EUROPEAN CHEMICALS AGENCY

Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350487-44-01/F
Substance name: 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one
EC number: 216-133-4
CAS number: 1506-02-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28.02.2014
Registered tonnage band: 1000+T

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. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance;**

2. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance:**
   - **10 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;**

3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species, rabbit, oral route with the registered substance;**

4. **Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD TG 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance;**

5. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) with the registered substance.**

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.

EUROPEAN CHEMICALS AGENCY

You are required to submit the requested information in an updated registration dossier by **21 June 2019**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained. ECHA notes that the registration dossier contains negative results for both these information requirements. Therefore, adequate information on in vitro gene mutation in mammalian cells 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 an *Unscheduled DNA synthesis (UDS) assay in rat primary hepatocytes with the test substance according to OECD TG 482*. However, this study does not provide the information required by Annex VIII, Section 8.4.3., because the UDS test is an indicator test measuring DNA repair of primary damage in liver cells but not a study investigating gene mutations per se. The UDS test can detect some substances that induce *in vivo* gene mutation because this assay is sensitive to some (but not all) DNA repair mechanisms. However not all gene mutagens are positive in the UDS test and this test is thus useful only for some classes of substances. A negative result in a UDS assay alone is not a proof that a substance does not induce gene mutation.

You have also provided an *in vivo* study on mammalian erythrocyte micronucleus according to OECD TG 474. Since the *in vivo* study provided does not cover gene mutation, the adaptation described in column 2 of Annex VIII, Section 8.4.3., does not apply.

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.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

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: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490).

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X 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 X. If the conditions described in column 2 of Annex X 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 the 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 provided

You have sought to adapt this information requirement according to Annex XI, Section 1. You provided the following justification for the adaptation:

"*In accordance with section 1 of REACH Annex XI, the 2-generation reproductive toxicity study for AHTN is waived based on the already available information and because this study will not provide additional needed information for the endpoint reproductive toxicity.*" and

"*that conducting an additional animal test for investigating reproductive toxicity will not be necessary, because the already available information is enough for assessing this endpoint.*"

You developed your argumentation using the data from the studies provided in the dossier, an enhanced OECD TG 408, an oral developmental study with rats (OECD TG 414) showing no effects on reproduction and provided information regarding the potential for endocrine disruption:

"*In addition to these conducted studies, in vitro assays showed very weak estrogenic and anti-estrogenic potency between 0.01 and 10 µMol/l, using a variety of cell lines. Marginal repressing effects were also found in vitro on the androgen and progesterone receptor. However, no estrogenic effects were observed in the mouse uterotrophic assay (according to the protocol of* [redacted] *1987) at 50 and 300 mg AHTN in the diet for two weeks."*

Furthermore, you provided a literature review analysis and concluded that:

"*The overall available information on AHTN for investigating reproductive effects (90-day, developmental toxicity, in utero exposure and F1 and F2 assessment, in vitro and in vivo screening assays on receptor binding) all show low toxicity. The available information does not warrant further reproductive toxicity testing and C&L.*
Conducting a two-generation study is not needed and would only limitedly add information on the potential of reproductive toxicity for AHTN. "

and:

"*the 2-generation reproductive toxicity study for AHTN is waived based on the already available information and because this study will not provide additional needed information for the endpoint reproductive toxicity.*"

You proposed to use a weight-of-evidence approach. ECHA has evaluated you proposal against the requirements in Annex XI, 1.2.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex XI; Section 1.2 as will be described in the following paragraphs:

The weight-of-evidence is based on the assumption that the registered substance has a "*low toxicity*" when investigating reproductive effects. ECHA emphasizes that assumptions of "*low toxicity*" and that "*Conducting a two-generation study is not needed and would only limitedly add information on the potential of reproductive toxicity*" *per se* are not sufficient to omit this information at Annex X because those assumptions do not meet any adaptation criteria following column 2 of Annex X, Section 8.7.3 or Annex XI rules. In particular, the use of weight-of-evidence approach to omit this test requires that absence or presence of dangerous (hazardous) properties with respect to sexual function and fertility and developmental toxicity should be demonstrated by using several independent sources of information, which are sufficient to support this notion (as specified in Annex XI, Section 1.2, of the REACH Regulation).

You have provided the following studies to support your adaptation: 90-day oral toxicity study in rats with screening of reproductive parameters (enhanced OECD TG 408), oral developmental toxicity study with rats (OECD TG 414), oral peri/postnatal toxicity study *in utero* exposure and F1 and F2 assessment (exposure of the F1 generation was only *in utero* during the perinatal phase or through transfer in the milk of the lactating dams), *in vitro* and *in vivo* screening assays on receptor binding. The following observations were noted:

- *"no effects on reproductive organs of male or female rats were seen at doses up to 50 mg/kg bw/day";*
- *"developmental toxicity was not seen at the highest dose administered 50 mg/kg bw/day";*
- *"no reproductive effects were observed in the dams or their F1 and F2 offspring at the highest dose tested, 20 mg/kg bw/day."*
- *"very weak estrogenic and anti-estrogenic potency"*
- *"no estrogenic effects were observed in the mouse uterotrophic assay"*

ECHA has assessed the weight of each of these lines of evidence separately and together, and the conclusions of this assessment within the meaning of Annex XI, section 1.2. of the REACH Regulation are reported below:

- The enhanced repeated dose toxicity study does not provide any information with regard to functional fertility or any information on effects in the offspring after *in utero* and postnatal exposure. The repeated dose toxicity studies may provide information on histopathological observable effects in adult reproductive organs and the exposure is limited to adult animals without reproduction phases.
- The pre-natal developmental toxicity study focuses on investigations on developmental toxicity due to in utero exposure and does not provide information on sexual function and fertility in relation to mating up to the implantation or any information on effects on gonads. Furthermore it does not address the sexual function and fertility of males or parturition and nursing and lactation of the females. It also lacks information on post-natal effects and addresses only limited life stages and phases of reproduction, namely from implantation to near the end of gestation.
- The study provided on the effects on peri- and post-natal development including maternal function in the rat ([redacted], 1996), investigates both the F1 and F2 generations. However, the exposure period is very limited and does not cover the life stages and exposure duration of an extended one-generation reproductive toxicity study. In the study provided by you, exposure to the test substance was only started from "

Day 14 of pregnancy (end of organogenesis) through to weaning on Day 21 Post-partum". Moreover, "*the only exposure the F1 generation had to the test substance was in utero during the peri-natal phase or through any transfer in the milk of the lactating dams*." Thus, exposure during relevant life stages for a comprehensive reproductive toxicity study was not included. Since in this case the extension of Cohort 1B is triggered, the exposure to the test substance had to be from premating, through mating, pregnancy, lactation of P generation, postnatal period of F1 generation until post-natal period of the F2 generation. In addition, many parameters relevant to Annex X, section 8.7.3 seem to be lacking. The study submitted by you ([redacted], 1996), fails to provide some of the extensive investigations after relevant exposure, such as histopathology, weight of reproductive and non-reproductive organs), haematology and clinical chemistry of P and F1 generations.

- The results of the *in vitro* and *in vivo* screening assays in relation of endocrine modes of action do not provide adequate information to conclude on hazardous properties on reproduction. They may give indications of involvement of certain limited endocrine modes of action.
- Taking together, the information provided does not adequately address the various aspects of reproduction to the extend necessary at Annex X, Section 8.7.3 to conclude on hazardous properties of a substance regarding to reproductive toxicity. Although exposure is covered for adult non-mating animals (OECD TG 408), main part of gestation (OECD TG 414), and postnatal period up to the weaning in F1 animals (peri/postnatal study), critical phases are missing such as mating, early pregnancy before and up to implantation, development and sexual function and fertility of F1 generation after weaning.

Taking into account the above limited information provided on reproductive toxicity, ECHA considers that your conclusion that "*the 2-generation reproductive toxicity study for AHTN is waived based on the already available information and because this study will not provide additional needed information for the endpoint reproductive toxicity*" is not adequately supported by the data, and it cannot be assumed/concluded that the substance has or has not effects on sexual function and fertility and development in relevant generations.

Therefore, your adaptation of the information requirement is rejected.

Hence, 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 Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

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 ECHA Guidance, the starting point for deciding on the length of 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 ten weeks exposure duration is supported 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.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a conducted 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 X 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 consumers and professionals because the registered substance is used by professionals as cleaning and maintenance products (PROCs 8a, 8b, 10, 11) and by consumers as scented articles / cleaning products / air care products among others.

In addition, there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure (the substance has a log Kow > than 4.5 and hence potential for bioaccumulation).

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 consumers, and there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure.

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 crystalline solid, ECHA concludes that testing should be performed by the oral route.

c. 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:

- 10 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

No triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the Cohorts 2A and 2B and/or Cohort 3 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 X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 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.

3. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on two pre-natal developmental toxicity studies in rats by the oral route using the registered substance as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

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.

The test in the first species was carried out by using a rodent species (rat). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

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 solid, ECHA concludes that testing should be performed by the oral route.

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 TG 414) in a second species (rabbit) by the oral route.

4. Long-term toxicity testing on plants (Annex X, Section 9.4.6)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification: "*In accordance with column 2 of REACH Annex IX, long-term toxicity studies were considered in view of the high potential to sorb to soil. Long-term toxicity tests on terrestrial organisms are available for 2 invertebrate species covering different taxa and sensitivities. As in the aquatic environment plants (algae) were the least sensitive, further tests on terrestrial plants were not performed. It was considered that controlling the risks to the more sensitive terrestrial invertebrates is also protective for controlling the risks to plants.*"

However, your justification for waiving does neither meet the specific criteria for adaptation of Column 2 of Annex X, Section 9.4 nor the general adaptation rules of Annex XI. According to Column 2 of Annex X, Section 9.4, "*These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.*" ECHA notes that the substance has professional and consumer wide dispersive uses (ERC 8a, 11b. Wide dispersive use indoor), for which exposure to soil cannot be excluded. Vapour pressure is 0.0682 Pa at 25C, and it is potentially very adsorptive (log Kow 5.4 & log Koc between 3.7 and 4.13 in soil). Therefore, the 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 ($logK_{ow}$ [5.4]).
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.
ECHA notes that long-term tests are suitable to simultaneously address the information requirements of section 9.4. of Annexes IX and X.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing long-term toxicity tests according to the information requirements of Annex X and that the lowest value obtained should be used to derive the PNEC soil.

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

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: Terrestrial plants, growth test (test method: OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification: *"In accordance with column 2 of REACH Annex IX, long-term toxicity studies were considered in view of the high potential to sorb to soil. Long-term toxicity tests on terrestrial organisms are available for 2 invertebrate species covering different taxa and sensitivities. As in the aquatic environment no effects were observed up to the water solubility limit, further tests on terrestrial micro-organisms were not performed. It was considered that controlling the risks to the more sensitive terrestrial invertebrates is also protective for controlling the risks to the terrestrial microflora."*

However, your justification for waiving does neither meet the specific criteria for adaptation of Column 2 of Annex X, Section 9.4 nor the general adaptation rules of Annex XI. According to Column 2 of Annex X, Section 9.4, "*These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely*." ECHA notes that the substance has professional and consumer wide dispersive uses (ERC 8a, 11b. Wide dispersive use indoor), for which exposure to soil cannot be excluded. Vapour pressure is 0.0682 Pa at 25C, and it is potentially very adsorptive (log Kow 5.4 & log Koc between 3.7 and 4.13 in soil). Therefore, the 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that the tests on terrestrial invertebrates you provided in the technical dossier and the test requested under point (4) above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

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 TG 216).

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 25 May 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 did not receive any comments by the end of the commenting period.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In carrying out the tests required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the tests to be assessed.