~~Confidential~~

Helsinki, 09 March 2022

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

Date of submission of the dossier subject to this decision
15/12/2020

Registered substance subject to this decision ("the Substance")
Substance name: Cinnamomum zeylanicum, ext.
EC number: 283-479-0

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 the deadline of ***15 December 2022***.

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

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

1. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310)

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annexes VII of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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;

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for

REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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

[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 A: Reasons to request information required under Annex VII of REACH

1. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 using the following supporting information:

i. EU-C.4-E on substance Eugenol, (CAS No. 97-53-0) ([redacted], 1999),
ii. OECD TG 301B on substance Eugenol, (CAS No. 97-53-0) ([redacted], 1994),
iii. OECD TG 301F on substance Eugenol, (CAS No. 97-53-0) ([redacted], 1993),
iv. Estimation based on hydrolysis behaviour on substance Eugenyl acetate, (CAS No. 93-28-7),
v. OECD TG 301C on substance Benzyl benzoate, (CAS No. 120-51-4 (MITI, 1996),
vi. OECD TG 301F on substance β-carophyllene, (CAS No. 97-53-0) ([redacted], 2007),
vii. OECD TG 301B on substance Alpha-Pinene (CAS No. 80-56-8) ([redacted], 2001),
viii. OECD TG 301C on substance Alpha-Pinene (CAS No. 80-56-8) (MITI, 2007),
ix. Headspace CO2 test on substance D Limonene (no CAS) ([redacted]1993),
x. OECD TG 301C on substance D Limonene (no CAS) (MITI, 1980),
xi. Ready biodegradation test results on substance D Limonene (no CAS) (publication Misra et al., 1996),
xii. OECD TG 301B on substance Terpinolene (no CAS) ([redacted]1996),
xiii. OECD TG 301F on substance Terpinolene (no CAS) ([redacted], 1997),
xiv. OECD TG 302C on substance Terpinolene (no CAS) [redacted], 1998),
xv. Rapidly biodegradable test results on substance Terpinolene (no CAS) (publication Misra et al., 1996),
xvi. OECD TG 301F on substance Heliotropin (no CAS) ([redacted]1998),
xvii. OECD TG 301B on substance Heliotropin (no CAS) ([redacted]1993),
xviii. OECD TG 301B on substance Cinnamic Aldehyde (CAS No. 104-55-2) (EPA, [redacted], 2001)
xix. QSAR on substance Safrole (CAS No. 94-59-7),
xx. QSAR on substance Cinnamyl acetate (CAS No. 103-54-8)

We have assessed this information and identified the following issues:

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have provided a read-across justification document in the endpoint summary for biodegradation.

You have provided the following reasoning for the prediction of biodegradation: ” *According to the NCS protocol (2009), the assessment of the biodegradability of an NCS should preferably be based on a constituent approach. The assumption is that if the constituents of the NCS are readily biodegradable, the NCS itself is readily biodegradable as well. Ready biodegradation tests have been developed for single substances; thus for mixtures like NCSs, these standard tests do not provide information on the biodegradability of individual*

constituents. Therefore relevant available information on the constituents should be gathered and its suitability for classification and labelling, risk assessment and persistency assessment evaluated."

You read-across between the structurally similar substances:
Eugenol, (CAS No. 97-53-0) ,
Eugenyl acetate, (CAS No. 93-28-7),
Benzyl benzoate, (CAS No. 120-51-4),
β-carophyllene, (CAS No. 97-53-0),
Alpha-Pinene (CAS No. 80-56-8),
D limonene (no EC or CAS No available),
Terpinolene (no EC or CAS No available),
Linalool, (CAS No. 78-70-6),
Heliotropin (no CAS),
Safrole, (CAS No. 94-59-7),
Cinnamic Aldehyde, (CAS No. 104-55-2) and
Cinnamyl acetate, (CAS No. 103-54-8)
as source substances and the Substance as target substance.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis that assumes that ready biodegradability can be predicted from the properties of its constituents. ECHA notes that for some constituents, no substance-specific information is available and you provided information on structurally similar substances.

ECHA notes the following shortcomings with regards to predictions of biodegradation:

1. Missing robust study summaries

Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). In order to make an independent assessment of a key study, a robust study summary must be provided (Guidance on IRs and CSA, Section R.6.2.6; Art. 3(28) and 10(a)(vii) and Annex I, Section 1.1.4/3.1.5 of REACH).

Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

You have provided only effect estimates and test guidelines, for the experimental studies provided in support of your read-across (i.e. source of information i. to iii. and v. to xviii. as listed above).

Therefore, you have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of these studies. In the absence of such information, these studies cannot be considered to provide an adequate and reliable coverage of the key parameters foreseen to be investigated in a study under to the corresponding OECD TG.

2. Use of QSAR estimation to assess ready biodegradation

ECHA Guidance R.7.9.5.1. specifies that (Q)SARs (including EPISUITE, BIOWIN) for predicting ready biodegradation are not sufficiently accurate to predict rapid degradation. However, when no useful information on degradability is available (either experimentally derived or

estimated), (Q)SAR predictions can be used as supporting evidence of that the substance is not rapidly degradable.

Your dossier provides (Q)SARs predictions (source of information xix. and xx. using EPISUITE BIOWIN) for some constituents of the Substance, without further justification. Based on this information you conclude that these constituents are readily biodegradable.

However, as explained above, and still valid today for the same reasons, (Q)SARs predictions alone is not adequate for the purpose of risk assessment, in this case PBT assessment. Therefore, this information cannot be considered as reliable supporting information for a conclusion of ready biodegradability in the context of your read-across adaptation.

3. Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

For ready biodegradability supporting information could be information to confirm similar bioavailability and degradation rates for the constituents of the Substance or structurally similar analogue substances.

For some constituents of the Substance, you provide studies (study ix. to xvii.) to support your prediction of ready biodegradability. However, as data on some constituents are not provided, your dossier does not include sufficient data to allow confirmation of similar bioavailability and degradation rates for the constituents of the Substance and the Substance.

In the absence of such information, you have not established that the Substance and these source substances are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Therefore, the information requirement is not fulfilled.

Appendix B: Requirements 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[2].

B. 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 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 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[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (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.

Appendix D: Procedure

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 3 February 2021.

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

ECHA did not receive any comments within the commenting period.

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

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

Appendix E: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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[7]

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[7] 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 F: Addressees of this decision and their corresponding information requirements

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[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.