EUROPEAN CHEMICALS AGENCY

Helsinki, 21 January 2021

Addressees
Registrant(s) of JS_136-60-7 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21/10/2019

Registered substance subject to this decision ("the Substance")
Substance name: Butyl benzoate
EC number: 205-252-7
CAS number: 136-60-7

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 in A.1 below by ***26 October 2021*** and all other information listed below if the study under section A.1 shows the Substance is poorly water soluble by ***28 April 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. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29)

2. Only if study under section A.1 indicates that the Substance is poorly water soluble, (i.e. water solubility below 1 mg/L) Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: OECD TG 211)

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Only if study under section A.1 indicates that the Substance is considered as poorly water soluble(i.e. water solubility below 1 mg/L, Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

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

- Appendices entitled "Reasons to request information required under Annexes VII to VIII 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;

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 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". 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.

Approved[1] under the authority of Christel Schilliger-Musset, 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. Water solubility

Water solubility is a standard information requirement in Annex VII to REACH.

You have provided a key study according to OECD TG 105 and you have concluded that water solubility value of the Substance is <1 mg/l.

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

Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH).

OECD TG 105 is the standard test guideline which establishes the requirements for the data to be reported for a water solubility study. It requires that the following conditions are met (among others):

1. Three measurements are required with equilibration at the test temperature for 24 hours, 2 days and 3 days, and the concentration in at least the last two flasks should not differ by more than 15%
2. EU test method A.6 and OECD TG 105 establish the requirements for the data to be reported for a water solubility study. For the & flask method, the following is required to be reported (among others):
    - The individual analytical determinations and the average where more than one value was determined.
    - The pH of each sample.
    - The test temperature.
    - The analytical method employed.

In the endpoint study record for the key study (OECD TG 105, 2018), you reported the following:

- A preliminary experiment was conducted with a 1mg/L solution, and after shaking it, a non dissolved material was observed by visual determination.
- Due to the contradiction of results between the one obtained experimentaly and the one obtained by EPISuite predictions, a new experimental study of water solubility was performed with a 5mg/L solution. A proportional increase of undissolved material was observed on the water surface by visual determination.
- Because of these results, you conclude that the water solubility of the Substance is below 1mg/L.

Your non-guideline method does not follow the OECD TG 105. In particular:

- It is not possible to determine if equilibrium was established between undissolved solid and solution because there was only one measurement indicated. Therefore, ECHA cannot ascertain if the used method (Adaptation of the OECD 105) is valid to determine the water solubility. Consequently, the aforementioned condition (1.) of the standard OECD test guideline is not met.
- you did not report pH of the saturated solution nor the temperature of the water solubility measurement. Consequently, the aforementioned condition (2.) of the standard OECD test guideline is not met.

In your comments to the draft decision, you acknowledge that the Substance has a low water solubility, but likely higher than 1 mg/L. You disagree to perform the water solubility test.

You justify not performing a definitive water solubility study as the data indicated in your comments to the draft decision which are based on software predictions, literature and the measurements in ecotox media, confirm that butyl benzoate has a rather low water solubility, but likely higher than 1 mg/L. Indeed, in your comments to the draft decision, you provided a number of water solubility values from a number of different sources of information (including QSARs) and indicate that you will provide a weight of evidence adaptation in a dossier update in order to fulfil this information requirement. The provided information indicates a value and the source of information but it is not substantiated. ECHA cannot assess it. If adaptation according to Annex XI, section 1.2 is provided for this decision by the set deadline, it should fulfil requirements of this Annex XI, section 1.2 and provided information should be sufficient to conclude that substance has or has not a particular property. Furthermore, if QSAR modelling data are provided in the registration dossier, only, for this decision by the set deadline, to address standard information requirement, it should meet conditions prescribed in Annex XI, section 1.3.

Therefore, the provided study is rejected and the information requirement is not fulfilled.

2. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH. However, pursuant to Annex VII, section 9.1.1, column 2, for poorly water soluble substances (i.e. water solubility below 1 mg/L) long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered instead of an acute test.

You have provided a short-term study to aquatic invertebrates performed according to OECD TG 202 (2018) with the Substance. You have not provided any data on long-term toxicity to aquatic invertebrates.

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

You have indicated in the technical dossier that the Substance is poorly water soluble <1 mg/l. However, as explained under request A.1, your dossier currently does not include reliable value on the water solubility of the substance.

In your comments to the draft decision, you state that reliable short-term studies on algae, daphnia and fish are available and that PNEC derived by these studies as well as the CSA indicate no need for long-term aquatic studies. In addition, you state that you may re-assess the water solubility of the Substance, although you believe that the solubility of the Substance is highly likely to be >1 mg/L.

However, as explained above in request A-1, you still do not provide reliable value on the water solubility of the substance and hence ECHA cannot assess whether the Substance is considered poorly water soluble. Further, column 2 is not a grounds for adaptation of the information requirement for long-term toxicity testing on invertebrates (see Board of Appeal decision A-011-2018). Therefore, your adaptation cannot be accepted.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances.

Therefore, if the information requested on water solubility (request A.1) confirms that the substance is poorly water soluble (i.e. water solubility below 1 mg/L), a long-term test must be conducted.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH. However, pursuant to Annex VIII, section 9.1.3, column 2, for poorly water soluble substances (i.e. water solubility below 1 mg/L) long-term toxicity study on fish (Annex IX, Section 9.1.6) must be considered instead of an acute test.

You have provided a short-term study to fish performed according to OECD TG 203 (2018). You have not provided any data on long-term toxicity to fish.

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

You have indicated in the technical dossier that the Substance is poorly water soluble <1 mg/l. However, as explained under request A.1, your dossier currently does not include reliable value on the water solubility of the substance.

In your comments to the draft decision, you state that reliable short-term studies on algae, daphnia and fish are available and that PNEC derived by these studies as well as the CSA indicate no need for long-term aquatic studies. In addition, you state that you may re-assess the water solubility of the Substance, although you believe that the solubility of the Substance is highly likely to be >1 mg/L.

However, as explained above in request A-1, you still do not provide reliable value on the water solubility of the substance and hence ECHA cannot assess whether the Substance is considered poorly water soluble. Further, column 2 is not a grounds for adaptation of the information requirement for long-term toxicity testing on fish (see Board of Appeal decision A-011-2018). Therefore, your adaptation cannot be accepted.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, if the information requested on water solubility (request A.1) confirms that the substance is poorly water soluble (i.e. water solubility below 1 mg/L), a long-term test must be conducted.

Appendix C: 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 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 9 July 2019.

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

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 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.

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[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

OECD Guidance documents[7]

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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: 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]
[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.