Helsinki, 25 June 2019

Addressee: [redacted]

Decision number: CCH-D-2114470722-49-01/F
Substance name: tricyclodecanedimethanol
EC number: 248-096-5
CAS number: 26896-48-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 05/02/2016
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

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

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

   - **Identification and quantification of the main constituent(s)**

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

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

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

5. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce systemic toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

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

12 °C with the registered substance;

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

You have to submit the requested information in an updated registration dossier by **3 January 2022**. 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 and 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, has to 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 **Claudio Carlon**, Head of Unit, Hazard Assessment

[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.

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

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

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

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

ECHA notes that an analytical report incuding Infra-Red (IR) spectroscopy, Gas Chromatography (GC) and Gas Chromatography/Mass Spectroscopy (GC/MS) data has been attached to the dossier. However, you have not provided a comprehensive report for the identification and quantification of the constituents in your substance.

In particular, the provided GC chromatogram displays several distinct peaks, thus indicating that the identification and quantification of the correspond constituents should technically be possible. The relative integral area of the peaks furthermore points at the presence of several constituents at such concentration levels that their identification and quantification is required. However the identity of the different major and minor constituents/isomers has not been specified properly. They have only be associated to names that do not refer to unique chemical structures [redacted]. From the information provided in the analytical report it is also not possible to conclude how the chromatogram relates to the substance composition which is currently reported in IUCLID Section 1.2 of the dossier. The IR and GC/MS data do not provide further information on the individual constituents contributing to the composition.

Therefore, you are requested to submit a description of the analytical methods for the identification and quantification of the constituents in your substance. The information provided shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. If the method is based on the chromatographic analysis, an appropriate chromatographic report including a peak table that contains not only the retention times and the peak areas, but also proper identification of the peaks and the quantification of the corresponding constituents shall be included.

As for the reporting in the registration dossier, the information should be included in IUCLID Section 1.4.

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

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity. ECHA noted incompliances on the composition of the registered substance.

According to chapter 4.3 of the "Guidance for identification and naming of substances under REACH and CLP" (Version: 2.1, May 2017) – referred to as the "SID Guidance" hereinafter, for UVCB substances such as the registered substance, you shall note that the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature; and
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In the present dossier you have identified the registered substance as a UVCB substance. In IUCLID Section 1.2 you have reported as constituent the substance itself (as identified by the EC number: 248-096-5, EC name: "tricyclodecanedimethanol") with a typical concentration of [redacted] (w/w) and concentration range of [redacted] (w/w).

In line with the observations made above under point 1 of this Appendix 1, the results of the analyses you submitted indicate that your substance contains constituents that should be identified and quantified. ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

You are accordingly requested to revise the composition of the registered substance by providing appropriate information on the identity and concentration levels of the constituents and groups of constituents required to be reported. The composition reported in Section 1.2 of IUCLID must be verifiable and therefore supported by the provided analytical data in IUCLID Section 1.4.

Regarding how to report the composition in IUCLID, the following applies: you shall indicate the composition of the registered substance in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are in the manual "How to prepare registration and PPORD dossiers" available on the ECHA website.

You shall ensure that the information on the composition of the substance is verifiable and therefore supported by a description of the analytical methods used for its identification, as required under Annex VI section 2.3.7. of the REACH Regulation.

Notes for consideration on the type of substance

The abovementioned requirements to resolve the incompliances on the composition have been established considering the type of substance selected by you which is "UVCB". Given the limited information currently included in the Registration dossier, ECHA cannot exclude that the individual substance you intend to cover with this registration is a well-defined substance (i.e. either a mono-constituent substance or a multi-constituent substance) as defined in section 4.2 of the SID Guidance.

If the registered substance is well-defined, you should note that, according to chapter 4.2 of the Guidance, the following applies to well-defined substances:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In case the registered substance turns out to be a well-defined one, you are requested to specify the composition to the abovementioned level of detail, pursuant to Annex VI, Section 2.3 REACH

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

Following the principles given in the SID Guidance, the naming of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances shall consist of two parts: (i) the chemical name (including the corresponding EC number (if available and appropriate) and CAS number (if available) and (ii) a more detailed description of the manufacturing process. ECHA noted incompliances on the naming of the registered substance and has an important remark regarding the substance type, as explained hereinafter.

(i). A chemical name representative of the registered substance must be specified

You have assigned the EC entry with EC number 248-096-5 and EC name 'tricyclodecanedimethanol' to the substance. This entry corresponds to a substance having an unspecific tricycloalkane backbone that is substituted by two hydroxymethylene groups at undefined positions. You also provided the CAS entry with CAS number 26896-48-0 as CAS information for your substance. This CAS entry refers to a substance with a specific tricycloalkane backbone (in this case Octahydro-4,7-methano-1H-indene) where the position of the two hydroxymethylene groups is partly defined. You furthermore provided the IUPAC name "tricyclo[2.2.2.2~1,4~]decane-2,5-diyldimethanol" for your substance. This name refers to a substance where the tricycloalkane backbone is different from the substance corresponding to the CAS number 26896-48-0 and where the position of the two hydroxymethylene groups is defined. For the reported name and identifiers, the stereochemistry of the substance has not been defined.

ECHA therefore concludes that the name and other identifiers reported for the registered substance are not consistent and the identification of the registered substance is ambiguous.

You need to ensure that the name and other identifiers of the substance are used consistently throughout the dossier. Therefore please review all chemical names and identifiers given in your dossier for consistency and correct them if necessary.

As for the reporting in the registration dossier, the information should be included in the relevant fields of the reference substance in IUCLID Section 1.1. You shall ensure that the substance is referenced using the correct name and other identifiers throughout the dossier.

In case the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID Section 1.1, the following: "The EC number 248-096-5 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 should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID Section 1.1.

You shall note that ECHA has established a process, subject to certain conditions available at ECHA webpage (https://echa.europa.eu/support/how-to-improve-your-dossier/how-to-change-your-substance-identifier), enabling registrants to adapt the identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. However, depending on 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 in this registration.

Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

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.

(ii). Details of the manufacturing process must be provided

You have provided the following description of the manufacturing process in the technical dossier: [redacted]

However the above description is not sufficiently detailed to verify the identity of the substance as the relevant operating parameters applied to control the composition (e.g. temperature, pressure, solvent, catalysis type *etc.*) as well as details on any extraction/isolation/purification step are missing from the dossier. Therefore the reported description is insufficiently detailed to enable the substance identity to be verified.

Therefore you shall provide the abovementioned information on the manufacturing process for the individual substance which is the subject of this registration.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the "Description" field in IUCLID Section 1.2. Additionally, in case you have information that complements the description of the manufacturing process (e.g. process workflows) you can provide these under the 'Attached description' in Section 1.2 of IUCLID.

You shall ensure that the chemical name and the manufacturing process description to be reported according to Annex VI, Section 2.1 of the REACH Regulation are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3 of the REACH Regulation.

Notes for consideration on the type of substance

The abovementioned requirements to resolve the incompliances on the naming of the substance have been established considering that the type of substance selected by the you is "UVCB". Given the limited information currently included in the Registration dossier, ECHA cannot exclude that the individual substance you intend to cover with this registration is a well-defined substance (i.e. either a mono-constituent substance or a multi-constituent substance) as defined in section 4.2 of the Guidance. You should note that, in this situation, specific conventions must be followed to derive the chemical name of the substance. The conventions are defined in chapters 4.2.1.1 and 4.2.2.1 of the Guidance.

If the registered substance is well-defined, you are then requested to replace the current chemical name specified in the "IUPAC name" field by a chemical name following the naming conventions for well-defined substances. You shall furthermore revise the "Type of substance" selected in section 1.1 of the IUCLID dossier from "UVCB" to "mono constituent" or "multi constituent" as appropriate.

In case your substance is best described as well-defined substance it is not required to provide a description of the manufacturing process.

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

Pre-natal developmental toxicity studies (test method 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 a pre-natal developmental toxicity study 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.

You have sought to adapt this information requirement according to Annex IX, Section 8.7.2., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX No. 8.7.2. further investigation through a pre-natal*

development study in a second specie does not seem to be justified as TCD Alcohol DM didn´t show any development effect in a combined 28-day repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422; required according to REACH Annex VIII No. 8.7.1). These results are confirmed by a pre-natal development study in rat (OECD 414), no adverse effects are caused at the highest tested dose (NOAEL =1000 mg/kg bw/day). These results do not suggest any potential for adverse effects on development".

Firstly, ECHA notes that you referred to "*column 2 of REACH Annex IX No. 8.7.2.*". However, the Substance is registered at Annex X and a pre-natal in the first species is already present in your dossier. Therefore, ECHA interpreted your justification as an attempt to adapt the information requirement according to the third indent of Annex X, Section 8.7., column 2 which stipulates that the studies (on reproductive toxicity) need not to be conducted if the three cumulative criteria are met:

- the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

ECHA has evaluated your adaptation with respect to this provision and ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex X, Section 8.7., column 2, third indent because of the following:

- You have not provided any "toxicokinetic data that no systemic absorption occurs via relevant routes of exposure" (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air);
- Your arguments regarding low toxicity is overturned by the fact that in the pre-natal developmental toxicity study (OECD TG 414) in a 1st species (rat) maternal toxic effects were observed at the highest dose tested (1000 mg/kg bw/day), namely statistically significant body weight loss and statistically significant lower overall bodyweight gain and reduced food consumption. Additionally two females at the highest dose were killed for welfare reasons showing rales, piloerection and hunched posture in two animals and undereactive behaviour, partially closed eyelids and abnormal gait in one animal; and
- The substance is used by professionals in cleaning products and in laboratories and by consumers in cosmetic products therefore the absence or no significant human exposure cannot be demonstrated.

In view of the above, the conditions set out in Annex X, Section 8.7., column 2, third indent are not met. Therefore, your adaptation of the information requirement is rejected.

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 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 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, 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: OECD TG 414) in a second species rabbit by the oral route.

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

The basic test design of an extended one-generation reproductive toxicity study (test method 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* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

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 not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to third indent of Annex X, Section 8.7., column 2.

You provided the following justification for the adaptation: "*Effects of TCD Alcohol DM on the reproductive system have been examined in a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (OECD TG 422). No effects were observed on reproductive function and performance as well as on reproductive organs and tissues. Similarly, no effects on the male and female reproduction organs, on the oestrus cycle, and on sperm parameters were seen in a 90-day rat oral gavage study (OECD 408) at doses up to and including 1000 mg/kg bw and day. These results do not suggest any potential for adverse effects on reproduction. Therefore, further investigation through an extended one generation toxicity study does not seem to be justified*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex X, Section 8.7., column 2, third indent because according to the third indent of Annex X, section 8.7.2., column 2, the studies (on reproductive toxicity) need not to be

conducted if the three cumulative criteria are met:

- the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

Nevertheless, ECHA observes the following:

- You have not provided any "toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air);
- ECHA considers that your arguments regarding low toxicity is overturned since in the pre-natal developmental toxicity study (OECD TG 414) in a 1st species (rat) maternal toxic effects were observed at the highest dose tested (1000 mg/kg bw/day), namely statistically significant body weight loss and statistically significant lower overall bodyweight gain and reduced food consumption. Additionally two females at the highest dose were killed for welfare reasons showing rales, piloerection and hunched posture in two animals and undereactive behaviour, partially closed eyelids and abnormal gait in one animal. Additionally, in a 90-day rat oral gavage study (OECD 408), there were three deaths during treatment in three females at the highest dose tested. Clinical signs included decreased activity, laboured/shallow/slow breathing, rales (wet), sneezing and dark eyes, excessive chewing, piloerection, prominent eyes, elevated gait and distended abdominal area. Macroscopic examination revealed abnormal contents (gas) and/or distension of the caecum, colon, ileum, jejunum, stomach and/or incomplete lung collapse in each of these animals. Histopathological examination revealed minimal haemorrhage that correlated to dark, multilobular, diffuse areas of the lungs and minimal apoptosis of the thymus correlating to dark thymus areas, small spleen, minimal lung and bronchi perivascular cell infiltrate and inflammation, inflammatory exudate in the lumen of the nasal cavity and nasopharynx, degeneration/regeneration/inflammatory cell infiltration of the epithelium and deformity/fusion of turbinates; and
- The substance is used by professionals in cleaning products and in laboratories and by consumers in cosmetic products therefore the absence or no significant human exposure cannot be demonstrated.

In view of the above, the conditions set out in Annex X, Section 8.7., column 2, third indent are not met. Therefore, your adaptation of the information requirement is rejected.
As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according 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 because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

The highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no relevant data to be used for dose level setting, it is recommended that a range-finding study (or range finding studies) is performed and that its results are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Species and route selection

According to the test method 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 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, 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 OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

While the specifications for the study design are given above, you shall also submit with the new endpoint study record a scientific justification on each of the following aspects: 1) length of the premating exposure duration and dose level selection, 2) reasons for why or

why not Cohort 1B was extended, 3) termination time for F2 generation, and 4) reasons for why or why not Cohorts 2A/2B and/or Cohort 3 were included.

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, 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 extension of Cohort 1B, 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 available information, together with 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* Chapter R.7a, Section R.7.6 (version 6.0, July 2017). 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.

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

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation: '*In accordance with column 2 of REACH Annex IX and X No 9.2, no further testing on aquatic and sediment biotic degradation and identification of degradation products needs to be conducted as the CSA does not indicate the need for further testing..... Based on valid screening tests, TCD Alcohol DM is considered to be persistent, and no further relevant information could be expected from additional testing.*'

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Section 9.2. The simulation test on ultimate degradation in water provides information on the rate of loss of the registered substance under environmentally relevant conditions by primary biodegradation and other environmental transformation processes and information on the resulting environmental transformation products resulting from biodegradation and other transformation processes. The ready biodegradation tests monitor only ultimate biodegradation (i.e. by carbon dioxide evolution in the OECD 301B key study and by oxygen consumption in the OECD 301F and OECD 301C supporting studies) and do not give information on primary degradation or other environmental transformation processes. Furthermore, there is evidence from the OECD 301C ready biodegradation supporting study that the registered substance is lost from the test media by oxidation: i.e. 15 to 22% removal of the parent substance after 28 days determined by GC analysis, resulting in the formation of 2 to 7% of an aldehyde (by oxidation of one of the hydroxymethyl groups) and 12 to 15 % of a carboxylic acid (by further oxidation of the formyl group). Therefore it cannot be concluded that the substance would not be degraded in a simulation test on ultimate degradation in water.

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable and is not highly insoluble (having a water solubility of 11g/l).

Furthermore, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

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

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

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Quantification of non-extractable residues (NER) is also recommended in surface water simulation degradation studies. Furthermore, when reporting NER in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER as described in Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) and R.11 (version 3.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309); The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

7. Identification of degradation products (Annex IX, 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in as also discussed in section 5 above.

Furthermore, ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

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

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation

half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the relevant degradation studies also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

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

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

Notes for your consideration

Before providing the above information you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

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 14 September 2018.

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

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. 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 grades registered to enable the relevance of the tests to be assessed.