~~Confidential~~

Helsinki, 09 September 2021

Addressees
Registrant(s) of dechlorane plus as listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject to this decision
20 October 2020

Registered substance subject to this decision ("the Substance")
Substance name:
1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene
EC number: 236-948-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By the decision of 13 December 2019 ("the original decision") ECHA requested you to submit information by 21 December 2020 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration dossier specified in the header above, and concludes that

Your registration still does not comply with the following information requirement(s):

A. Information required from all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

You are therefore still required to provide this information requested in the original decision.

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annexes IX to X of REACH".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them

under Article 126 of Regulation No 1907/2006 (penalties for non-compliance)[1].

Authorised[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] See paragraphs 61 and 114 of the judgment of 8 May of the General Court of the European Court of Justice in Case T-283/15 Esso Raffinage v. ECHA

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

Appendix A: Reasons to request information required under Annex IX of REACH

1. Pre-natal developmental toxicity study in one species

You were requested to submit information derived with the registered substance for Pre-natal developmental toxicity study in a first species.

In response, you provided:

- In Section 7.8.2 of your dossier an adaptation referring to Annex XI, Section 3 and to low toxicity of the Substance.
- An expert statement by [redacted] (2020), supporting the low toxicity argumentation in the adaptation, partly based on the OECD TG 422 study below.
- An OECD TG 422 study (2008) with the Substance included in IUCLID section 7.8.1.

We have reviewed this information and identified the following issue(s):

A. Evaluation of the adaptation under Annex XI, Section 3 (Substance-tailored exposure-driven testing)

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a),(b) or (c) shall be met. In particular:

- 3.2 (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:
    1. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
    2. a DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes[3]; and
    3. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

- 3.2 (b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply;
- 3.2 (c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is

[3] For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of Section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study. For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.

demonstrated and documented that all of the following conditions i) to (iii) are fulfilled, where the first condition is

1. the substance is not released during its life cycle.
2. the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and
3. the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

In your adaptation statement in Section 7.8.2 of your dossier you conclude that "*For application of Dechlorane Plus in* [redacted] *and* [redacted] *both used for* [redacted] *no significant emissions to environment or workers through the whole substance life cycle are expected. Only one consumer use exists where the substance is tightly bound in the article matrix and no exposure is expected.*"

ECHA identified the following issues with a view to the above conditions:

The first criterion 3.2(a) requires "*absence of or no significant exposure in all scenarios of the manufacture and all identified uses*". ECHA notes first that exposure to the substance cannot be excluded in worker exposure scenario 1, contributing scenario 6, handling/transfer of solid masterbatches. You estimate exposures of [redacted]. Likewise, in exposure scenario 2, contributing scenario 7, handling/transfer of extrudates you estimate exposures of [redacted]. Furthermore, no relevant DNEL is available for the information requirement.

The second criterion 3.2(b) requires a demonstration that "*throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)*" apply. But the Substance is not handled under strictly controlled conditions as demonstrated by your exposure estimates discussed in the previous paragraph. In particular, condition (a) as set out in Article 18(4) is not fulfilled because it has not been demonstrated that the substance is rigorously contained by technical means during its whole lifecycle. Therefore criterion 3.2(b) for exposure-based adaptation is not satisfied.

The third criterion 3.2(c) you state that the substance is tightly bound in the article matrix, but you have not provided evidence that demonstrates that the substance is not released from the article throughout its life cycle.

ECHA conclusion

Based on the above, the information you provided do not fulfil the requirements for an adaptation under Annex XI, Section 3.

B. Evaluation of the adaptation under Annex IX, Section Column 2 (low toxicity)

To be compliant with Annex IX, Section 8.7.2. Column 2 it needs to be demonstrated that 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.

In your adaptation statement in Section 7.8.2 of your dossier you conclude that " *The registrant does not expect any risks for prenatal development as several toxicological studies for repeated dose toxicity (2008, 2013, 1975, 1975), genetic toxicity (2008, 2019, 1980) and reproductive toxicity (2008) presented in this dossier demonstrate no hazardous property for humans, which would justify an additional animal testing. This is in line with the opinion of the evaluating member state UK which lead to classification as vPvB but not as PBT since the MS could not find any hint concerning to toxicity to humans in their report. A detailed justification about the waiving of the prenatal developmental toxicity study and the conclusion of the low toxicity of Dechlorane Plus is reported by as external toxicologist prepared on 30. June 2020 and included to this IUCLID section as pdf file for your attention."*

Your adaptation is supported by the expert statement by (2020) which contains, *inter alia*, a comparison of the information requirements in the OECD TGs 422 and 414, respectively.

Although you do not refer to a legal provision for this part of the adaptation, ECHA considers that you may have considered an adaptation under Annex IX, Section Column 2 (low toxicity).

ECHA identified the following issues with a view to the above conditions for such an adaptation:

1. "No significant exposure" is addressed in above section "A.". In particular, exposure to the substance cannot be excluded on the basis of the information in your registration dossier. Therefore this criterion is not fulfilled.
2. There is no evidence for lack of absorption of the Substance. In the Toxicokinetic summary section of IUCLID you state that *"Absorption from the gastrointestinal tract was between 6 and 16.5%".* Therefore also this criterion is not fulfilled.

ECHA conclusion

The adaptation according to Annex IX, Section 8.7.2., Column 2 is rejected. ECHA's evaluation of the provided OECD TG 422 study is recorded below in Section C.

C. Evaluation of the OECD TG 422 study

Regarding the "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422) provided in your registration dossier ECHA finally refers to the original decision number CCH-D-2114493585-34-01/F of 13 December 2019.

D. Overall conclusion

For all these reasons, the information provided in your registration dossier does still not fulfil the information requirement.

As detailed above, the request in the original decision was not met, and you are still required to provide information on Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance.

Appendix B: equirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

B. Test material

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

Appendix C: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2021.

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision of 13 December 2019 ("the original decision"). Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 41 of the REACH Regulation.

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments within the notification period.

ECHA notes that on 30 May 2021, i.e. one day before the end of the commenting period, the Registrant ceased the manufacture and its status was set to inactive in REACH-IT. Article 50 (2) and 50(3) of the REACH Regulation does not apply to this decision, because it does not contain a request for further information. It only states that ECHA examined the provided information under Article 42(1) of the REACH Regulation, that the registration still does not comply with the information requirement and that the enforcement authorities will be informed of the decision. Consequently, this decision does not give a new deadline as the deadline set in the original decision of 13 December 2019 still applies. Since Article 50(2) and 50(3) of the REACH Regulation only exclude requesting "further information", ECHA is not prevented from issuing this decision, as ECHA does not request information in addition to the one already requested in the initial, already adopted evaluation decision. Therefore, the registrant continues to be bound by the original evaluation decision of 13 December 2019 and is required to provide the requested information regardless of its cease of manufacture of the Substance.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix D: List of references - ECHA Guidance[6] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.