EUROPEAN CHEMICALS AGENCY

Helsinki, 1 April 2020

Addressees
Registrants of JS_1118-46-3 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
23/01/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N-butyltin trichloride
EC number: 214-263-6
CAS number: 1118-46-3

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below.

A. Requirements applicable to 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) with the Substance;

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method) with the Substance;

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance;

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method EU C.7./OECD TG 111) with the Substance;

2. Adsorption/Desorption coefficient (Annex VIII, Section 9.3.1.; test method OECD TG 123) with the Substance;

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa;

- you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa;

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendices of this decision state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

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

You must submit the information requested in points A.1 to A.3, B.1 and B.2 above in an updated registration dossier by ***7 July 2021***.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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[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 for the requests to comply with Annex VII of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to the REACH Regulation.

1. Water solubility (Annex VII, Section 7.7.)

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

You have adapted this information requirement based on Annex XI section 2 (testing technically not possible) and Annex VII Section 7.7., column 2. You base your justification for adaptations on the assumption that:

1) the Substance is hydrolytically unstable, and
2) the Substance is insoluble in water such that it is not possible to analyse it with any technique.

We have assessed this information and identified the following issues:

a) Under Annex XI, Section 2, testing may be omitted if it is technically not possible to conduct as a consequence of the properties of the substance.

ECHA understands that you refer to the insolubility of the substance and associated technical difficulties in analysis to justify the omission of the test. However, your assertion that the substance is insoluble in water is contradicted by the information provided in your dossier. In the aquatic acute toxicity tests provided (IUCLID sections 6.1.1. and 6.1.3.) the Substance was measured and quantified up to 100 mg/L in the test media.

Therefore the information reported in your dossier does not demonstrate that the substance is insoluble to the extent that the test would not be technically possible. This is confirmed by the statement joined to your adaptation that *"information now indicates the substance may in fact behave differently than originally thought. A new water solubility study is therefore to be attempted to try and obtain a definitive result. The study is expected to be finished second quarter 2019 and the registration is proposed to be updated to take account of this information in late second quarter/third quarter 2019"*.

b) Under Annex VII, Section 7.7, Column 2, the study does not need to be conducted if the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours).

ECHA understands that you refer to the hydrolytic instability to justify the omission of the test. However, your assumption that the substance is hydrolytically unstable is contradicted by the information provided in your dossier. In IUCLID section 5.1.2. there is a key study ([redacted]) which shows that the substance is stable to hydrolysis for up to 6 days in pure water and even more stable under acidic conditions.

Therefore the information reported in your dossier currently does not demonstrate that the substance is hydrolytically unstable at pH 4, 7 and 9 with a half-life of less than 12 hours. This is confirmed by the statement joined to your adaptation that *"the substance was considered to exhibit properties such that a waiver has been submitted to address this end point based on data to suggest the substance rapidly hydrolysed. This is no longer believed to be the case and new information now indicates the substance may in fact behave differently than originally thought"*.

Consequently, your adaptations according to Annex XI, Section 2 and Annex VII, Section 7.7, Column 2 are rejected and the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the study. You specify that you have anticipated the need to conduct a feasibility test as there are technical difficulties in conducting the analytical monitoring. You indicate that these feasibility tests would be finalized by end of July 2019.

You request to "*split the test requirement under this heading* [i.e. Annex VII requirements] *into a step-by-step approach, i.e. a feasibility test first* [...] *and then the main tests if the feasibility study is positive*". You request "*to adjust the deadline to carry out the main tests accordingly (12 months after finalization of the feasibility test)*".

ECHA notes that the timeline you provided to conduct the feasibility test has already passed. Therefore the 12 months deadline as set out in the draft decision is sufficient to conduct the requested studies.

Guidance for determining appropriate test methods for Water solubility is available in the ECHA Guidance R.7a, Section R.7.1.7.3.

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.)

Partition coefficient n-octanol/water is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement based on Annex XI section 2 (testing technically not possible) and Annex VII Section 7.8., column 2. You base your justification for adaptations on the following:

1) The Substance rapidly decomposes in contact with water,
2) The Substance is assumed insoluble in water such that it is not possible to analyse it with any technique,

You have also provided a QSAR value which you consider unreliable.

We have assessed this information and identified the following issues:

a) Under Annex XI, Section 2 testing may be omitted if it is technically not possible to conduct it as a consequence of the properties of the substance.

   ECHA understands that you refer to the insolubility and hydrolytic instability of the substance (decomposition in water) and associated technical difficulties in analysis as the properties which justify the omission of the test. However, as explained above in section A.1., the information reported in your dossier does not demonstrate that the substance is insoluble and hydrolytically unstable.

   You also state that "*new information now indicates the substance may in fact behave differently than originally thought. A new partition coefficient study is therefore to be attempted to try and obtain a definitive result. The study is expected to be finished second quarter 2019 and the registration is proposed to be updated to take account of this information in late second quarter/ third quarter 2019.*"

b) Under Annex VII, Section 7.8, Column 2, if the test cannot be performed e.g. the substance decomposes, or does not dissolve in water or n-octanol a calculated value for partition coefficient must be provided.

As explained under point a) above it has not been demonstrated that the test cannot be performed and so the Column 2 requirement for a calculated value is not triggered. Nevertheless, ECHA agrees with you that the calculated value you provided for the Substance is not reliable as there are no validated QSAR models for organometallic substances.

Consequently, your adaptations according to Annex XI, Section 2 and Annex VII, Section 7.8, Column 2 are rejected and the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the study. The comments covered in A.1 also apply to this request.

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.1.8 (version 6.0, July 2017).

3. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C1./OECD TG 201).

Growth inhibition study on aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided an OECD TG 201 study ([redacted]) as a key study. Additionally, you have provided two supporting studies which you consider unreliable. One is a non-guideline study (Wong) and the second is a QSAR estimate (Huang).

We have assessed this information and identified the following issue:

Under Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH, a robust study summary must be provided for the study/ies giving rise to the highest concern. A robust study summary must cover critical information and allow an assessment of the validity and reliability of the study. The principle of the OECD 201 test involves measurement of growth and growth inhibition in a series of algal cultures over time. Effect values are set based on inhibition of growth. Growth and growth inhibition are quantified from measurements of algal biomass (dry weight per volume). Since it is difficult to directly measure algal biomass, surrogate parameters are often used and converted to biomass. The validity criteria of the test require accurate measurement of biomass and growth rate in the control and test cultures over time. Consequently, the robust study summary must include information on the method used to calculate biomass and subsequently determine effect values including, among others:

- A description of method for determination of biomass and evidence of correlation between the measured parameter and dry weight,
- details of any stimulation of growth found in any treatment, and
- details of any other observed effects, e.g. morphological changes of the algae

However, in the study summary of your key study ([redacted]), you have not provided the above listed critical elements. Therefore, the data provided does not allow an independent assessment of the validity and reliability of this study and its results for use in hazard assessment.

Based on the above, the documentation of the OECD 201 ([redacted]) study is not reliable. In addition, ECHA agrees with you that the supporting studies are not reliable. Consequently, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the study. The comments covered in A.1 also apply to this request.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to the REACH Regulation.

1. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.)

Hydrolysis as a function of pH is a standard information requirement in Annex VIII to REACH.

You have provided a non-guideline key study ([redacted]) and an OECD TG 111 supporting study ([redacted]) in your dossier. In addition, you have adapted the information with reference to Annex XI Section 2 (testing technically not possible) and Annex VIII, Section 9.2.2.1., Column 2. You base your justification for adaptations on the assumption that the Substance is insoluble in water such that it is not possible to analyse it with any technique.

We have assessed this information and identified the following issues:

a) Under Annex XI, Section 2, testing may be omitted if it is technically not possible to conduct as a consequence of the properties of the substance. ECHA understands that you refer to the insolubility of the substance and associated technical difficulties in analysis as the properties which justify the omission of the test.

   In addition, under Annex VIII, Section 9.2.2.1., Column 2, the study does not need to be conducted if the substance is highly insoluble in water.

   However, as already explained in relation to request A.1, the substance is not proven to be highly insoluble in water.

b) Under Article 13(3) of REACH, tests on substances must be conducted in accordance with OECD test guidelines or another recognised international test method.

   The key study ([redacted]) was not performed according to the OECD TG 111 guideline.

c) Under Annex XI, Section 1.1.2., tests not carried out according to GLP or the test methods referred to in Article 13(3) can still be used if they provide "*adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3)*". OECD TG 111 is the recognised method for determination of hydrolysis as a function of pH. For a study conducted according to OECD 111 the following key parameters (among others) need to be investigated:
   1. Hydrolysis at pHs 4, 7 and 9,
   2. Identification of hydrolysis products, and
   3. Hydrolysis rates

   The above listed key parameters were not investigated in the key study ([redacted]).

In addition, ECHA agrees that the supporting study ([redacted]) is not reliable. Your statement being that *"this study in fact used an unsuitable test system for these types of substances. A more modern study conducted 14 years later confirms that the results of this older study should not be considered reliable."*

In your comments on the draft decision, you agreed with ECHA's assessment and to conduct the study. You specify that you intend to conduct the study at pH 4, 7 and 9, at 50°C.

However, ECHA notes that these test conditions correspond to the preliminary test (Tier 1) in OECD TG 111. Higher Tier kinetic tests must be carried out with a minimum of three temperatures (including the test at 50 °C) unless the test substance is stable to hydrolysis as determined by the Tier 1 testing.

Based on the above, the provided studies are not adequate to fulfil the information requirement. Consequently, the information requirement is not fulfilled.

2. Adsorption/Desorption coefficient (Annex VIII, Section 9.3.1.)

Adsorption Desorption as a screening test is a standard information requirement in Annex VIII to REACH.

You have adapted the information with reference to Annex XI Section 2 (testing technically not possible) and Annex VIII, Section 9.3.1., Column 2. You base your justification for adaptations on the following:

1) The Substance rapidly decomposes in contact with water,
2) The Substance is assumed insoluble in water such that it is not possible to analyse it with any technique,
3) The Substance cannot by analysed by HPLC so the HPLC method is not possible

You also provided an estimation of LogKow and Koc using a QSAR model (EPISUITE).

We have assessed this information and identified the following issues:

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

   ECHA understands that you refer to the insolubility of the substance and associated technical difficulties in analysis as the properties which justify the omission of the test. As explained above in section A.1., the information reported in your dossier does not demonstrate that the substance is insoluble.

b) According to Annex VIII, Section 9.3.1., Column 2, the study does not need to be conducted if the substance and its relevant degradation products decompose rapidly.

   As explained in detail above in section A.1., the information reported in your dossier does not demonstrate that the substance decomposes rapidly.

c) To perform the required test, ECHA Guidance R7a., R7.1.15 recommends to use alternative Test Guideline within others: OECD TG 106, TG 121, or TG 312 or ISO 18749.

   HPLC corresponds to OECD TG 121. You claim that the Substance cannot be analysed by HPLC. However, ECHA notes that there are, at least, two other suitable methods (e.g. the batch equilibrium method OECD TG 106) which may be used.

d) Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

1. the substance falls within the applicability domain of the QSAR model;
2. adequate and reliable documentation of the applied method is provided;

However, in your calculation of LogKow and Koc you indicated that the estimation is considered not to be a suitable alternative; as this QSAR (EPISUITE) is known to produce unreliable results for organometallic substances.

Indeed, as you indicated, the Substance does not fall within the applicability domain of the model (see ECHA Guidance R.6, Section R.6.1.5, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.2) and is not considered as fulfilling condition 1. of Annex XI, Section 1.3.

Furthermore, you have not provided any documentation for the QSAR prediction and do not fulfill condtion 2. of the Annex XI Section 1.3.

In your comments on the draft decision you did not comment on ECHA's assessment. You indicate that you have identified a publication by [redacted] (2001) which report sorption /desorption study in sediment-pore water systems. You acknowledge that here are some deviations from a standard adsorption/ desorption study. In particular, the study provides coefficients determined from desorption of sediment-sorbed butyltin compounds. You intend to cover this information requirement with this study.

We have assessed the information provided in your comments on the draft decision and identified the following issue:

Test on substances must be conducted in accordance with the OECD test guidelines or another internationally recognised international test method (Article 13(3) of REACH). For this endpoint the preferred test methods are OECD TG 106, or TG 312 or ISO 18749.

The publication by [redacted] (2001) was not performed according to any recommended test guideline. In addition, the measurements were conducted butyltin compounds but not on the Substance itself.

Therefore this study does not fulfil the conditions of the recommended test guidelines.

Consequently, your adaptations are rejected and the information requirement is not fulfilled.

Guidance for determining appropriate test methods for Adsorption/Desorption is available in the ECHA Guidance R.7a, Section R.7.1.15.3.

Appendix C: Procedural history

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 Regulation.

The compliance check was initiated on 08 November 2018.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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 requests.

Included in your comments, you outlined your tonnage volumes. As explained in ECHA's practical guide of January 2019 "How to act in Dossier evaluation", if you decrease the tonnage upon receipt of a draft decision, you still need to comply with the requests as per your tonnage indicated in the decision. This is because ECHA uses the information provided for registration purposes, as the basis for further processing (see section 5.4. of ECHA's Practical Guide[2]). As this matter does not affect the decision making process of this decision, ECHA is also addressing this in a separate communication to you.

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.

[2] ECHA's Practical Guide How to handle dossier evaluation - https://echa.europa.eu/documents/10162/13643/pg_dossier_evaluation_en.pdf/5788b5ee-f6c0-df56-c7ea-c693740acf87)

Appendix D: Observations and technical guidance

1. This compliance check 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[3]'.

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"[3].

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

5. List of references of the ECHA Guidance documents[4]

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)5

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.

[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

Appendix E: 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]