible, because Dioctyltin oxide will be strongly adhere at filter, centrifugation vessel.*"

You have argued that the test is technically not possible due to the physicochemical properties of the registered substance. However, on the basis of the information provided ECHA does not consider that testing is technically not possible. While ECHA acknowledges that the properties of the substance will likely lead to difficulties in testing due to analytical limitations there are studies available in the registration dossier wherein the substance was detected and quantified e.g. tin analysis via ICP-MS and ICP-AES. Furthermore, there are acute aquatic toxicity tests in the dossier where a method of analysis was developed and used.

You also argue that there will be little exposure to aquatic organisms given the polymeric and insoluble nature of dioctyltin oxide. ECHA considers that there is presently insufficient evidence in the registration dossier to support this claim of complete insolubility due to the polymeric form of the substance. Furthermore, the water solubility values reported in the dossier contradict this claim as the values provided indicate low water solubility.

ECHA considers that exposure of the soil compartment cannot be excluded because the substance is used in industrial, professional and consumer applications where the environmental release is likely. Wide dispersive outdoor uses are declared with roller/brushing (PROC 10) and non-industrial spraying (PROC 11) applications.
You report minimal environmental release in chemical safety report for professional and consumer uses as a catalyst process regulator. However, ECHA considers that absence of significant releases to the environment from these uses and also from other industrial and professional uses is not demonstrated.

The justification for waiving provided does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According 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), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

ECHA notes that no PNEC aquatic has been derived. The justification provided is "*Dioctyltin oxide is not soluble enough to cause adverse effects in the aquatic environment*". Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

According to section R.7.11.5.3., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (estimated logKow >9) and is not readily biodegradable. Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.

In your comments on the draft decision you state that "*The exposure of the earthworm is via soil which is ingested and organic matter is absorbed and later excreted. A direct transfer via water is impossible. The GI tract of the earthworm separates the organic matter from the soil. Based on the very high partition coefficient (min. 11.8 for the polymeric) and the high molecular weight (>1000) it is not expected, that there is a resorption of Dioctyltin in the earthworm*" and "*For the exposure of terrestrial plants via soil, good water solubility of the test item is essential. As mentioned in above discussion, Dioctyltin oxide is completely insoluble. Thus the polymeric form of Dioctyltin oxide cannot be mobilized and is not available for terrestrial plants. The same applies to soil microorganisms.*

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

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 section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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).

Notes for your consideration

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.

10. Classification and labelling (Annex VI, Section 4.1.)

Article 10(a)(iv) of the REACH Regulation requires that the technical dossier shall include the classification and labelling of the substance as specified in Annex VI, Section 4 of the REACH Regulation.

In the IUCLID dossier, section 2.1. the substance is classified as STOT SE 2. However, in IUCLID section 7.5. you state that "*In accordance with the Regulation (EC) No. 1272/2008 and Directive 67/548/EEC, based on the observations in the thymus, the substance is classified as STOT Rep. Exp. 1: H372: Causes damage to organs (thymus) through prolonged or repeated exposure and T; R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed respectively.*" In the CSR the substance appears to be classified as STOT Rep. Exp. 1.

In the classification section (IUCLID 2.1.) of the dossier for STOT RE, you state *"conclusive but not sufficient for classification".*

Therefore, it is unclear which classification you consider appropriate for this substance and neither is it clear on which classification the risk measurement measures are based.

ECHA notes that thymus effects (lymphoid depletion with extensive loss of cortical and medullary small lymphocytes) were seen at very low concentration (25 mg/kg diet groups) in the OECD 422 study in female rats. This dietary concentration (25 mg/kg diet) was equivalent to 1.5-2.5 mg/kg bw/day for female animals.

One of the criteria for classification of a substance as STOT Rep. Exp. 1 is the presence of significant and/or severe toxic effects at generally low exposure concentrations: for oral exposure (rat) the guideline value to assist in STOT Rep. Exp. category 1 classification for a 90 day repeated dose toxicty study is ≤10 mg/kg bw/day. For studies of shorter duration the guidance values can be extrapolated on a case by case basis.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 13 October 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendments were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-48 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.