EUROPEAN CHEMICALS AGENCY

Helsinki, 13 January 2021

Addressees
Registrants of JS_32588-76-4 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
15/06/2017

Registered substance subject to this decision ("the Substance")
Substance name: N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)
EC number: 251-118-6
CAS number: 32588-76-4

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 ***20 April 2023***.

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)

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

1. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

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

- Appendices entitled "Reasons to request information required under Annexes VII to IX 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 Annexes VII to REACH, for registration at 1-10 tpa;
- the information specified in Annexes VII, 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;

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 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.

In your dossier, you have provided:

- an adaptation according to Annex XI, Section 2 with the following justification:
  - *"EBTBP is a high melting point (456 degrees C) soild* [and is therefore expected to] *have poor solubility in any solvent"*;
  - *"EBTBP's poor solubility has precluded development of specific methods of analysis"*;
  - *"It's water solubility, based on the chemical structure alone, is estimated to be 3.02e-9 mg/L (EPI v4.0). Estimates made with entry of EBTBP's measured vapor pressure and melting point were lower by approximately an order of magnitude"*;
  - *"Preliminary work for the water solubility study confirmed that BT93 demonstrated no significant solubility (<10 ppm) in water or 12 different organic solvents"*.
- A non-guideline study ([redacted], 1976) in which the water solubility was estimated to be < 1 mg/L.

We have assessed this information and identified the following issues:

A. According to Annex XI, Section 2, testing for a specific endpoint may be omitted if it is technically not possible to conduct a study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Articles 13(3), more specifically on the technical limitations of a specific method must always be respected. Annex VII, Section 7.7, Column 2 further states that if the Substance appears 'insoluble' in water, a limit test up to the detection limit of a sensitive analytical method must be performed.

   You have provided a supporting study ([redacted], 1976). The water solubility was determined to be < 1 mg/L. No details on the analytical monitoring method including its limit of detection (LOD) and limit of quantification (LOQ) is provided.
   In Section 5.3.1 of your technical dossier, you have provided a non-guideline bioaccumulation study via aqueous exposure (Hardy *et al.* 2004) for which you assigned a reliability score of 2. Test solutions were prepared using a carrier. The detection limit of the analytical method (HPLC-UV-VIS) is reported as 0.05 ppm.

   As explained below under issue B., the supporting study you have provided does not fulfil the information requirement because it does not provide reliable coverage of the key parameter investigated in an OECD TG 105 study. Furthermore, the water solubility is reported as < 1 mg/L while you have provided information indicating that an analytical method with a 20-fold higher sensitivity is available for the Substance. Therefore your adaptation is rejected.

B. To fulfil the information requirement, a study must comply with the OECD TG 105 or the EU Method A.6 (Article 13(3) of REACH). Therefore, the following requirements must be met:
   - The shake-flask method is generally applicable to substances having a water solubility limit ≥ 10 mg/L;
   - Solids are pulverized before testing;
   - Three flasks are included which are shaken/stirred for 24, 48 and 72 hours,

respectively;
- After shaking/stirring, each flask is equilibrated for 24 hours at 20°C.

You have provided a non-guideline study ([redacted], 1976) which has some similarity with a shake-flask method. The water solubility was estimated to be < 1 mg/L which indicates that the Substance is out of the applicability domain of the shake-flask method and that a column elution method must be used instead. Furthermore, based on the information you have provided, the additional requirements of the shake-flask method listed above were not fulfilled. Based on the above, this study does not fulfil the information requirement.

Therefore, the information requirement is not fulfilled.

You agreed to perform a new test on water solubility in your comments to the draft decision.

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

1. Identification of degradation products

Identification of the degradation products is a standard information requirement at Annex IX of REACH. Annex IX, Section 9.3.2, Column 2 further states that the information does not need to be provided if the substance is readily biodegradable.

You have adapted this information requirement with the following justification:

- *"We were unable to analytically determine BT93's water solubility or octanol-water partition coefficient, and will not be able to quantitate levels in water, diet, tissue, soil or sediment"*, and
- *"Further, EBTBP's insolubility, high molecular weight, large molecular volume and folded configuration will limit it accessibility to bacteria. This in turn will limit bacteria's ability to biotransform the substance"*.

ECHA understands that you have provided two adaptations:

1. an adaptation according to Annex XI, Section 2 as you consider the substance to be too insoluble to allow its quantification in water, soil or sediments. In your comments on the draft decision, you repeat your concern regarding to the difficulty to define if there are any degradation products at all under biodegradation conditions, as the molecule was designed to be stable in use. You also point out the difficulties to develop proper analytical methods to detect and quantify the degradation products of the Substance that will need to undergo radiolabelling and synthesize of a representative radiolabeled test material.
2. an adaptation according to Annex IX, Section 9.2. column 2 as you consider that bacteria will have limited ability to biotransform the Substance.

We have evaluated this information and identified the following issues:

A. According to Annex XI, Section 2, testing for a specific endpoint may be omitted if it is technically not possible to conduct a study as a consequence of the properties of the substance.

   However, the guidance given in the test methods referred to in Articles 13(3), more specifically on the technical limitations of a specific method, must always be respected.

   You can obtain information on the identity of the transformation/degradation products using biodegradation simulation testing in water and/or sediment and/or soil (i.e. OECD TG 309 and/or OECD TG 308 and/or OECD TG 307). These studies are generally applicable to (non-labelled or radiolabelled) substances for which an analytical method with sufficient accuracy and sensitivity is available. You can also use other appropriate and suitable test methods to provide this information for example an enhanced screening level degradation test or modelling tools.

   As explained under request A.1, the information requirement for water solubility is not fulfilled. While it is expected that the Substance has low water solubility, you have not demonstrated that the water solubility is so low that is not possible to quantify the Substance in water. Additionally, you have not provided any information to support your assertion that the Substance cannot be quantified in other environmental matrices such as sediment and soil.

Furthermore, as you indicate in your comment on the draft decision your plan to radiolabel the Substance, the detection of the degradation products would be possible. Therefore your comment is not relevant with the issues identified above.

Therefore, you have not demonstrated that the recommended biodegradation simulation testing guidelines are not technically feasible. Finally, you have not provided any justification as to why none of the alternative approaches to provide information on degradation products are applicable to the Substance. Therefore your adaptation is rejected.

B. This information requirement may be adapted under column 2 if the Chemical Safety Assessment (CSA) demonstrates and documents that risks arising from the Substance are controlled (Annex I, Section 0.1; Annex IX, Section 9.2, Column 2).
To this end, you need to provide a justification as why there is no need to provide any further information on the identification of the degradation products taking into account the PBT/vPvB properties of the Substance itself and of any of its constituent, impurity or transformation/degradation product present in concentration ≥ 0.1% (w/w) (Annex I, Section 4). This information is also needed for the risk assessment of the Substance (Annex I, Section 6).

You justified the adaptation by stating that due to the properties of the Substance (*i.e.* low solubility, high molecular weight, large molecular volume and folded configuration), the ability of bacteria to biotransform the Substance is expected to be limited. You have concluded the Substance as not readily biodegradable (0% biodegradation observed after 14 days in a non guideline study; Anonymous, 1981) and you have not provided any information on degradation products.

Ready biodegradability tests are conducted under stringent conditions to identify substances that are likely to undergo rapid and ultimate biodegradation under most environmental conditions (ECHA Guidance R.7b, Section R.7.9.4.1). The standard duration of ready biodegradability tests is normally 28 days in OECD TG 301 and 310. Therefore, the lack of mineralisation after 14 days observed in the ready biodegradability study included in your dossier does not demonstrate that the Substance will not form any transformation/degradation product under environmentally relevant conditions. In the absence of supporting evidence that transformation/degradation products are not formed to any significant extent, your chemical safety assessment (CSA) does not demonstrate that there is no need to provide information on the degradation products for the PBT/vPvB assessment and risk assessment. Therefore, your adaptation is rejected.

Finally, in your comment on the draft decision, you raised confidentiality concerns with regard to the possible variation of the Substance composition and content in impurities among the different addressees of the decision. Concerning the test material identification or composition and how relevant the radiolabelled one would need to be with the potential impurities, ECHA considers that the test material radiolabelled has to be representative and identified to the extent possible for all the joint submission members. The selection of a test material that is representative for the members of the joint submission is explained in detail in Section B of Appendix C. Confidentiality considerations are usually addressed by different methods commonly used among registrants including, for instance, the determination of a representative test material by a independent third-party (so-called trustee).
While ECHA takes account of your comment, it does not justify the waiving of the information requirement that is still considered as not fulfilled.

Study design

Regarding the appropriate and suitable test method you are recommended to perform the OECD TG 308 test. To overcome the potential analytical limitations in the identification and quantification of major transformation products you may use higher concentrations of the test substance and a temperature of 20°C.

In your comments on the draft, you raised concerns regarding the technical difficulties in performing an OECD TG 308. However, you may also use other appropriate and suitable test methods to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. In this case, you will need to provide a scientifically valid justification for the chosen method.

The provided information must include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log Kow and potential toxicity of the transformation/degradation may be investigated if they can be detected and quantified.

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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 19 August 2019.

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

In your comments on the draft decision, you argued that a similar request asking OECD TG 308 was made under the Substance evaluation process and consequently the identification and quantification of the degradation products would be disproportionate with regard to the ongoing Substance evaluation process.

However, it is necessary to highlight that the document you are refering to is a draft decision and not a final decision. Therefore, this document is not legally binding and does not require you to perform a test. Moreover, you have been informed by a letter from ECHA of 30 March 2020 (D(2018)4034-DC) that the Substance evaluation process was suspended pending the outcome of the compliance check process.

The timeline indicated in the draft decision to provide the information requested is 18 months from the date of adoption of the decision.
In your comments you requested an extension of the timeline to 39 months.
You justified your request stating that it is difficult to:
- perform radiolabelling,
- characterize the radiolabelled test material,
- develop specific analytical methods,
- extract from complex matrices sufficient degradation products and,
– that it implies performing 2 tests at 20 and 12 C.
You have provided a document from a CRO (Contract Research Organisation) illustrating the difficulties to perform radiolabelling and a detailed testing plan from a CRO.
However, we consider that the overall timeline of 39 months is not justified as :

- the identification of degradation products does not require to conduct a study at both 12 and 20 C.
- the analytical method development, extractability in the study matrices and protocol preparation and review are already accounted for in the standard 18 months deadline given.

We do however recognise, that there may be technical challenges with the radiolabbeling of the testing material. Therefore, ECHA has partially granted the request and set the deadline to 24 months.

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]
[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.