~~Confidential~~

Helsinki, 15 November 2023

Addressees
Registrants of JS_IFF_HHCB as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
14 June 2021

Registered substance subject to this decision ("the Substance")
Substance name: 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran
EC/List number: 214-946-9

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***20 August 2026***.

Requested information must be generated using the Substance unless otherwise specified.

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

1. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23/OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

The reasons for the request are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

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

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

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

Appendix 1: Reasons for the request

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Reasons related to the information under Annex IX of REACH

1. Soil simulation testing

1 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

1.1. Triggering of the information requirement

2 A high potential for adsorption is indicated by lipophilicity e.g. when log K_{ow} > 4, log $K_{oc,soil}$ > 4 (Guidance on IRs and CSA R.7.9.4.3) or other mechanisms than driven by the lipophilicity e.g. ionising substances (at pH 4-9), surface active substances, substances that bind chemically with soil components.

3 The Substance has a high partition coefficient based on log K_{ow} of 5.3 to 5.9 and high adsorption coefficient based on log K_{oc} of 4.16 and therefore has high potential for adsorption to soil.

1.2. Information provided

4 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following experimental data on the Substance:

(i) a non-guideline lysimeter study (Difrancesco, 2004);

(ii) a biodegradation simulation study in soil similar to OECD TG 307 ([redacted], 1998);

(iii) a non-guideline biodegradation assay using a fungal/soil microcosm ([redacted] 1997).

1.3. Assessment of the information provided

1.3.1. Weight of evidence adaptation rejected

5 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

6 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

7 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

1.3.1.1. Lack of documentation justifying the weight of evidence adaptation

8 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach.

9 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

10 Beside this critical deficiency common to all information requirements under consideration, your weight of evidence approach has additional deficiencies.

11 Information that can be used to support weight of evidence adaptation for the information requirement of Annex IX, Section 9.2.1.3. includes similar information that is produced by the OECD TG 307. OECD TG 307 requires the study to investigate the following key parameters:

(1) Key parameter 1: the rate of aerobic transformation of the test material in four soil types, and
(2) Key parameter 2: the identity and rates of formation and decline of transformation products in at least one soil type.

1.3.1.2. Key parameter 1

12 The sources of information (i) and (ii) may provide relevant information on the rate of aerobic transformation of the test material in soil. However, source of information (i) was conducted with a single soil and the source of information (ii) with only three soil types. The source of information (iii) does not provide any information on key parameter 1.

1.3.1.3. Key parameter 2

13 The source of information (iii) provides information on the rates of formation and decline of transformation products. However, it provides only limited information on the identity of the formed transformation products (only retention times are provided with no information on chemical identity). The source of information (i) and (ii) do not provide any information on key parameter 2.

14 On this basis, the sources of information supporting your adaptation only provides a partial coverage of the key parameters investigated by the required study.

15 In addition, these sources of information are affected by methodological deficiencies impacting the reliability of the information as explained further below.

16 To inform on soil simulation testing, normally a study performed according to OECD TG 307 must be provided. The OECD TG 307 requires the following specifications to be met:

Validity criteria

a) recoveries (i.e. mass balances) range from 90% to 110% for labelled chemicals and from 70% to 110% for non-labelled chemicals;

Technical specifications impacting the sensitivity/reliability of the test

b) the purity of the test material is ≥ 95 %;

c) the soil must be freshly collected from the field;

Reporting of the methodology and results

d) tabulated results expressed as % of applied initial dose and, where appropriate, as mg/kg DW soil in each replicate test vessel are provided.

17 In the provided sources of information:

Validity criteria

a) no information on mass balance is provided for source of information (i). For source of information (ii), total recovery reached only 52% in agricultural soil (soil #1).

Technical specifications impacting the sensitivity/reliability of the test

b) for source of information (i), you state that the test was conducted with "*a cocktail of the 22 fragrance materials including HHCB*" and that the "*amount of cocktail was 10 times the concentration of HHCB*". For source of information (ii), you have not provided information on purity.

c) for source of information (iii), you describe the soil sample as a "*composite soil consisted of: equal amounts (~100 g) of a sludge-amended soil, a forest soil, an agricultural soil, a river sediment, a salt marsh sediment, a cedar water sediment, a garden soil; and ~20 ml each of an anaerobic digester sludge and an aerobic sludge from a waste water facility (Hazlet, NJ)*". The composite soil was enriched with fungal strains selected for their potential to degrade the Substance.

Reporting of the methodology and results

d) tabulated results expressed as % of applied initial dose and, where appropriate, as mg/kg DW soil in each replicate test vessel are not provided for sources of information (i) and (ii).

18 Based on the above,

- in the absence of information on mass balance for source of information (i), the validity of the reported results cannot be ascertained. Furthermore, the source of information (ii) only provides adequate recoveries for two soil samples while soil #1 does not have adequate recovery as highlighted under a).
- the source of information (i) was conducted on a 'cocktail' of fragrance substances, and it is therefore unclear whether this study provides a reliable estimate of the degradation kinetics of the Substance when tested alone. Furthermore, for source of information (ii), you have not provided information on purity and therefore no assessment is possible.
- for source of information (iii), you have used a composite soil enriched with fungal strains selected for their potential to degrade the Substance that cannot be considered equivalent to a 'natural soil'. Therefore, it is unclear to what extent such study reflects biodegradation potential under relevant environmental conditions.
- for sources of information (i) and (ii), in the absence of adequate reporting of the results of these studies, ECHA cannot conduct an independent assessment of the interpretation of the results.

1.3.1. Conclusion

19 In summary, the provided sources of information only provide a partial coverage of the key parameters normally investigated to cover this information requirement. Furthermore, the reliability of these sources of information is severely impacted by the deficiency listed above and therefore cannot contribute to the conclusion on the key parameters investigated by the required study.

20 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for Soil simulation study.

21 Based on the above, your adaptation is rejected.

22 Therefore, the information requirement is not fulfilled.

1.4. Study design

23 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

24 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

25 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

26 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

27 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2022.

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.

The compliance check was initiated on 13 March 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

In your comments to the draft decision, you requested an extension of the deadline to provide information from 24 to 30 months from the date of adoption of the decision. You justified the request by additional time required to complete the testing due to anticipated delays in finding an appropriate laboratory to conduct the studies and difficulty to perform the radiolabelling.

ECHA acknowledges the difficulties in obtaining the radiolabelled test material and in conducting the test, ECHA has agreed with your request for a deadline extension. On this basis, ECHA has extended the deadline to 30 months.

ECHA took into account your comments and did not amend the request.

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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 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 (https://echa.europa.eu/practical-guides).

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(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 variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- 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.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

2. General recommendations for conducting and reporting new tests

2.1 Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach", (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found under Appendix 1.