ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004808-64-08/F Helsinki, 7 October 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For dichloromethylbenzene, CAS No 29797-40-8 (EC No 249-854-8), registration number: [redacted]

Addressee [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for dichloromethylbenzene, CAS No 29797-40-8 (EC No 249-854-8), submitted by [redacted] (Registrant). With reference to the requirement of Annex X, Section 8.7.2. of the REACH Regulation, ECHA notes that a pre-natal developmental toxicity test for the first species was requested to be submitted by 2 October 2013 in a decision on a testing proposal (TPE-D-0000002138-77-05/F). The information requirements regarding such a test in a second species was addressed in that decision and consequently a testing proposal was submitted by the Registrant. The decision on the testing proposal in a second species was issued on 25 September 2014 (TPE-D-0000004808-64-09/F).

The present decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 4 April 2013.

On 25 July 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 23 August 2013 ECHA received comments from the Registrant on the draft decision. On 31 October 2013 the Registrant updated his registration dossier (submission number [redacted]).

The ECHA Secretariat considered the Registrant's comments and update. On the basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 March 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendmends of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment (PfAs) to the draft decision were submitted.

On 11 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 the Registrant provided comments on the PfAs and on the draft decision. The Member State Committee took the comments of the Registrant on the PfAs into account. The Committee did not take into account the Registrant's comments on the draft decision as they were not related to the PfAs made and are therefore considered outside the scope of Article 51(5).

The present decision relates solely to a compliance check examination relating to the in vitro gene mutation study in bacteria (Annex VII, 8.4.1), sub-chronic toxicity study (90-day (Annex IX, Section 8.6.2.), simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2), effects on terrestrial organisms (long-term toxicity testing on invertebrates (Annex X, 9.4.4.), long-term toxicity testing on plants (Annex IX, 9.4.6.); effects on soil micro-organisms (Annex IX, 9.4.2.) and revised environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6). The other compliance check requirement of the two-generation reproductive toxicity study (Annex X, 8.7.3) is addressed in a separate decision although all requirements were initially addressed together in the same draft decsion.

After discussion in the Member State Committee meeting on 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. In vitro gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102, as specified in section III.1 below.
2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test

method: EU B.26./OECD 408) in rats modified to include urinalysis and a full histopathological examination which is to include immunohistochemical investigation of renal pathology to determine if the pathology is mediated by alpha-microglobulin nephropathy.

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test, EU C.25./OECD 309) to be conducted at a temperature of 12 °C.
4. Effects on terrestrial organisms (Annex X, 9.4. and Annex IX 9.4.), as specified in section III.4 below.
    a. Long-term toxicity testing on invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232).
    b. Long-term toxicity testing on plants (Annex IX, 9.4.6.; test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).
    c. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Justification of environmental release factors used in the exposure estimation for relevant exposure scenarios. Alternatively, the Registrant may choose to use Environment Release Categories' (ERC) default release factors for his exposure estimation. (Annex I, section 5.2.2.)

In the absence of the above new information ECHA notes that Annex I (0.5) applies: *"While waiting for results of further testing, he (*the manufacturer or importer*) shall record in his chemical safety report, and include in the exposure scenario developed, the interim risk management measures that he has put in place and those he recommends to downstream users intended to manage the risks being explored."*

The Registrant shall reconsider the DNELs and PNECs and reassess related risks after the results of the tests required are available and have been taken into account by the Registrant . The chemical safety report shall be amended accordingly. In this regard ECHA notes that the results of a pre-natal developmental toxicity study requested by ECHA decision TPE-D-0000002138-77-05/F are already included in the dossier. The decision on the testing proposal in a second species was issued on 25 September 2014 (TPE-D-0000004808-64-09/F)

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **14 April 2016**. The timeline has been set to allow for sequential testing as appropriate.

D. Note for consideration by the Registrant

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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 the Member States.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

1. *In vitro* gene mutation study in bacteria

"*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by *E.coli* WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

The Registrant has provided a test from 1992 according OECD 471 and GLP with an assigned reliability score of 2. The test used four different strains of *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100. However, since the test was conducted, significant changes have been made to OECD guideline 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

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.

In the comments to the draft decision the Registrant agreed to provide the requested information.

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: Bacterial reverse mutation test (test method: EU B.13/14./OECD 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

2. Sub-chronic toxicity study (90-day)

"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.

Column 2 of section 8.6.2. of Annex IX provides that the 90-day study does not need to be performed, if

- *"a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or*
- *a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or*
- *a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or*
- *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."*

Registrants may also seek to adapt this information requirement according to the the general rules on adaptation set out in Annex XI to the REACH Regulation.

The updated dossier contains the following statement: *"No sub-chronic (90 day) sudy is available. The registrant enclosed a waiving in the initial dossier due to the following arguments: "No 90 day Study is available for the test substance, but a subacute study for*

the test substance was performed. A subacute oral toxicity study (28-days; [redacted]) with the test substance revealed overall a low toxicity with hyaline droplet nephropathy as the predominant effect, that is species specific and not relevant for humans. It is not assumed that a study with a longer duration of 90 days would substantially change the assessment of the substance. Therefore, taking also into consideration the need to balance the value of information generation by animal testing with a subchronic (90-days) repeated dose toxicity study with animal welfare considerations the subchronic study is regarded to be of low priority and therefore is waived."

ECHA requested in a draft decision on the compliance check of the dichloromethylbenzene (dichlorotoluene) dossier (registration number: [redacted], dated 25 July 2013) that the Registrant shall conduct a sub-chronic toxicity study, inhalation route in rats including immunohistochemical investigation of renal pathology to determine if the pathology is mediated by alpha-2u globulin nephropathology.

Whereas the Registrant still regards the value of a subchronic (90-days) repeated dose toxicity study in the specific situation as low. If the study is still requested by ECHA particular attention should be given to select an appropriate species and exposure route.

According OECD and EU test guidelines the rat is the preferred species, but other rodent species, e.g. the mouse may be used. If ECHA still concludes that a 90 day study is necessary for human risk assessment it is proposed to perform such a study not in rats, but in mice, as the mouse is know not to be prone to Hyaline Droplet Nephropathy."

The Registrant then provided detailed reasons for his choice of species and route (see below). Furthermore he included in his updated dossier a testing proposal on a repeated dose oral toxicity study in mice according OECD Guideline 408.

ECHA notes that a testing proposal for this information requirement is inadmissable since the testing is addressed already in this compliance check process, thus precluding another regulatory process on the same issue to be started in parallel. Furthermore, ECHA notes that no valid adaptation according to Column 2 of section 8.6.2. of Annex IX or Annex XI is provided. Therefore, 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.

Regarding the test method, ECHA considers that OECD test guidelines 408 is an appropriate test method to gather information on sub-chronic toxicity (90-day).

According to the test method OECD 408 the rat is the preferred species. In his comments to the draft decision the Registrant provided arguments why in this specific case the mouse should be the test species. In the 28-day study in rats kidney toxicity in males was the main observation which was demonstrated to be based on male rat specific hyaline droplet formation due to alpha-2-microglobulin accumulation. The Registrant argues that this mechanism is not relevant to human health risk assessment, since human do not possess this protein. Furthermore the male rats are weakened by the kidney toxicity preventing to obtain meaningful results. Therefore the Registrant concludes that rat is not a suitable animal model to provide a starting point for a human DNEL calculation and proposes the mouse as test species for the sub-chronic toxicity test.

In his comments to the PfAs submitted by the MSCAs the Registrant repeated that he regards the mouse as the relevant species for any further testing. The Registrant stated

also that he agrees to investigate the alpha-2-microglobulin mediated nephropathy in the 90-day repeated dose toxicity study, if the rat is chosen by ECHA as test species.

The Member State Committee considered the arguments and came to the conclusion that the information provided on the basis of the 28-day study results is consistent with a male rat specific hyaline droplet accumulation due to alpha-2-microglobulin accumulation but that the Registrant did not prove for the registered substance that this mechanism is indeed causal for the observed kidney effects. Furthermore, the kidney effects observed in the 28-day study appear to be adverse only at higher doses (500 mg/kg bw in the 28-day study) and it is not expected that the detection of other possible systemic adverse effects in the requested 90-day study will be negatively influenced. The rat is therefore regarded as the most appropriate species to be tested. A study in the rat will also provide the opportunity to prove or disprove the claimed alpha-2-microglobulin mediated nephropathy. For this reason, urinalysis (which is optional in paragraph 30 of OECD 408, and the relevant part of Section 1.5.2.2. of EU Method B.26) to investigate kidney function is included in the request for a sub-chronic toxicity study. Furthermore, a full histopathological examination (paragraph 36 of OECD 408, Section 1.5.2.4. of EU Method B.26) including immunohisto-chemical investigation of renal pathology is to be conducted to determine if the pathology is indeed mediated by alpha-2-microglobulin.

Regarding the appropriate route, according to Column 2 in section 8.6.2 of Annex IX testing by the inhalation route is appropriate, if

> *"exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size."*

In the present case, ECHA considers that exposure of humans via inhalation is likely but low. The vapour pressure of the substance is low (65.3 Pa at 25°C), and in the updated dossier the CSR reports professional use with the potential for aerosol generation (i.e. PROC 11: non-industrial spray application). For this spray application the substance use results in long term exposure estimates of 0.91 mg/m^{3}according the the calculations provided by the Registrant.

The Registrant states that both the inhalation and oral routes would provide relevant data for systemic toxicity. But on the basis of the information in the dossier with regard to observations in the acute inhalation toxicity study and the irritation potential on skin and eyes the Registrant does not consider that there is a specific trigger for the inhalation route of exposure. Since from these data local effects do not appear to be the predominant factor and the Registrant considers oral dosing as technically less demanding and allowing a more precise dosing he considers the oral route as the most appropriate route.

ECHA concludes that in this case there is no specific trigger for the inhalation route and that the oral route is the most appropriate exposure route for the sub-chronic toxicity test.

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: Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD 408) in rats, modified to include urinalysis and a full histopathological examination which is to include immunohistochemical investigation of renal pathology to determine if the pathology is mediated by alpha-2-microglobulin nephropathy.

3. Simulation testing on ultimate degradation in surface water

"Simulation testing on ultimate degradation in surface water" is standard information requirements 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 these information requirement.

The Registrant has waived simulation testing on ultimate degradation in surface water using the following justification: "*Studies are not needed since the chemical safety assessment according to Annex I does not indicate the need to investigate further the degradation (see Annex IX of Regulation (EC) No 1907/2006).*"

The justification for waiving simulation testing on ultimate degradation in surface water provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2, i.e. simulation testing on ultimate degradation in surface water can be waived if the substance is highly insoluble in water or is readily biodegradable, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

ECHA notes that as summarised by the Registrant in section 4.8 of IUCLID dossier, the water solubility of the substance is 11.2 mg/l. This value is not considered by ECHA as indication of high insolubility of the substance in water. Furthermore, as summarised by the Registrant in section 5.2.1 of IUCLID dossier "*dichloromethylbenzene mixture is not readily biodegradable*".

In addition, ECHA notes that a conclusion on the P (persistent) or vP (very persistent) status of the substance in the PBT assessment has not been reached by the Registrant as summarised in section 8 of the Chemical Safety Report (CSR). As concluded by the Registrant "*conclusion on P / vP properties: no conclusion can be reached based on available information*".

As explained above, the information available on this endpoint (simulation testing on ultimate degradation in surface water) for the registered substance in the technical dossier does not meet the information requirements. ECHA considers that it is important to understand the behaviour of the substance in surface water, i.e. determine the rate of transformation of the substance, and the nature and rates of formation and decline of degradation products, to which aquatic organisms may be exposed. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 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 1.2, November 2012) 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.16-9 (version 2.1 October 2012) indicates 12 °C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. ECHA considers that performing the test at the temperature of 12 °C is within the applicable test conditions of the Test Guideline OECD 309.

In his comments to the PfAs submitted by the MSCAs, the Registrant stated that he does not regard the request for a simulation test in surface water as justified. The arguments relate to (1) the substance would not meet the PBT or vBvP criteria since at least the B/vB criterium is not fulfilled; (2) the results of the distribution modelling would show that the main compartment for distribution is air and only small amounts are distributed in water, soil and sediment; (3) a refinement of the environmental exposure and more strict Risk Management Measures would show very low RCRs for surface water.

In the clarifications on his comments to the PfAs submitted by MSCA, the Registrant stated in the Member State Committee meeting on 10 June 2014 that there is no professional use for the registered substance, neither outdoor nor indoor, and that all uses are industrial and well controlled. The professional uses currently described in the dossier therefore would be removed from the updated dossier. Bearing in mind the remaining identified uses and the information available on physico-chemical and fate properties of the substance, the Registrant considers that the simulation testing in surface water is not relevant.

ECHA considers that at the moment there is no relevant information in the dossier which would allow to consider the information requirement of Annex X, 9.2.1.2. as fulfilled.

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: 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 309) to be conducted at a temperature of 12 °C.

However, as stated in section II, the Registrant may adapt the standard information requirement requested by this decision 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, provided the rules of the Annexes are met and a scientific explanation is provided.

4. Effects on terrestrial organisms

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and Annex X, section 9.4. of the REACH Regulation. Adequate information on effects on long-term toxicity to invertebrates (Annex X, section 9.4.4.) and long-term toxicity to plants (Annex X, section 9.4.6.) and effects on soil micro-organisms (Annex IX, section 9.4.2.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex X, section 9.4. specifies that long-term toxicity testing shall be proposed by the Registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. Furthermore, it should be noted that 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.

In his updated registration dossier the Registrant has waived testing on soil organisms (terrestrial invertebrates, plants and microorganisms) using the following two arguments:

1) *"According to column 2 of REACH Annex IX, the equilibrium partitioning method can be applied to assess the hazard of soil organisms. Based on REACH guidance document R7c, Table R7.11-2 (ECHA 2012), EPM can be applied if the substance is not highly adsorptive*

and/or not highly persistent in soil. Furthermore the substance is not classified as very toxic.

	Criteria according to Table R.7.11-2	*Properties of Dichlormethylbenzene (mixture of isomers)*
Highly adsorptive	*logKow > 5*	*logKow 4.2 - 4.3*
Highly persistent	*DT50 in soil >180 d*	*DT50 in soil ca. 90 - 120 d **
Very toxic to aquatic organisms	*EC/LC50 < 1 mg/L*	*EC50 1.26 mg/L (lowest acute value)*

** The degradation in soil was determined in a non-guideline test under methanogenic conditions. The half life for the three main isomers 2,4-DCT, 2,5-DCT and 3,4-DCT was measured to about 90 days. The main isomers represent >[redacted]% of the whole isomeric mixture. The two minor isomers 2,3-DCT and 2,6-DCT are degraded slower, and no concrete half-life could be calculated. According to the graphs given in the publication a half-life of about 180 days for these 2 isomers can be estimated. The concentration of each of the 2 minor isomers is in the range up to [redacted]%. Taking all information into account a half-life for the whole substance of 90 to 120 days is estimated.*
Following REACH guidance document R7c, Table R7.11-2, performing of EPM is possible as long as the risk characterisation ratios are below 1.
According to REACh Regulation (EC) No 1907/2006, Annex X, Column 2, tests on long-term toxicity to terrestrial organisms shall be proposed by the registrant if the results of the chemical safety assessment indicate the need to investigate further effects of the substance and/or relevant degradation products on terrestrial organisms. This is however not the case: The outcome of the CSA showed that all risk characterisation ratios in soil are below 1. For this reason, the performance of a test on the toxicity of dichloromethylbenzene for the terrestrial organisms is not needed."

2) *"According to section 3 of REACH Annex XI, testing is omitted based on the exposure scenarios developed in the Chemical Safety Report. According to sub-section 3.2a), the regitrant has demonstrated that*
i) in all relevant exposures through the whole life-cycle no or no significant exposure occurs to soil
ii) a PNEC could be derived based on EPM
iii) the comparison of PEC and PNEC resulted in RCRs well below 1:
Scenario 1: RCR 0.003
Scenario 2: RCR 0.057
Scenario 3: RCR 0.04
Scenario 4: RCR 3E-07
Scenario 5: RCR 9E-04
Scenario 6: RCR 9E-04"

Both arguments of the Registrant make use of the results of equilibrium partitioning method (EPM). However, ECHA considers long-term testing necessary for the reasons explained below:

1. Soil exposure is likely;
2. The substance falls into a soil hazard category 4 because of a) high persistency and b) high aquatic toxicity;
3. Equilibrium partitioning method (EPM) does not apply to soil hazard category 4 substances.

These points are further explained below.

1. Soil exposure is likely

ECHA considers that the potential exposure to soil cannot be considered as unlikely. At least indirect exposure can be foreseen for the professional uses indicated by the Registrant (at least for the use as solvent in mixtures used outdoor in open systems, such as brushing and spraying). Furthermore, ECHA observes that the Registrant performed a screening risk assessment by using estimated exposure concentrations in soil (not equal to zero). Therefore, ECHA considers that exposure of soil is likely and the long-term toxicity testing cannot, according to Column 2 of Annex IX, section 9.4 or Annex XI, be waived on the basis of absence of soil exposure.

ECHA notes that the integrated testing strategy (ITS) for effects on terrestrial organisms is explained in ECHA Guidance on information requirements and chemical safety assessment, chapter R.7c (ECHA, November 2012). If there is no data on soil toxicity available, but sufficient information is available for assigning a substance into a "soil hazard category", a screening assessment according to Table R.7.11-2 can be performed. Substances are assigned to soil hazard categories based on aquatic toxicity data and persistence (in soil) and/or adsorption potential in soil. According to the criteria provided in the footnote to the above mentioned Table R.7.11-2, the substance subject to the present decision has to be considered as highly persistent in soil if half-life of the substance in soil is more than 180 days (default setting, unless classified as readily biodegradable) and as very toxic to aquatic organisms if effect/lethal concentration causing death of 50% of test organisms (EC /LC50) is below 1 mg/l for algae, *Daphnia* or fish.

2. The substance falls into soil hazard category 4

   a. High persistence

ECHA notes that data on biodegradation (transformation) in soil provided in the registration dossier are based on a non-standard study. In this study "*the anaerobic metabolism was evaluated in soil slurry microcosms under anaerobic, methanogenic conditions*", i.e. transformation under aerobic conditions, which is a standard part of a test performed according to the Guideline OECD 307, Aerobic and Anaerobic Transformation in Soil. Furthermore, it is underlined on pages 170-171 of ECHA Guidance on information requirements and chemical safety assessment, Chapter R. 7B (ECHA, November 2012) that "*there is a vast amount of non-standardised biodegradation data that has been published in the scientific literature. [...]There is a general reluctance to use these types of data on regulatory purposes. However, they may be valuable, as part of a Weight of Evidence assessment, and attempts should be made to gather, evaluate and when appropriate use these types of information.*" Also it should be noted that two of constituents of the registered substance had a slower degradation in the non-standard test performed and their half-lives might be longer than 180 days. Therefore, ECHA considers that overall (under anaerobic and aerobic conditions) persistency of the substance in soil cannot be reliably assessed on the basis of results of the provided non-standard test. Therefore, the substance should be assigned to the soil hazard category by using results of standard ready biodegradability testing. According to the information provided in the dossier the substance is not readily biodegradable. Thus, ECHA considers that the substance is of high persistence.

   b. High aquatic toxicity

According to the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures substances with EC/LC50 ≤ 1 mg/l for algae, daphnia or fish would merit classification as aquatic Category Chronic 1 (degradability and bioaccumulation potential of a substance to be considered). Amendment of the Regulation (EC) No 1272/2008 (Commission Regulation (EU) No 286/2011) introduced additional criteria for

substances to be classified into the aquatic hazardous categories based on the chronic toxicity data. This means that substances with equivalent level of concern might be identified on the basis of either available EC/LC50 or chronic NOEC/EC_x. According to the amended criteria non-rapidly degradable substances for which adequate chronic toxicity data are available will be classified as aquatic Category Chronic 1 when chronic NOEC or EC_x ≤ 0.1 mg/l for algae, crustacea or fish. One of constituents, 3,4-dichlorotoluene, has a long-term No Observed Effect Concentration (NOEC) to fish of 0.078 mg/l and this value was used for the chemical safety assessment of the registered substance by the Registrant. Therefore, the substance can be considered as very toxic to aquatic organisms (as NOEC for non-rapidly degradable substance is less than 0.1 mg/L).

According to the above mentioned Table R.7.11-2 a substance should be assigned to the soil hazard category 4 if there is an indication for high adsorption or high persitence of the substance in soil and there is an indication that the substance is very toxic to aquatic organisms. As noted above ECHA considers that the substance is of high persistence and is very toxic to aquatic organisms. Therefore, the registered substance should be assigned to soil hazard category 4.

3. EPM is not applicable to substances falling into soil hazard category 4

The ECHA Guidance, chapter R.7c (Table R.7.11-2) for soil hazard category 4 substances states clearly: "*Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms.*" This is further explained in section R.7.11.5.3 of this Guidance: "*The use of the EPM method, however, provides only an uncertain assessment of risk and, while it can be used to modify the standard data-set requirements of Annex IX, and X, it cannot alone be used to obviate the need for further information under this Annex.*" Thus, ECHA disagrees with using EPM in the waiving statement since ECHA considers – even with the information in the updated dossier – that the substance falls into soil hazard category 4 due to its persistence and aquatic ecotoxicity properties as outlined above.

ECHA concludes that neither of the waiving arguments provided by the Registrant in the registration dossier are acceptable as they are based on the PNEC for soil based on EPM. In contrast, long-term tests according to the standard information requirements should be performed.

In addition, it should be noted that toxic effects of the substance on aquatic microorganisms were observed and are reported in the dossier. It is indicated in the above mentioned Guidance, Chapter R. 7c that where inhibition of sewage sludge microbial has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived. ECHA notes that this reference addresses data requirements given in Annex VIII, section 9.1.4. for activated sludge respiration inhibition testing. Therefore, if to cover this standard data requirement testing on specific aquatic microorganisms is performed in line with Guidance on information requirements and chemical safety assessment, chapter R.7B (ECHA, November 2012) and effects on these microorganisms are observed "*a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived*".

As explained above, the information requirements for effects on terrestrial organism for the registered substance in the technical dossier are not met. Consequently there is an information gap and it is necessary to provide information for effects on terrestrial organisms.

ECHA considers that OECD test guidelines 222, 220 and 232 are appropriate test methods to gather information on long-term toxicity of a substance to terrestrial invertebrates.

ECHA considers that ISO test guideline 22030 and OECD test guideline 208 are appropriate test methods to gather information on long-term toxicity of a substance to terrestrial plants.

Furthermore, ECHA notes that the OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on 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. The long-term toxicity 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.

ECHA considers that OECD test guidelines 216 is an appropriate test method to gather information on effects of a substance on soil micro-organisms.

In his comments to the PfAs submitted by the MSCAs the Registrant considers that the requests for terrestrial testing are not justified. He based his main arguments on (1) distribution modelling (2) more strict risk assessment measures and reduced tonnage which reduced the possibility of soil exposure and (3) more information on the persistence in soil.

In the clarifications on his comments to the PfAs submitted by MSCA, the Registrant stated in the Member State Committee meeting on 10 June 2014 that there is no professional use for the registered substance, neither outdoor nor indoor, and that all uses are industrial and well controlled. The professional uses currently described in the dossier therefore would be removed from the updated dossier. Thus, the Registrant considers that the exposure of the soil compartment is unlikely.

ECHA considers that at the moment there is no relevant information in the dossier which would allow to consider the information requirements of Annex X, 9.4.4. and Annex IX, 9.4.6. and 9.4.2. as fulfilled.

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:

a. Long-term toxicity testing on terrestrial invertebrates

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

b. Long-term toxicity testing on plants

   Terrestrial plants, growth test (test method: OECD 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).

c. Effects on soil micro-organisms

Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216)

However, as stated in section II, the Registrant may adapt the standard information requirements requested in this decision 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, provided the rules of the Annexes are met and a scientific explanation is provided. ECHA notes that if the Registrant decides to use, after the decision is issued, 'exposure' considerations as basis for justifying adaptation for the testing of effects on terrestrial organisms, he should adress unlikeliness of the soil exposure via both routes, direct and indirect exposure (e.g. via application of the sewage sludge from (municipal) waste water treatment plants).

B. Information related to the chemical safety assessment and chemical safety report

1. Justification of environmental release factors used in the exposure estimation for relevant exposure scenarios

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Pursuant to Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Pursuant to Annex I, section 5.2.2., emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. These RMMs and OCs should be included in the ESs provided in a CSR.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default environmental release categories (ERCs) of the ECHA guidance. As far as possible, spERCs have to be linked to the applied RMM and OC driving the release estimation.

In the present case, in the CSR the Registrant has provided 6 ESs: 1) manufacture; 2) formulation and (re)packing of substances and mixtures; 3) Use at industrial site: Solvent; 4) Use by professional worker as a solvent; 5) Use at industrial site: Sealing liquid in vacuum pumps; 6) Use at industrial site: Use in exhaust air scrubbers.

ECHA notes that, in order to cover any exposures that may be related to the identified hazards, exposure estimation for most of the ESs (except ES 1), as stated by the Registrant in the CSR, is based on the release factors provided in the so-called ESVOC (European Solvents Volatile Organic Compounds) SpERCs developed by European Solvents Industry Group (ESIG). ECHA observes that a summary of ESIG/ESVOC relevant SpERCs may be

found in the form of a table provided on the ESIG website as well as more detailed information can be found in SpERC factsheets provided on the same website. ECHA notes that release factors in these two sources of information are provided in different units. Also for some of SpERCs efficiency of necessary RMMs is reported. ECHA notes that the Registrant has not correctly used information provided for ESVOC SpeRCS (e.g. applied different release factors than ones noted in the SpERCs, did not detail which type of RMMs has to be applied and did not specify efficiency of necessary RMMs to control releases). Furthermore, ECHA notes that for ES 1 the Registrant claimed other release factors than those underlying ERC 1, which is used by the Registrant to describe ES 1. It is not clear how these values of release factors were derived/estimated by the Registrant. Finally, ECHA notes that there are different grades of effectiveness of municipal sewage tretament plants claimed by the Registrant in different ESs and there is no explanation provided in the CSR for the use of such different values for the effectiveness.

Thus, ECHA considers that clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for using other than default ERC release factors in exposure estimation is not provided in the CSR.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide for all ESs, where non-default ERC release factors are used for exposure estimation, a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for any non-default ERC release factor. Alternatively, the Registrant may choose to use ERCs' default release factors for his exposure estimation. The chemical safety report shall be amended accordingly.

In his comments to the PfAs submitted by the MSCAs the Registrant stated that his future revision of the Exposure Scenarios in the CSR will demonstrate that there is no or only insignificant release to water, air and soil during the uses of dichloromethylbenzene.

In the clarifications on his comments to the PfAs submitted by MSCA, the Registrant stated in the Member State Committee meeting on 10 June 2014 that there is no professional use for the registered substance, neither outdoor nor indoor, and that all uses are industrial and well controlled. The professional uses currently described in the dossier therefore would be removed from the updated dossier.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested another study (two-generation reproductive toxicity study (Annex X, 8.7.3)). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 18 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

In carrying out the studies 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. If the registration of the substance covers different grades, the sample used for the new studies 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 studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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