Helsinki, 10 February 2020

Addressees
Registrants of JS_701-279-8 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
07/12/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: benzyl butyl cis-cyclohexane-1,2-dicarboxylate
EC number: 701-279-8
CAS number: 1931129-39-3

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***17 August 2022***.

Requirements applicable to all the Registrants subject to Annex IX of REACH[1]

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

2. 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;

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

4. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test (OECD 232) with the Substance;

5. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3. column 2.; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 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) with the Substance;

6. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21/OECD TG 216) with the Substance.

[1] Testing required under this Annex can only be started or performed after the decision has been adopted according to Article 51.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore, you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa.

Appendix A state the reasons for the requests for information to fulfil the requirements set out in Annex IX of REACH.

The testing material used to perform the required studies shall be selected and reported in accordance with the specifications prescribed in Appendix Observations and technical guidance.

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

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

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

[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 for the requirements applicable to all the Registrants subject to Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)**;

A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

The information on this endpoint is not available. You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You proposed testing by the oral route. ECHA agrees with your proposal.

You proposed testing in rats. ECHA agrees with your proposal.

In your comments on the draft decision, you agreed to perform the test.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species**;

A Pre-natal developmental toxicity study (OECD TG 414) in one species is a standard information requirement in Annex IX to REACH.

The information on this endpoint is not available. You have submitted a testing proposal for a Pre-natal developmental toxicity study in rats according to OECD TG 414 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in the ECHA Guidance[3]. Since the Substance is a solid, ECHA concludes that testing should be performed by the oral route.

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

You proposed testing in rats. According to OECD TG 414 rat is the preferred rodent species and rabbit is the preferred non-rodent species. You may conduct the study in either rat or rabbits.

In your comments on the draft decision, you agreed to perform the test.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.);

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have submitted a testing proposal for the Substance for Fish, early-life stage toxicity test, OECD TG 210.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Long-term toxicity to fish. You did not provide your considerations by the given deadline.

Although you have not provided any justification, the proposed study is appropriate to fulfil the information requirement for the reasons given below.

As reported in your dossier, the highest achievable test concentration in the aquatic toxicity testing was 620 µg/L. Therefore ECHA considers the Substance to be poorly water soluble. Poorly water soluble substances require longer time to be taken up by the organisms as steady-state conditions are likely not to be reached during the short-term toxicity tests and for that reasons the short-term tests may not give the true measures of toxicity and long-term effects to aquatic organisms cannot be excluded. For the same reasons it is not possible to determine the species sensitivity and therefore, the Integrated Testing Strategy (ITS) outlined in ECHA Guidance[4] is not applicable and the long-term studies on both invertebrates and fish are needed.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6. to REACH.

In your comments on the draft decision, you agreed to perform the test.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

4. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Effects on terrestrial organisms is a standard information requirement in Annex IX to REACH. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for the Substance for a long-term toxicity test to invertebrates (Collembolan reproduction test in soil, OECD TG 232).

[4] ECHA Guidance R.7b, Section R.7.8.5.

According to the provided information, the Substance has a potential to adsorb to soil (log $Kow_{calculated\ by\ EPISuite}$ [5.29]) / log $Kow_{experimental}$ [4.56]) and is considered very persistent, which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available. Therefore, ECHA agrees that a long-term testing is required.

The earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test (OECD TG 232), are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. For the highly adsorptive substances with the log Kow above 5, the test according to OECD TG 232 is not appropriate, as the dominant route of exposure for Collembolans is via pore water.

As your substance has log K_{ow} close to 5, the above consideration may be relevant to you. Thus, the choice of the most appropriate and suitable test guideline among those listed above is left to you.

Please refer to ECHA's response to your comments on the draft decision under section A.5 below.

Under Article 40(3)(b) of the REACH Regulation, you are requested to carry out the proposed test under modified conditions, as explained above.

5. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Effects on terrestrial organisms is a standard information requirement in Annex IX to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have sought to adapt this standard information requirement by referring to the testing proposed for terrestrial invertebrates (addressed under request A.4 above) as sufficient to fulfil information requirement for this endpoint. ECHA understands that you intended to use the results of this study in combination with the Equilibrium Partitioning Method (EPM) as indicated in Column 2 of Annex IX, Section 9.4.

To be able to assign the substance to an appropriate soil hazard category and to apply the screening assessment through the use of the EPM approach (in accordance with Column 2 of Annex IX, section 9.4.) there has to be adequate data for a reliable $PNEC_{water}$ (ECHA Guidance R.7c, section R.7.11.6 and table R7.11-2).

You have proposed a toxicity test on fish (request A.3 above) and the results of this proposed test may lead to a revision of the currently derived $PNEC_{water}$. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance, is not possible at this moment of time.

Since a screening assessment for terrestrial organisms is not possible, your adaptation is rejected and testing on terrestrial plants is considered necessary.

In your comments on the draft decision, you agreed to assign first the correct soil hazard category (based on the results of newly conducted studies on biodegradation and the long term toxicity to fish (request A.3)) and if confirmed necessary, to perform terrestrial testing in a tiered approach starting with the Collembolan reproduction test in soil (OECD 232).

As your substance has a potential for adsorption and is considered very persistent (as explained under request A.4. above), long-term testing is indicated.

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test(s), as indicated above. If based on the outcome of the new studies on biodegradation and long-term toxicity to fish you decide that no terrestrial testing or only one long-term terrestrial study is required you will need to include a scientifically justified adaptation of the terrestrial information requirement(s) (Annex IX, 9.4.1. and/or Annex IX 9.4.2) in your registration dossier.

6. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Effects on terrestrial organisms is a standard information requirement in Annex IX to REACH. The requirements in Annex IX, Section 9.4. must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants.

You have sought to adapt this standard information requirement by referring to the testing proposed for terrestrial invertebrates (addressed under request A.4. above) as sufficient to fulfil information requirements for this endpoint. ECHA understands that you intended to use the results of this study in combination with the Equilibrium Partitioning Method (EPM) as indicated in Column 2 of Annex IX, Section 9.4.

The screening assessment through the use of the Equilibrium Partitioning Method (EPM) approach does not apply as the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore, the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3 does not apply for the present endpoint.

Please refer to ECHA's response to your comments on the draft decision concerning your terrestrial testing strategy under section A.5 above. ECHA emphasises that the test on toxicity on soil microorganisms needs to be conducted irrespective of the need to conduct a second long-term toxicity terrestrial test.

Your adaptation is rejected since information on toxicity on soil microorganisms is necessary, in addition to the requested studies on invertebrates and plants (addressed under requests A.4. and A.5. above) to fully address the effects on terrestrial organisms.

To address this endpoint, the nitrogen transformation test (EU C.21/OECD TG 216) is considered a suitable method (ECHA Guidance R.7c, Section R.7.11.3.1).

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test(s), as indicated above.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 15 November 2018, following the necessary clarification of the identity of your substance.

ECHA held a third party consultation for the testing proposals from 10 December 2018 until 24 January 2019. ECHA did not receive information from third parties.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

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

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 C: Observations and technical guidance

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

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

3. Test guidelines, GLP requirements and reporting

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

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

   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: 'How to report robust study summaries[5]'.

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[6].

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

5. Ecotoxicity testing

Due to the water solubility issues of the substance you should consult OECD Guidance Document, ENV/JM/MONO (2000)6 REV1 and ECHA Guidance[7], summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

Once the test requested under point 3 of the present decision is conducted and $PNEC_{water}$ derived, you are advised to check whether Integrated testing strategy (ITS) as recommended in ECHA Guidance R.7c, Section R.7.11.6 applies to your case.

6. List of references of the ECHA Guidance documents8

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[9]

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.

[7] ECHA Guidance R.7b, Table R. 7.8-3
[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]