EUROPEAN CHEMICALS AGENCY

Helsinki,19 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114360352-57-01/F
Substance name: reaction mass of (1S,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate, (1R,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate and 2-methyl-2-{[(1R,2R)-2,6,6-trimethylcycloheptyl]oxy}propyl propanoate
EC number: 604-250-7
CAS number: 141773-73-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08.05.2013

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. **Name(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.) of the registered substance;**

2. **Composition of each substance (Annex VI, Section 2.3.) of the registered substance;**

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

4. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD TG 408) in rats with the registered substance;**

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

6. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method:**
   a. **Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or**
   b. **Enchytraeid reproduction test, OECD TG 220, or**
   c. **Collembolan reproduction test in soil, OECD TG 232), or,**

   Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2; test method:
   d. **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,**
   e. **Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030)**

with the registered substance;

7. **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.

You are required to submit the requested information in an updated registration dossier by **27 May 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/web/guest/regulations/appeals.]

Authorised[2] by Claudio Carlon, Head of Unit, Evaluation E2

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

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

IDENTIFICATION OF THE SUBSTANCE

In order to ensure that potential hazardous properties of substance are not underestimated, the information that is necessary to resolve the substance identification deficiencies, below, must be available to you before identifying the test sample to be used for the testing requested in the present decision.

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

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

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that you identified the registered substance as multi-constituent with the chemical name "*reaction mass of (1S,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate, (1R,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate and 2-methyl-2-{[(1R*,2R*)-2,6,6-trimethylcycloheptyl]oxy}propyl propanoate*" and the CAS entry with CAS number 141773-73-1 associated to the list number 604-250-7. Furthermore, in the description and synomyms fields another identifier referring to ELINCS number 415-490-5 and name "Helvetolide" is mentioned to identify the substance.

ECHA points out that the identity of the substance is not clear as inconsistent information has been provided. The CAS name and number used for defining the registered substance refer to a substance containing all the possible isomers of "[redacted]". However, the submitted chemical name describes a substance containing 2 specific enantiomers of "[redacted]" also with a constituent containing several "[redacted]" isomers.
Therefore the CAS identifiers and the chemical name given to the registered substance are not consistent as they refer to different substances.

You are accordingly requested to provide appropriate identifiers corresponding to the specific multi-constituent substance covered in this registration. The chemical name shall follow the generic format "Reaction mass of [names of the main constituents]". All main constituents present in the registered substance shall be reflected in the name of the registered substance. All the constituents present at a concentration <10% (w/w) should be listed under the impurities and not be part of the name. You shall also specify any available and appropriate CAS number and name reflecting the identity of the main constituents of the substance. You shall delete from the registration any information referring to different substances than the multi-constituent substance which is the subject of this registration.

You shall ensure that the identifiers are consistent with the composition required to be provided according to Annex VI, Section 2.3.

You shall note that in accordance with the criteria for substance sameness specified in the Guidance for identification and naming of substances under REACH and CLP (Version: 2, December 2016) - referred to as "the SID Guidance", multi-constituent substances with different main constituents shall be regarded as different substances under REACH.

You shall note that the registration is currently linked to chemical identifiers (including the list number 604-250-7) for the substance "[redacted]". Should the substance intended to be covered by this registration refer to a different substance, you can however not remove or modify at this stage identifiers such as the list number for technical reasons, the registration being linked to that number in REACH-IT. To ensure unambiguous identification of the registered substance, you shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The list number 604-250-7 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

However, pending the resolution of all the incompliances highlighted in the present decision, the adaptation of the identifier can only be effective once ECHA is at least in a position to establish unambiguously the identity of the substance intended to be covered by the Registrant with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when the identifier adaptation process shall be initiated.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise Section 1.2 of your IUCLID dossier addressing the information requirement in an update of the registration. ECHA will examine such information only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted.
However, following a quick screening of the dossier updated submitted on 27/05/2016 (submission number [redacted]), ECHA points out that the revised chemical name provided in the IUPAC name field in IUCLID section 1.1 is still inconsistent with the CAS entry as "[redacted]" refers also to [redacted] derivatives, whereas the CAS entry refers to [redacted] derivatives only.

Therefore, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements and the request of this draft decision is not amended.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

2. Composition of the substance (Annex VI, Section 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

In accordance with the Guidance, a multi-constituent substance is a well-defined substance consisting of several main constituents present at concentrations generally ≥ 10% and < 80% (w/w). All constituents (except additives) which are not the main constituents in a multi-constituent substance are considered to be impurities.

According to the manufacturing process description reported by you in section 3.1[1] of the IUCLID dossier, the registered multi-constituent substance is obtained by [redacted]. You furthermore specified in the Remarks field of the reference substance assigned in IUCLID section 1.1 that, besides [redacted]

The composition reported in section 1.2 of the IUCLID dossier is overall consistent with this statement from you. However, due to certain inconsistencies in the stereochemistry of the reported constituents, further compositional information of the registered substance is necessary, as required under Annex VI, Section 2.3 of the REACH Regulation.

ECHA observes that the identifiers and the stereochemistry of the first and second constituents are unclear as the submitted information is inconsistent. In IUCLID section1.2,

- For the constituent with chemical name [redacted] the IUPAC name refers to (1S,1R) enantiomer however the SMILES and InChI notation refer to (1R,1R)-isomer and the structural formula to (1S,1S)-isomer.
- For the constituent with chemical name "[redacted]" the IUPAC name refers to the racemate (RS) and the structural formula refers to the (1R,1R)-isomer, whereas the SMILES and InchI notation refer to the (1S,1R)-isomer.
- The constituent identified as [redacted] refers to the racemate and the related structural information is provided for the (1R,2S)-stereoisomer only.

Furthermore, this latest constituent is reported both as a constituent with a typical concentration of [redacted] % w/w and as an impurity with the typical concentration [redacted] % w/w. Information on the concentration of the individual stereoisomer has not been specified in the IUCLID dossier.

As a result ECHA cannot confirm the identity of the registered substance and concludes that the compositional information has not been provided to the required level of detail.

You are accordingly requested to revise the consistency of all the identifiers of the constituents and to clarify the stereochemistry of the constituents reported in the composition of the registered substance, for ECHA to have a complete chemical representation of what the substance consists of.

[1] IN IUCLID 6 this information is in section 1.2

Regarding how to report the composition in IUCLID, the following applies: You shall report separately all individual stereoisomers present in the substance under the appropriate headers of the composition (the "constituents" header for the main constituents and the "impurities" header for the other constituents). For each stereoisomer, at least one of the following identifiers shall be specified: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in IUCLID section 1.2.

Further technical details on how to report the composition of multi-constituent substances in IUCLID are available in paragraphs 2.1 and 2.2.1.2 of the Data Submission Manual 18 on the ECHA website.

You shall ensure that the reported composition is verifiable and therefore supported by a description of the analytical methods for the identification of the registered substance, as required under Annex VI, Section 2.3.7.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise Section 1.2 of your IUCLID dossier addressing the information requirement in an update of the registration. ECHA will examine such information only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted.
However, following a quick screening of the dossier updated submitted on 27/05/2016 (submission number [redacted]), ECHA points out that the revised composition reported in section 1.2 still contains inconsistent information (e.g. molecular structures vs SMILES and InChI notation of all the constituents). In addition one constituent has been reported also among the impurities. Therefore, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements and the request of this draft decision is not amended.

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

Annex VI, Section 2.3.7 of the REACH Regulation requires that each registration dossier contains a sufficiently detailed description of the analytical method used for establishing the composition of the registered substance and therefore its identity. This information shall be sufficient to allow the method to be reproduced.

ECHA notes that you have not provided sufficient information and appropriate description of the analytical methods used to determine the identity and composition of the registered substance. Specifically, you have provided a full set of analytical data (IR, UV, NMR and GC/MD). However, the information provided in the file "[redacted]" is not sufficient for the identification and quantification of the stereochemistry of constituents present in the composition of the substance and their respective concentration values.

You provided a gas chromatographic analysis (GC) with a chromatogram which shows several major peaks to quantify the substance. However, it is not clear how the assignment of the peaks refers to the stereoisomers present in the composition of the substance. Furthermore, the description of the methods with details of calibration and calculation used to identify the peaks and determine the concentration and the stereochemistry of the constituents were not included in the dossier.

Consequently the registration does not include sufficient description of the analytical methods required for the identification and quantification of the registered substance.

In accordance with Annex VI, Section 2.3.7, you are therefore requested to provide a description of methods used for the identification and quantification of the registered substance including its constituents. This information shall be sufficient to enable the substance identity in IUCLID section 1.1 of the dossier and all constituents reported in IUCLID section 1.2 to be verified. The information is required to be sufficient for each method to be reproduced and shall include details of the experimental protocol followed, the calculations used and the results obtained.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise Section 1.4 of your IUCLID dossier addressing the information requirement in an update of the registration.
Following a quick screening of the dossier updated submitted on 27/05/2016 (submission number [redacted]), ECHA points out that the information in the file "[redacted]" provides the explanation how the composition has been determined. However, some points remain unclear, i.e. what compounds named 1, 4, 6, 7 and 8 refer to; why the MS spectra of peak 5 and 6 are identified with the same name, i.e. [(1RS,2RS)...]. Therefore, ECHA considers that this updated analytical information is in line with the information requirements in the draft decision.

However, due to the remaining unclear issues described before, and because ECHA will examine such information only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted, the request in the DD is not amended.

PROPERTIES OF THE SUBSTANCE

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

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 "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

You have sought to adapt this information requirement. You provided the following justification for the adaptation: "study scientifically unjustified". You argued that, "in conclusion, Helvetolide is unreactive (lack of local effects and mutagenicity), only slightly soluble, and not inhalable as vapours at ambient temperature, the latter two being indicators of low exposure potential.

There was no evidence of toxicity in a 28-day and a one-generation toxicity studies up to 1000 mg/kg bw/day. Therefore, although absorption potential is expected, it is not deemed necessary to perform a 90-day study."

While you have in the technical dossier not explicitly referred to any specific adaptation mentioned in the REACH Regulation, you have provided information that could be interpreted as an attempt to adapt the information requirement in accordance with Annex XI of the REACH Regulation. You claim that the study is scientifically unjustified and thus you may wish to refer to Annex XI, Section 1 (Testing does not appear scientifically necessary). As neither Annex XI, Section 1.1 (Use of existing data) nor 1.3 (Qualitative or Quantitative structure-activity relationship) nor 1.4 (in vitro methods) nor 1.5 (grouping of substances and read-across approach) applies, you most probably refer to Annex XI, Section 1.2 (Weight of evidence, WoE). Further, the arguments brought forward by you may also indicate that it was your intention to refer to the adaptation possibility of Annex IX, Section 8.6.2, column 2 of the REACH Regulation. Therefore ECHA has analysed these adaptation possibilities for the registered substance as follows.

Weight of evidence (WoE) approach according to Annex XI, Section 1.2:

In a WoE approach there has to be sufficient evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion. However, ECHA notes that this adaptation, with your conclusion as cited above, does not meet the general rules for adaptation of Annex XI, Section 1.2. because of the reasons outlined below.

You have provided in your technical dossier data on an oral 28-day repeated-dose toxicity study and on an oral one-generation reproductive toxicity study, both studies performed in rats. ECHA notes that the oral 28-day study has a shorter exposure duration, as compared to the information requirement (90-days), and is insufficient to fulfill the information requirement on its own for this reason. In the one-generation study, the duration of administration exceeded 90 days for males, but was less than 90 days for females. Furthermore, less organs and tissues were taken and examined histopathologically in the one-generation study than required for a 90-day study (12 tissues versus some 45 tissues which are required for a 90-day study). Haematological and clinical chemical examinations (showing some effects in the 28-day study, although considered as toxicologically not relevant by the Registrant) have also not been performed in the one-generation reproductive toxicity study. In conclusion, the data for the one-generation study does not have adequate and reliable coverage of the key parameters foreseen to be investigated in the test method of a 90-day study, in particular information on histopathology of organs and tissues and on haematological and clinical chemical parameters, and so the data for the one-generation study is insufficient to fulfill the information requirement on its own for this reason.

ECHA notes that there are particular concerns for more potent effects with increasing exposure duration. Target organs in both studies were kidneys and liver and there was dose-response relationship. Whereas there were no findings in the 28-day study at a dose of 250 mg/kg body weight, there were findings in these organs in the one-generation study at the same dose This indicates that the substance causes effects at lower doses when administered for longer exposure duration.

You argue that no additional adverse effects were observed in the one-generation study compared to the 28-day study. However, in addition to the greater potency of effects seen in the one-generation study (see the paragraph above), additional effects may not have been detected because they have not been investigated (histopathology, haematological and clinical chemical parameters) as also noted above. Thus ECHA considers that the claim of '*no additional adverse effects were observed in the one-generation study compared to the 28-day study*' is not supported by the data provided.

ECHA considers that the elements of the argument that you have provided, "*Helvetolide is unreactive (lack of local effects and mutagenicity), only slightly soluble, and not inhalable as vapours at ambient temperature, the latter two being indicators of low exposure potential. There was no evidence of toxicity in a 28-day and a one-generation toxicity studies up to 1000 mg/kg bw/day.*

Therefore, although absorption potential is expected, it is not deemed necessary to perform a 90-day study", do not provide a reliable basis on which to conclude there is sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property (90-day repeated dose toxicity).

Specifically, ECHA considers that the 'unreactive' nature of the substance, its slight solubility and lack of inhalability provide negligible reassurance as to the properties of the substance in 90-day repeated dose toxicity, particularly in view of the demonstrated toxic effects of the substance in 28-day and one-generation studies. ECHA considers that the data from the 28-day and a one-generation toxicity studies provide evidence of toxicity at doses including 1000 mg/kg (specifically, liver, kidney and thyroid effects), and that this argument and data about the level of toxicity seen in a 28-day and a one genereration study do not anyway provide a valid reasoning whereby there is sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property (90-day repeated dose toxicity), such that the shortcomings of the individual studies to fulfil the information requirement (as outlined above) can be addressed.

In summary, for all the arguments and data provided, ECHA considers that the requirements for the adaptation in accordance with Section 1.2 of Annex XI are not met as there is not sufficient evidence from several independent sources of information leading to the assumption/conclusion that the registered substance has or has not a particular dangerous property and your weight of evidence adaptation of the information requirement cannot be accepted.

In your comments to the draft decision, you have provided a further weight of evidence adaptation using arguments under the titles 'Study Duration', 'Key Parameters', 'Potency of Effects', and 'Additional Effects') and conclude:

"The registrant firmly believes that the weight of evidence from the two available studies demonstrate that the substance is not toxic after sub-acute (28-days) and sub-chronic exposure (77 or 126 days). The effects observed in these two studies (increased liver weight, kidney weight in males, and thyroid weight) are all well recognised adaptive responses that are considered to be non-adverse (ECETOC TR0085, 2002). Indeed, the evidence of these two studies suggests that these adaptive responses may indeed diminish with duration of dosing. Consequently, the absence of histopathological data for some tissues is considered to be not relevant to the overall toxicological assessment of this substance and insufficient justification to use a further 80 animals in another study.

The two different study directors both reached the same conclusion, that the NOAEL for this substance is 1000 mg/kg and it may be predicted with a high level of confidence that the same result would be achieved in an OECD 408 study."

ECHA addresses each of these titles, as follows:

Study Duration

ECHA agrees that the study duration for males in the 1-generation study (OECD 415) was comparable or even longer than required by the test method OECD 408. While females were dosed for 77 days, the OECD guideline requires that "[t]he test substance is orally administered daily in graduated doses to several groups of experimental animals, one dose level per group for a period of 90 days." The 77 day exposure to females is therefore not compliant with the OECD 408 Test Guideline.

ECHA also pinpoints that in the draft decision sent to the Registrant the number of tissues/organs to be evaluated in a 90-day study has been compared to the corresponding number of tissues/organs examined in the 1-generation study, and not to the number of tissues/organs examined in the 28-day study, as erroneously written by the Registrant.

Key Parameters

As described above in the decision, histopathological examination performed for the 1-generation study does, in the view of ECHA, not cover the key parameters for a sub-chronic (90-day) study. You also address the histopathology of the 28 day study in comparison to requirements for a 90 day study. ECHA notes that histopathology of the following organs, required for a 90 day study, is missing in the 28-day study: pituitary, parathyroid, oesophagus, salivary gland, pancreas, aorta and female mammary gland.

You have proposed that histopathological examinations in the one-generation study cover all key target organs, but ECHA notes that in the 28-day study a statistically significant increase in absolute and body weight-related thyroid weights was apparent in males dosed at 1000 mg/kg bw/d, and although all treated females showed an increase in bodyweight related thyroid weights, no data for thyroid weights or histopathology of the thyroid is available from the 1-generation study. Thus all known target organs are not examined in the one-generation study.

Furthermore, ECHA rejects your implicit argument that the examination of organs in a 28-day study is sufficient to identify all the histopathological effects that would be seen after 90-day exposure. The information stemming from the 28-day study and from the 1-generation study is not sufficient to address all key elements of a sub-chronic (90-day) study.

Potency of effects

ECHA acknowledges your comment, which provides information on relative liver weight as an indication that effects are more potent in the 28-day study, as compared with the one-generation study. ECHA does not accept the proposed interpretation of the relative liver weight information, and considers that the transience of the effect, and the age of the animal, are important variables which are not taken into account, and invalidate your conclusions.

Furthermore, ECHA disagrees with your comment on the kidney findings:

- The main findings in the 28-day study were tubular basophilia at the high dose of 1000 mg/kg bw in males and females and tubular mineralisation in high dose females. Therefore the Registrant's comment that ""effects in the kidney are male rat specific" is contradicted by the data.

- In the 1-generation study the incidence of "globular accumulations of eosinophilic material" was statistically significantly higher in males of all test substance groups compared to the control animals. This finding has not been reported for the 28-day study. Therefore the argument of a higher power of the statistical analysis in the 1-generation study is not relevant.

ECHA therefore still considers that the findings made in the 1-generation study, in particular the histopathological findings in the kidneys, raise a concern for more potent effects with increasing exposure duration, i.e. that the substance may cause effects not seen in the 28 day study when administered for 90 days and even at lower doses.

Additional effects
ECHA acknowledges your comment and agrees with your interpretation of the salivation finding, and has removed the respective argument.

Summary
ECHA considers that, for reasons as set out above, the information provided does not within the meaning of Section 1.2 of Annex XI provide sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that the registered substance has or has not a particular dangerous property. Thus your proposed adaptation cannot be accepted.

Adaptation according to Annex IX, Section 8.6.2, column 2
According to Annex IX, Section 8.6.2., column 2 no sub-chronic toxicity study needs to be conducted if "the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure."

You have however not justified or demonstrated with data or information that the cumulative conditions of that adaptation possibility are fulfilled. For example, in the 28-day repeated-dose toxicity study and in the oral one-generation reproductive toxicity study provided in the technical dossier liver and kidneys have been identified as target organs and systemic absorption has been proved. Further, there is consumer use, and the substance is used in cosmetics, air-care products, washing and cleaning products, polishes and wax blends and there is indoor use.

ECHA notes that this adaptation does not meet the specific rules for adaptation of Annex IX, Section 8.6.2., column 2, because the cumulative conditions for that adaptation are not fulfilled. Therefore, an adaptation of the information requirement according to Annex IX, section 8.6.2, column 2 cannot be accepted.

Conclusion and the study specifications

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 has evaluated the most appropriate route of administration for the study under consideration according to REACH Annex IX, Section 8.6.2. Based on the information provided in the technical dossier and the chemical safety report the conditions for testing by the dermal route are not met.

Based on the information provided in the technical dossier, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, the available oral studies indicate a concern for systemic toxicity (increased absolute and relative organ weights for liver, kidneys and thyroid, histopathological findings in liver and kidneys) that requires further information on repeated dose toxicity by the oral route.

According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

5. 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.

You have sought to adapt this information requirement. You provided the following justification for the adaptation "study scientifically unjustified". You argued that according to ECHA Chapter R.7A information on developmental toxicity can also be obtained from observations of the offspring in a one- or two-generation study: *"So, if a generation study is available, a prenatal developmental toxicity study (EU B.31, OECD TG 41) in the rat may not provide any additional information that would have an influence on the classification decision or risk assessment, and therefore the conduct of this study in the rat may not always be necessary. In this dossier, a one-generation study was conducted on rats.*

Onset and duration of landmarks of physical development were observed and reflexological assessment of offspring was performed. There were no treatment-related effects upon offspring viability, growth or development. The NOEL for developmental toxicity was determined to be 1000 mg/kg bw/day." You argue that therefore it is not deemed necessary to perform a pre-natal developmental toxicity study on the registered substance.

While you have in the technical dossier not explicitly referred to any specific adaptation mentioned in the REACH Regulation, you have provided information that could be interpreted as an attempt to adapt the information requirement in accordance with Annex XI of the REACH Regulation.

You claim that the study is scientifically unjustified and thus you may wish refer to Annex XI, Section 1 (Testing does not appear scientifically necessary). As neither Annex XI, Section 1.1 (Use of existing data) nor 1.3 (Qualitative or Quantitative structure-activity relationship) nor 1.4 (in vitro methods) nor 1.5 (grouping of substances and read-across approach) applies, you most probably refer to Annex XI, Section 1.2 (Weight of evidence, WoE). In a WoE approach there has to be sufficient evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property.

ECHA notes that this adaptation does not meet the general rules for adaptation of Annex XI, Section 1.2., because a WoE approach requires several independent sources of information, whereas you have provided only one source with regard to development (the one-generation reproductive toxicity study). The provided one-generation reproductive toxicity study aims for fertility of the parental generation and peri-/ and postnatal development of the F1 generation. It does not cover the endpoints required to fulfil the standard information requirement for a pre-natal developmental toxicity study, in particular information on skeletal and visceral alterations.

According to the information given in the technical dossier, post mortem macroscopic examinations of the pups for internal and external abnormalities have been performed in the course of the one-generation study. However, these macroscopic examinations cannot provide the information obtained from examinations of the foetuses for skeletal and soft tissue alterations as requested in OECD TG 414 in paragraphs 30-32. Further, it cannot be excluded that stillbirths with developmental defects were not detected in that study (due to cannibalism by the dams) and there remains uncertainty on possible pre-natal developmental toxicity.

In your comments to the draft decision, you made an adaptation according to Annex XI, 1.2, arguing essentially that any severe developmental effects would have been seen in a one-generation study, with the support of the 28-day study.

In your comments to the draft decision you note that "*if there had been pups born with severe developmental defects, sufficient to induce the dams to cannibalise them, then there would have been a commensurate significant reduction in the litter size of the affected exposure groups; there were no such significant effects.*"

ECHA states that the above is correct only if the number of malformed foetuses was high enough to be reflected in statistical evalution of litter size. If for example only 6 foetuses were malformed and cannibalised, this would not cause a statistically significant reduction in the mean litter size (e.g. 20 litters with normal mean litter size of 10: 200 foetuses - if 6 were cannibalised this would lead to 194 foetuses resulting in a mean litter size of 9.7 vs 10). Thus, rare malformations cannot be detected by observing the litter size.

In your comments to the draft decision you also explain that if there had been a treatment-related increase in skeletal and soft-tissue defects then this would have been revealed by at least one of the following observations, which are repeated below and commented by ECHA:

1. *"a reduction in survival rate during the lactation period"*:
   A reduction in survival rate during the lactation period would have been detected only if the malformation would have been lethal and at high incidence. Non-lethal malformations and variations and lethal malformations at low incidences would not be detected based on reduction of survival rate.

2. *"clinical signs in the pups during the post-natal observation period"*:
   Only skeletal and soft-tissue malformations which would lead to clinical signs, such as certain heart malformations could be detected. Most of the skeletal and soft tissue minor malformations and variations are likely to be non-symptomatic and do not cause any clinical signs.
3. *"effects on offspring bodyweight gain during lactation":*
   Body weights may be low in foetuses with severe malformation(s), however, minor malformations and variations generally have not been linked to smaller foetal size.
4. *"differences in developmental landmarks":*
   Severe malformations are likely to affect developmental landmarks, but it is unlikely that e.g. minor skeletal and visceral malformations or variations could affect these.
5. *"effects on offspring reflexological responses":*
   Major malformations and certain neural/muscular/skeletal malformations may cause changes in reflexes. However, many visceral and skeletal malformations and variations may not be detected by investigations of reflexes.
6. *"macroscopic internal or external abnormality findings in the offspring at the post mortem observation":*
   Macroscopic internal or external investigations in OECD TG 415 do not address all the organs and visceral and skeletal malformations and variations which are subject to an examination according to OECD TG 414.

In your comments to the draft decision you further considered that based on the information from OECD TG 415 (conducted up to 1000 mg/kg bw/day) and a 28-day study it can be assumed/concluded that the substance does not have a particular hazardous property regarding to prenatal developmental toxicity.

ECHA stresses that a 28-day study does not provide any information on prenatal developmental toxicity and, thus, does not contribute the WoE adaptation justification. This means that there is left only one piece of information, the OECD TG 415 study, which alone cannot fulfil the requirement of a WoE adaptation in terms of Annex XI, section 1.2 of the REACH Regulation under which several pieces of information are needed to conclude/assume if the substance has or has not a particular hazardous property. The only piece of information provided includes investigations on parameters which may at best provide only indirect information on prenatal development of pups if severely affected. You have not justified how the investigated parameters are linked to information on prenatal developmental toxicity addressing growth and survival *in utero*, external, visceral and skeletal malformations and variations which are investigated in OECD TG 414 and are used as a basis of concluding on prenatal developmental toxicity.

Therefore, your adaptation of the information requirement 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.

According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rats or rabbits as a first species.

According to the test method EU B.31/OECD TG 414, the test substance is usually administered orally. On the basis of this default consideration, ECHA considers testing should be performed by the oral route.

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

6. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2), or Long-term toxicity to plants (Annex IX, Section 9.4.3., column 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.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.
You have waived the standard information requirements of Annex IX, section 9.4. using the following justification: *'Based on a conservative estimation from Chesar, the chemical safety assessment of the substance indicates no need to investigate terrestrial testing'*.

Your justification for waiving 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. Furthermore, ECHA notes that the substance has wide dispersive uses and soil releases are identified within the exposure assessment, therefore direct/indirect exposure of the soil compartment cannot be excluded.

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.7.11.5.3., 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 is likely to be very persistent. 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.

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

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD 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 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

In your comments to the draft decision, you indicated that the current version of Chapter R.7c of ECHA's Guidance on information requirements and chemical safety assessment (version 2.0, November 2014) was not available at the time of the dossier submission (submission number: [redacted], submitted 08/05/2013). However, ECHA notes that the integrated testing strategy for effects on terrestrial organisms, including soil hazard categories and screening assessment, was defined within chapter R7.11.6 of the original version of the abovementioned guidance, published in May 2008. In this respect the updated guidance has not changed. In addition, no new standard information requirements regarding terrestrial organisms have been introduced in the REACH Regulation in the meantime.

In your comments to the draft decision, you agree to perform an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. However, you propose a new testing strategy, you indicate that in reality the soil is more likely exposed to the principal degradation product, Helvetol, than to the registered substance, Helvetolide. You also indicate your intentions to update the environmental risk assessment with all data available on the biodegradation product, Helvetol. You also indicate the confirmatory long-term soil toxicity test, a chronic earthworm study (OECD 222) on Helvetol and the environmental risk assessment on soil, using the metabolite, Helvetol based on the available information rather than on the registered substance.

You support this new testing strategy by indcating that the available biodegradation screeening test (OECD 301C) is sufficient to show that the registered substance is not readily biodegradable but due to primary degradation, is broken down to form Proprionic acid (which based on the available information is completely mineralised), and Helvetol. ECHA agrees that the registered substance undergoes primary degradation. However a screening study does not provide a rate of degradation i.e. half life for the registered substance. Based on available information, currently, ECHA does not know the extent of any potential exposure of the registered substance to soil organisms. Consequently, ECHA is unable based on available information to conclude on whether your proposed new testing strategy is compliant with the respective information requirement as any adaptation needs to have a scientific justification, referring and conforming to the appropriate rules of the REACH Regulation, and an adequate and reliable documentation.

In your comments to the draft decision, you also provided QSAR predictions for acute and chronic aquatic toxicity predictions using ECOSAR and iSafeRat. You have concluded that Helvetol is deemed not to be very toxic to aquatic organisms i.e. > 1 mg/L. However, concerning ECOSAR you have not provided adequate documentation, showing that the predictions are within the applicability domain. Concerning iSafeRat, no training set was provided in order to verify that the substance is within the applicability domain and that the prediction is reliable. Thus, currently, it is not possible for ECHA to conclude that any of these predictions meet the requirements set for acceptance in Annex XI section 1.3. Consequently, ECHA considers that the aquatic toxicity predictions for Helvetol do not meet the criteria set out in Annex XI section 1.3 and cannot currently be accepted. Therefore, currently the available information is insufficient to support your claim that Helvetol would fall within soil hazard category 3.

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. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following: if the QSAR predictions are reliable and adequate, and support that "*Helvetol, the degradation product of the registered substance, should be classed as a soil hazard category 3, and thus, in the context of an integrated testing strategy for soil toxicity, an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test should be performed on Helvetol*", then it would be necessary to perform the long-term terrestrial testing on the metabolite.

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.

Note, following the completion of the preferred Earthworm reproduction testing using the OECD 222, you may adapt the terrestrial plant testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation. Any adaptation will be evaluated by ECHA at the follow-up stage. However, if it is not possible to adapt the terrestrial plant testing requested, the testing request will need to be fulfilled as per this decision.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD TG 222), or Enchytraeid reproduction test (test method: OECD TG 220), or Collembolan reproduction test in soil (test method: OECD TG 232), or, 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).

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

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.

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

You have waived the standard information requirements of Annex IX, section 9.4. using the following justification: *'Based on a conservative estimation from Chesar, the chemical safety assessment of the substance indicates no need to investigate terrestrial testing'*.

Your justification for waiving 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. Furthermore, ECHA notes that the substance has wide dispersive uses and soil releases are identified within the exposure assessment, therefore direct/indirect exposure of the soil compartment cannot be excluded.

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.

ECHA notes that the test requested under point (6) above is 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.

In relation to your comments to the draft decision, regarding the initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test and your intentions to update the environmental risk assessment with all data available on the biodegradation product, Helvetol, please see response in item 6 above. However, in summary, ECHA is unable based on available information to conclude on whether your proposed new testing strategy is compliant with the respective information requirement as any adaptation needs to have a scientific justification, referring and conforming to the appropriate rules of the REACH Regulation, and an adequate and reliable documentation.

In your comments to the draft decision to justify the non-performance of a soil microorganisms nitrogen transformation test on Helvetol, in summary, you indicate, in the screening non-GLP biodegradation study on Helvetol (OECD 301F): no toxicity of Helvetol (tested at 104.5 mg/L), the toxicity test (test item + reference material) attained 26% degradation after 14 days thereby confirming that the test item helvetol was not toxic to the sewage treatment micro-organisms used in the study and the biodegradation in the toxicity test (test item Helvetol + reference substance) was greater than 25% within 14 days which according to the guideline confirms that the test item is not inhibitory.

The test material attained 0 % degradation after 28 days. Therefore the test material cannot be considered to be readily biodegradable under the strict terms and conditions of OECD Guideline. Positive reference, Sodium Benzoate attained 80% degradation after 14 days thereby confirming the suitability of the inoculum and test conditions; The second evidence is the predicted toxicity effect of Helvetol in activated sludge, with iSafeRat® QSAR model. The 30-180 min-EC50 (ASRIT) was considered greater than the solubility limit of Helvetol. Therefore, no toxicity is predicted on sludge dwelling microorganisms.

You disagree to perform the soil microorganisms due to available weight of evidence showing low toxicity to aquatic microorganisms. To substantiate the low-toxicity weight of evidence on soil microorganisms, you have raised the following two studies, screening non-GLP biodegradation study on Helvetol (OECD 301F) and the activated sludge respiration inhibition (OECD 209)(ASRIT).

Based on the above information, ECHA agrees that you have provided some evidence in a weight of evidence (WoE) approach according to the general rules in Annex XI of the REACH Regulation and indicated that the level of toxicity to microorganisms appears to be > 100 mg/L (EC50 (3 h)). However, ECHA considers that only one line of evidence is indicated as activated sludge media is used in activated sludge respiration inhibition (OECD 209). For an acceptable WoE ECHA considers that further lines of evidence would be required. ECHA notes the Registrant could use in addition another line of separate evidence using results from a study conducted using another media.

In addition, concerning iSafeRat, no training set was provided in order to verify that the substance is within the applicability domain and that the prediction is reliable. Thus, currently, it is not possible for ECHA to conclude that this prediction meets the requirements set for acceptance in Annex XI section 1.3. Consequently, ECHA considers that the aquatic toxicity predictions for Helvetol do not meet the criteria set out in Annex XI section 1.3 and cannot currently be accepted. Therefore, currently the available information is insufficient to support your claim of non-performance of a soil microorganisms nitrogen transformation test on Helvetol.

Finally, also in your comments on the draft decison, you indicate according to the strategy presented in point (6) above, the RCRsoil for Helvetol will be quite low, lower than 0.5 even for the worst case scenario, with a RCRsoil for combined wide dispersive uses lower than [redacted].

However, as stated under point 6 above, ECHA is unable based on available information to conclude on whether your proposed new testing strategy, that in reality the soil is more likely exposed to the principal degradation product, Helvetol, than to the registered substance, Helvetolide is compliant with the respective information requirement as any adaptation needs to have a scientific justification, referring and conforming to the appropriate rules of the REACH Regulation, and an adequate and reliable documentation. it is also insufficient to support your claim of non-performance of a soil microorganisms nitrogen transformation test on the registered substance, Helvetolide.

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. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Consequently, the information gap is valid and it is necessary to provide the requested information.

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

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, 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 consideration by the Registrant

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term terrestrial toxicity test, specified above), which you are requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the remaining standard information requirements of section 9.4 of Annex IX, of the REACH Regulation.

Therefore, once results of the requested terrestrial toxicity test are available, you should consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX, and if necessary, submit testing proposals for additional terrestrial toxicity tests. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, section 9.4. of the REACH Regulation.

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.

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 8 October 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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 proposals for amendment.

ECHA received proposals for amendment and did not modify the draft decision.

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

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-53 written procedure 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 2016.

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 carrying out the test(s) 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 test(s) 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 test(s) to be assessed.