EUROPEAN CHEMICALS AGENCY

Helsinki, 28 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114348526-44-01/F
Substance name: diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
EC number: 278-355-8
CAS number: 75980-60-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 07/03/2016
Registered tonnage band: 100-1000T

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. **Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **At least two 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;**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31./OECD 414) in rabbits, oral route;**

3. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance;**

4. **Identification of degradation products (Annex IX, 9.2.3) using an appropriate test method with the registered substance;**

5. **Robust study summary for Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.);**

You 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **4 June 2019**. You shall also update the chemical safety report, where relevant.
The reasons of this decision are set out in Appendix 1. The procedural history is described in

Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

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.

Appendix 1: Reasons

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

Pursuant to Articles 10(a) and 12(1) 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 information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with 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. Further detailed guidance on study design and triggers is provided in in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information requirement

ECHA considers that adverse effects on reproductive organs or tissues are observed. More specifically, the available repeated dose toxicity studies (one 28-day study and two 90-day subchronic studies) consistently show effects in the testes. In the 28-day study, rats dosed at 750 mg/kg/day showed "*testicular atrophy*" while in first of the 90-day studies rats dosed at 300 mg/kg/day showed "*marked diffuse atrophy of the testicular parenchyma*" and in the second 90-day testicular toxicity study in rats dosed at 1000 mg/kg/day "*All testes showed a diffuse atrophy of seminiferous tubules with gradings of 2(slight) up to 4(severe). In 4 test animals, an edema and Leydig cell hyperplasia of minimal to slight degree were recorded in addition. All 8 epididymides with a reduced organ size were examined histopathologically and correlated with an oligozoospermia up to grade 5(azoospermia).*"

Pursuant to Annex IX, Section 8.7.3. an extended one-generation reproductive toxicity study is thus an information requirement for registrations of the registered substance.

You have sought to adapt this information requirement stating that: *"According to REACH, article 25, animal testing should only be performed as a last resort. In several repeated dose studies effects on testes have been observed. This data has been considered sufficient for classification by the RAC in 2010, leading to a harmonized classification of this substance. No significant gain of information is expected by performing a 2-generation study, and it is therefore considered unnecessary due to scientific and animal welfare reasons".*

You have applied the harmonised classification of the substance as Repr. 2 H361: Suspected of damaging fertility of the unborn child.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex IX, Section 8.7, column 2, classification to category 2 for reproductive toxicity. However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 8.7, column 2 because criteria for classification to category 1A or 1B for reproductive toxicity (H360F: May damage fertility) is required to be met before adaptation is possible.

Therefore, your adaptation of the information requirement was rejected in the initial draft decision which was sent to you for comments.

Upon receipt of the draft decision you submitted comments explaining that: *"In 2010, the RAC decided that diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide should be legally classified for adverse effects on fertility. They assigned the category 2, because former classification criteria required demonstration of the impairment of fertility in in vivo studies, which are not available for the registered substance. According to the current version of the CLP, Annex 1, 3.7.1.3. adverse effects on fertility include "alterations to the female and male reproductive system" and "adverse effects on [...] gamete production and transport". In the current case, testicular atrophy, either described as diffuse or affecting the parenchyma or eminiferous tubules, in combination with testicular weight loss and interstitial edema were observed in two 90-day studies. This confirmed the results of a previous 28-day study. The second subchronic toxicity study also reported oligo- to azoospermia in 8 of 10 males. These effects occurred in the absence of significant generalized toxicity."*

You state that on the basis of this data *"fertility will be adversely affected when mating the F1 generation in the requested OECD 443 study, since the premating exposure for the F1 generation will be sufficient to cause testicular atrophy and a reduction in the number of sperm."* Consequently you do not consider *"any new information will be gained from an OECD 443 study"* and *"that the available information is sufficient to demonstrate that the criteria for classification as Reproduction Toxicity Category 1B are met, i.e., clear evidence of severe adverse effects on male reproductive organs not secondary to systemic toxicity in animal studies. There are also no information available to show that this mechanism is not relevant to humans. According to REACH annex IX, section 8.7, column 2, no study on fertility needs to be conducted in this case."*

You also mention that you are going to contact the German competent authority to propose the change in the harmonised classification.

ECHA notes that according to the RAC opinion (2010), the category 2 was assigned using a weight-of-evidence approach based on the following elements: (i) no data available to show that the observed effects in the testes would lead to reduced male fertility or how severe that impact on fertility would be; (ii) lack of reproducible data; and (iii) no fertility tests with the registered substance. Due to these limitations the evidence was not sufficiently convincing to place the substance in Category 1 and so classification as Reproductive toxicity 2 was recommended. ECHA considers that after the RAC opinion was adopted in 2010 (i) no significant and relevant new data was made available to support the classification of 1B, and (ii) there were no relevant changes in the classification criteria, and so it is unclear on which basis you consider that the RAC would change its evaluation of the substance as category 2 for Reproductive Toxicity.

Under any circumstances, the waiver of Annex IX, Section 8.7., column 2, requires that the substance has an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment. Currently, the substance has a harmonized classification as reproduction category 2, and ECHA considers that the substance does not have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F). Therefore the proposed adaptation cannot be accepted.

As explained above, the information provided 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. Thus, an extended one-generation reproductive toxicity study according to Annex IX, Section 8.7.3., is required. The following part (b) refers to the specifications of this required study.

b) The specifications for the required study

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015), the starting point for deciding on the length of the premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required if 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 4.1, October 2015). In this specific case, animals of Cohort 1B are mated to produce the F2 generation and, thus, the premating exposure duration will be 10 weeks for these Cohort 1B animals and the fertility parameters will be covered allowing an evaluation of the full spectrum of effects on fertility in these animals. Thus, shorter premating exposure duration for parental (P) animals may be considered. However, the premating period shall not be shorter than two weeks and must be sufficiently long to reach a steady-state in reproductive organs as advised in the ECHA Guidance. The consideration should take into account whether the findings from P animals after a longer premating exposure duration would provide important information for interpretation of the findings in F1 animals, e.g. when considering the potential developmental origin of such findings as explained in ECHA guidance.

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.
If there is no relevant data to be used for dose level setting, it is recommended that results from a range-finding study (or range finding studies) 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 professionals because the registered substance is used by professionals for: mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact); transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non/dedicated facilities; and roller application or brushing (PROCs 5, 8a, 8b and 10). You are also referred to additional information from the SCCS opinion on the registered substance describing wide dispersive use by professionals.[2]

In addition, there are indications for endocrine-disrupting modes of action because of clear effects in endocrine sensitive reproductive organs (testis and epididymides) are observed in repeated dose toxicity studies.

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 professionals and there are indications of modes of action related to endocrine disruption from available studies (Repeated-dose 28-day oral toxicity study in rodents ([redacted]); Repeated-dose 90-day oral toxicity study in rodents ([redacted]); and Repeated-dose 90-day oral toxicity study in rodents ([redacted])).

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

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 assumption, 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 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a powder, ECHA concludes that testing should be performed by the oral route.

c) Outcome

Based on the available information, 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:

[2] The SCCS opinion is available in the Internet at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_149.pdf

- At least two 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;

Notes for your consideration:

Currently, Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) are not requested.

However, you may expand the study by including Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. This includes information available from the requested extended one-generation reproductive toxicity study such as early results related to hormone-sensitive endpoints (e.g. the anogenital distance and retention in male offspring of nipples/areolae) as well as considering the effects from repeated dose toxicity studies and any other relevant information.. 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 4.1, October 2015): e.g. for DNT: abnormalities observed in the central nervous system or nerves; any signs of behavioural or functional adverse effects on the nervous system; specific mechanism/mode of action that has been closely linked to (developmental) neurotoxic effects; and for DIT: abnormalities/functional adverse effects observed in the immune system; specific mechanism/mode of action that has been closely linked to (developmental) immunotoxic effects.

You may also expand the study 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.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2) in a second species

Pursuant to Articles 10(a) and 12(1) 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 information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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. Annex IX, Section 8.7.2., column 2 provides that the decision on the need to perform a pre-natal developmental toxicity study on a second species at a tonnage level of 100 to 1000 tonnes per year should be based on the outcome of the first test and all other relevant and available data. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier contains a pre-natal developmental toxicity study in rats by the oral route. This study fulfils the standard information requirement for a pre-natal developmental toxicity study in a first species (Annex IX, Section 8.7.2.).

However, with reference to Annex IX, Section 8.7., column 2, ECHA sees a need to request a pre-natal developmental toxicity study with a second species. According to the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6.2.3.2 (version 4.1, October 2015), a study on the second species is necessary since the pre-natal developmental toxicity study, with the rat species, shows prenatal developmental toxicity.

The observed effects are not sufficient for the substance to meet the classification criteria to Category 1B but they cause further concern for prenatal developmental toxicity. Another pre-natal developmental toxicity study on the second species is needed for a comprehensive evaluation of prenatal developmental toxicity, including determination of the classification category.

The reported NOAEL for maternal toxicity and developmental toxicity is 150 mg/kg bw/day, on the basis of the effects of reduced body weight and bent limb bones and ribs, respectively. All foetuses at the highest dose level had bent limb bones and bent ribs and the incidence of skeletal variations were increased. ECHA notes that the bent limb bones should not be considered as simple temporary variations. According to the study only a small percentage of the litter that had retarded skeletal ossification and lower foetal body weights were considered to be related to the decreased maternal body weights (-7%). Hence, the delayed ossification seems not to be clearly secondary to maternal toxicity (decreased maternal body weights). ECHA agrees with you that though this information from the PNDT in rats "*might still indicate a teratogenic potential*" and is sufficient to meet classification criteria to Category 2 reproductive toxicant, it "*is not considered sufficient evidence to warrant classification into category 1B*". However, the findings of this pre-natal developmental toxicity study in rats require further investigation to fully determine the classification of this test substance.

In the comments to the draft decision you disagreed with the information request mainly because of the effects observed in the pre-natal developmental toxicity study in rats, which have not been considered as being "*severe enough*". According to you "*since no substance specific data exist, classification with category 2 seemed warranted*" and "*there are currently no reasons to believe that different effects would be observed in rabbits*".

With reference to your comments to request no. 1 for an extended one generation reproductive toxicity study, you again mention "*that the substance already fulfils the criteria for classification into category 1B for fertility*". "*The developmental toxicity study in the first species was proposed (and performed) to exclude that teratogenic effects occur at lower doses than those affecting fertility*". Moreover you indicate that the "*NOAEL and LOAEL values for developmental effects are higher than those for effects on fertility*" and that "*the available DNELs based on effects on fertility thus cover the effects on the unborn child.*" Consequently, according to you "*there is no advantage in performing an additional teratogenicity study in the rabbit*".

ECHA refers to the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6.2.3.2 (p.372-373) (version 4.1, October 2015). The observed developmental effects in the rat study were not considered to be sufficient to meet the classification criteria to 1B reproductive toxicant however they are still considered as being triggers and indications of pre-natal developmental toxicity.

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.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is 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 rabbit as a second 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 rabbits] by the oral route.

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

Pursuant to Articles 10(a) and 12(1) 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 information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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 simulation testing on ultimate degradation in water in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2.

Instead you have provided an adaptation: "*Biodegradation in a water screening test demonstrated that there was no substantial microbial metabolism of the submission item. Therefore, it is likely that the submission item also does not significantly degrade in sediment and soil*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.2, column 2 because the respective adaptation conditions are not fulfilled. The registered substance is not shown to be readily biodegradable (screening test OECD TG 301F (0-10% in 28d)) and the water solubility is reported to be 11.9 mg/l at 20 °C which cannot be considered as highly insoluble. In addition, in the IUCLID section 5.1.2, hydrolysis, you state that "*The submission item does not contain easily hydrolysable functional groups and is therefore considered stable in aquatic media*".

ECHA notes that you have not provided any justification in the chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision you state that "*The information available on the biodegradation of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide demonstrates very poor transformation of the registration item. It is very likely that, under the conditions of a study according to OECD 309, no substantial biodegradation will be observed as well. Consequently, the evaluation of the P criterion in the context of the PBT and the vPvB assessment, respectively, will likely have the same result as the current one, which is that the P criterion is fulfilled. However, as the registration item clearly does not fulfill neither the B nor the vB criteria, the overall conclusion is – and will remain – that diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is neither a PBT nor a vPvB substance.*

Furthermore, a risk assessment has been performed for the registration item, demonstrating the safe use of the substance throughout its entire lifecycle. To predict environmental exposure from the uses of the substance, worst case defaults have been used for the degradation rates in the model. Therefore, the resulting estimates are maximally conservative. Half-lifes that may be derived from a study according to OECD 309 will therefore not lead to higher RCRs, i.e. not to RCRs exceeding the threshold of 1 indicating unsafe uses."

ECHA notes that the evaluating member state for this substance under substance evaluation has indicated a concern for terrestrial bioaccumulation in their justification document[3] for the selection of a CoRAP substance which states that "*The available information on bioaccumulation shows that the substance does not fulfill the screening criteria for B (log KOW values > 4.5) as the available experimental log KOW value is 3.1 and a QSAR value is 3.87 (KOW = octanol/water partition coefficient). A Fish bioaccumulation study indicates that the bioconcentration factor is below the criterion for B. Therefore, the substance does not indicate a concern for aquatic bioaccumulation. However log KOA value is high (12.3 estimated by KOAWIN), indicating possibility for terrestrial bioaccumulation (KOA = octanol/air partition coefficient)*". The substance already fulfils the T criterion on the basis of a harmonized classification for Rep. Tox. Cat 2. Consequently, ECHA considers that simulation testing is relevant in the context of PBT assessment. Additionally, as outlined above, there is no adaptation provided in accordance with Annex XI, 9.2.1.2 column 2.

As explained above, the information provided 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, Chapter R.7b* (version 3.0, February 2016) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment".

[3] http://echa.europa.eu/documents/10162/2e3e22bc-0d69-403e-9b21-ae871fdd0587

The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

Notes for your consideration:

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

4. Identification of degradation products (Annex IX, 9.2.3) using an appropriate test method with the registered substance

Pursuant to Articles 10(a) and 12(1) 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 information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

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.

The results of the ready biodegradability test according to OECD TG 301 F, that you have submitted to ECHA, indicates that the registered substance is not readily biodegradable (0-10% in 28days). Furthermore, you have not provided any information on the degradation products in your registration.

As explained fully in section (3) above, ECHA considers that you have not in your CSA nor in the technical dossier justified why there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

As explained above, the information provided 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.

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. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration:

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Chapter ECHA Guidance on information requirements and chemical safety assessment Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

5. Robust study summary on short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Pursuant to Articles 10(a) and 12(1) 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 information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. 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.

In the technical dossier you have provided a study record for a JIS K 0102-1986, 71 "Bioaccumulation study in Carp on Lucirin LR 8728". However, the summary provided is not sufficiently detailed as to allow an independent assessment of the study performed and so cannot be considered a robust study summary as defined by Article 3 of the REACH Regulation.

As explained above, the information provided 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 a robust study summary for the short term toxicity to fish test provided in the registration dossier.

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 18 March 2016.

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 did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) 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-50 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. 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 your Member State.

4. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new test(s) 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 or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.