Helsinki, 26 November 2021

Addressees
Registrant(s) of bis(2-ethylhexyl)amine listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: bis(2-ethylhexyl)amine
EC number: 203-372-4
CAS number: 106-20-7

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

DECISION ON SUBSTANCE EVALUATION

Under Article 46 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below:

A. Information required to clarify the potential risk related to PBT/vPvB properties

1. Ready biodegradability (test method: Closed bottle test, OECD TG 301 D) (Request A.1), on the Substance, specified as follows:
   - With analytical verification of the Substance concentrations, at least on days 0, 1, 7, 14 and 28 and with at least three replicates for each day;
   - Including a sterile control containing no inoculum and a sterile control with (sterilized) inoculum. Maintenance of the test substance concentrations, in sterile controls, must be verified during the test with analytical determinations
   - With optional extension of the test duration up to 60 days;
   - Accounting for nitrification, as indicated in the test guideline;
   - Using effluent from a municipal waste water treatment plant located in a rural area as inoculum, which is not pre-adapted and which has not been exposed to structurally similar substances.

Deadline

The information must be submitted by ***31 August 2022*** *from the date of the decision*

Conditions to comply with the information requested

To comply with this decision, you must submit the information in an updated registration dossier, by the deadline indicated above. The information must comply with the IUCLID robust study summary format. You must also attach the full study report for the corresponding studies in the corresponding endpoint of IUCLID.

You must update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You will find the justifications for the requests in this decision in the Appendix entitled 'Reasons to request information to clarify the potential risk'.

You will find the procedural steps followed to reach the adopted decision and some technical guidance detailed in further Appendices.

Appeal
This decision 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] by 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.

Basis for substance evaluation

The objective of substance evaluation under REACH is to allow for the generation of further information on substances suspected of posing a risk to human health or the environment ('potential risk').

ECHA has concluded that further information on the Substance is necessary to enable the evaluating Member State Competent Authority (MSCA) to clarify a potential risk and whether regulatory risk management is required to ensure the safe use of the Substance.

The ECHA decision requesting further information is based on the following:

(1) There is a potential risk to human health or the environment, based on a combination of hazard and exposure information;
(2) Information is necessary to clarify the potential risk identified; and
(3) There is a realistic possibility that the information requested would allow improved risk management measures to be taken.

The Appendices entitled 'Reasons to request information' describe why the requested information are necessary and appropriate.

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix A – Reasons to request information to clarify the potential risk related to PBT/vPvB properties

1. Potential risk

1.1 Potential hazard of the Substance

Following its assessment of the available relevant information on the Substance, the evaluating MSCA and ECHA have identified the following potential hazard(s) which must be clarified.

a) Potential P/vP properties

If a substance fulfils the criteria in Section 1.1.1 or 1.2.1 of Annex XIII to REACH, it is considered that it has persistent (P) or very persistent (vP) properties.
For the purpose of the P/vP assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.1 to Annex XIII, including results from simulation tests, must be considered.
If no such data are available, it is necessary to consider the screening information of Section 3.1.1 to Annex XIII, such as ready biodegradability studies or QSAR predictions.

Evidence based on experimental data

No water, soil or water-sediment simulation test is currently available for the Substance.

- One inherent biodegradability study comparable to OECD TG 302 B but non GLP is available:
  - The test results indicate 93% elimination of the Substance after 15 days based on COD determination. The initial test substance concentration was 1000 mg/L. This test has major deviations from the guideline, namely source of inoculum unknown, lack of procedure control and reference substance not specified. The applicability of the method is questionable due to the adsorption potential of the Substance and expected inhibition of the bacteria at the tested concentration. In this sense inherent biodegradability data was not used for the assessment of persistence.

- Three enhanced ready biodegradability studies according to OECD TG 301 B (and GLP) are available:
  - The first test ([redacted] 1997) obtained 50% degradation after 39 days (based on CO_2 removal) and the plateau in the degradation curve was not reached. The test substance concentration used was 19.8 mg TOC/L. In this test no abiotic sterile control was performed. The degradation of the test substance and reference substance was 22% based on $ThCO_2$ within 14 days (which is below 25%) indicating possible toxicity of the test substance towards the inoculum.
  - In the second test 0% degradation based on CO_2 production and 83% DOC removal was obtained after 28 days. The exposure was extended to 60 days but only 0.9% degradation (based on CO_2 production) was obtained. Possible adsorption to test vessels or to the activated sludge was identified ([redacted] 2012).
  - The third test ([redacted] 2016) was performed also under enhanced test conditions by extending the test duration to 60 days. The test substance concentration used was 10 mg TOC/L and 91% degradation based on CO_2 production at 60 days was obtained. Potencial exposure of the inoculum to the substance or to structurally similar substances could not be disregarded, since the municipal waste water treatement plant, which was the inoculum source, receives both domestic and industrial waste water (EBS, 2013; EBS, 2019).

- For the design of these studies, no consideration was taken on the cationic behaviour of the Substance nor on its surface active properties.

Considering that the ready biodegradability tests were performed according to OECD TG 301 B and GLP, but conflicting test results are reported, possible differences in the test conditions and design were investigated. Namely, different inoculum sources were used and potential inoculum pre-adaptation in one of the tests could justify different results. Additionally, different test concentrations ranging from 10.0 to 21.2 mg/L as TOC were tested, which could have inhibited the inoculum in the higher concentrations, and adsorption losses could have occurred.

In your comments to the original draft decision, you agreed to conduct the OECD TG 301 D test and proposed that in addition, two OECD TG 301 B studies, with an optional extension of the test duration up to 60 days would be performed, in 5-L vessels (3-L liquid volume), with inoculum sources from different WWTP.

It is considered that requesting a ready biodegradability test, under OECD TG 301 D, is appropriate to avoid performing a simulation test to clarify the P properties. The registration dossier already includes three enhanced ready biodegradability tests performed according to OECD TG 301 B, with the registered substance, which did not allow to conclude on ready biodegradability. Therefore performing 2 additional tests according to OECD TG 301 B is not considered adequate for concluding on the P/vP properties.

In your comments to the Proposals for Amendments, you refer to preliminary results from three ongoing biodegradation studies with the Substance, however you did not comment on the Proposals for amendments and therefore these comments are not reflected in the this decision.

In your comments to the original draft decision, you highlighted that the third ready biodegradability study according to OECD TG 301 B ([redacted], 2016) was performed without major deviations from the guideline. Additionally you emphasized that the inoculum was non-adapted activated sludge, domestic, from the wastewater treatment plant of Mannheim/Germany. You argued that the observed biodegradability differences in the three enhanced ready biodegradability studies available, according to OECD TG 301 B, is due to the different sources of the inocula.

ECHA notes that in [redacted] 2016 test, all validity criteria are met except the content of DIC 0.6 mg/L (guideline indicates <0.5mg/L) in the blank control at start of exposure at the test concentration of 10 mg/L TOC. This concentration of the Substance was lower than the concentration in the 2012 test, where no toxicity in the toxicity control was observed, and the reference substance reached 99% biodegradation after 14 days, thus confirming the suitability of inoculum and test conditions.

ECHA Guidance R.7b states that "An inoculum is considered adapted not only if special arrangements were made with the aim to adapt the inoculum to the substance but also if the inoculum used was previously exposed to the substance or structurally similar substances". In [redacted] 2016 test the source of inoculum is the Mannheim WWTP (Germany) that receives wastewater from Industry and domestic discharges, according to information from Wastewater Department of the city of Mannheim (EBS, 2013; EBS, 2019). Therefore potential exposure of the inoculum to the substance or to structurally similar substances could not be disregarded.

On the basis that the tests ([redacted], 2012 and [redacted], 2016) are GLP but provide contradicting results, no conclusion on ready biodegradability can be made.

In your comments to the original draft decision, you argue that the OECD TG 301 does not address how to deal with substances with cationic behaviour or surface active properties and no further advice is given in the ECHA Guidance R.7b. You conclude that these specific properties seem to have no/low relevance for biodegradability testing.

ECHA acknowledges that OECD TG 301 does not address the cationic behaviour of substances. Although no reference is made in the different guidance documents, it is not possible based on scientific evidence to conclude that these properties are of low relevance for biodegradability testing, because cationic substances tend to be highly adorptive, as for this Substance. This reduces the bioavailability for microorganisms in the OECD TG 301 tests and the possibility for biodegradation.

In your comments to the original draft decision, you argue that if the outcome of a ready biodegradability test results in a low biodegradability, it does not mean that the substance is not biodegradable under environmental conditions. You consider that the result indicates "…that more work will be necessary to establish biodegradability." (OECD TG 301) and also that "Due to the fact that the test methodology for the screening tests on ready biodegradability is stringent, a negative result does not necessarily mean that the substance will not be degraded relatively fast under environmental conditions." ECHA Guidance R.11. This is also in accordance with ECHA Guidance R.7b.

ECHA acknowledges the points raised, however the available results do not demonstrate that the Substance is readily biodegradable and therefore not persistent. As explained above, further information is required in order to conclude on the P/vP properties.

Evidence based on model predictions

- QSAR estimates for biodegradability of the Substance, by applying BIOWIN (v4.11) and OASIS Catalogic (v.5.14.1.5) are available, indicating that the Substance is expected to be readily biodegradable and not readily biodegradable, respectively. Since no reference substances similar to the Substance, namely with cationic surfactant properties, are available within the database or for the assessment of the applicability domain of these models, none of these estimations was used as supporting evidence for the assessment of the Substance biodegradation.

In your comments to the original draft decision, you consider that as reliable ready biodegradability studies were available in the Registration dossier, the QSAR results were not intended to be used for the assessment of the Substance ready biodegradability. You also refer that the Substance was within the applicability domain of the submodels BIOWIN 1 to 6 and also in the model Catalogic 301C.

ECHA notes that although BIOWIN provides an estimation based on fragments and molecular weight, considering the Substance properties this estimation should be used with caution due to the lack of reference substances (cationic surfactants) in the database. Regarding CATALOGIC predictions these use an automated calculation of log Kow and water solubility which have some limitations for predicting the Substance properties.

The available information does not allow to draw a conclusion on the potential P/vP properties of the Substance

b) Potential B/vB properties

If a substance fulfils the criteria in Section 1.1.2 or 1.2.2 of Annex XIII to REACH, it is considered that it has bioaccumulative (B) or very bioaccumulative (vB) properties.
For the purpose of the B/vB assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.2 of Annex XIII must be considered, including bioconcentration factor (BCF) values.
If no such data are available, it is necessary to consider the screening information of Section 3.1.2 to Annex XIII, such as QSAR predictions.

Evidence based on experimental data

- No experimental data for bioaccumulation in aquatic species is available for the Substance.

- You submitted a measured log Kow (7.3) using the HPLC method at 25 °C and pH 7.5, which exceeds the screening criterion for bioaccumulation potential indicated in ECHA Guidance R.11. However, the Substance is a cationic surfactant and log Kow is not a good descriptor for assessing the bioaccumulation potential of surface active substances (ECETOC, 2014). Log Kow only mimics passive diffusion across lipid membranes, but does not predict other bioaccumulation mechanisms, e.g. protein binding (ECETOC, 2014).

In your comments to the original draft decision, you agree that there might be other mechanisms for some groups of substances driving the bioaccumulation potential. You indicate as potential mechanisms: a) apparent distribution coefficient (log D) and the octanol-water partition coefficient (log Kow), b) protein binding of substances, c) toxicokinetics and metabolism of organisms, d) permeability of cell membranes, e) ion trap, f) electrical attraction and concluded that metabolism is the most relevant for the Substance.

From a literature review on bioaccumulation potential of ionizable compounds it should be noted that according to Arnot and Gobas (2006) more research is required for ionizable substances that do not predominantly partition to lipids, to better understand their partitioning behaviour and to ascertain the factors controlling elimination.
More recently Armitage et al (2017) noted that there is substantial scatter in the empirical BCF data for ionizable organic chemicals (IOCs) andrefer "our knowledge of the behavior of neutral organic chemicals already provides a basic conceptual understanding of the general behavior of IOCs, and the main challenge is to modify available models to account for any important deviations that may exist."
ECHA notes that substance specific information available does not allow to understand the substance metabolism, neither conclude on its relevance for bioaccumulation. To validate the potential mechanisms identified for ionizable organic chemicals more measured BCF data is needed.

Evidence based on model predictions

- Four QSAR BCF estimations for the registered Substance were submitted. The estimates use log Kow for the prediction and lack representative substances with cationic

surfactant properties. Additionally, the estimation results have significant quantitative differences (from 66.5 to 22131 L/kg).

In your comments to the original draft decision, you argue that a maximum diameter higher than 17.4 Å ([redacted], 2006 cited in Registrants comments) could be used as cut-off criteria for indication of limited bioaccumulation. The bioaccumulation potential of the Substance would be reduced as although the average diameter of the molecules is slightly lower, the maximum diameter (19 Å) exceeds the identified cut-off value.

However, more recently ECHA Guidance R.11 establishes a Weight-of-Evidence approach with expert judgment for concluding as not B if average maximum diameter is greater than 1.7 nm plus a molecular weight greater than 1100. As this is not the case forthe Substance, this point was not considered in the bioaccumulation assessment.

In your comments to the original draft decision, you refer that the available and relevant estimated data on the bioaccumulation potential of the Substance, and other mitigation factors like metabolism and molecular size that additionally reduce the BCF, and concluded that the critical BCF value of > 2000 for B and vB properties is not exceeded.

However, as explained above, ECHA's view is that the available information in the dossier does not allow to draw a conclusion on the Substance's potential B/vB properties.

c) Potential T properties

If a substance fulfils the criteria in Section 1.1.3 of Annex XIII to REACH, it is considered that it fulfils the toxicity (T) properties.
For the purpose of the T assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.3 of Annex XIII, including results from long-term toxicity tests, must be considered.
If no such data are available, it is necessary to consider the screening information of Section 3.1.3 to Annex XIII.

Evidence based on experimental data

- A GLP compliant OECD TG 422 study was submitted, no adverse toxicity was observed at any dose level. In a dose finding test, a LOAEL of 100 mg/kg for local irritation effects was obtained, which does not fulfil the mammalian T criteria.

- There are no indications that the Substance has genotoxic concerns, therefore it does not trigger the mammalian T criteria.

- You have submitted a long-term toxicity test on Daphnia magna with a 21 day NOEC for reproduction of 0.069 mg/L.

- You have submitted an algae growth inhibition study, non GLP, according to a guideline similar to OECD TG 201. The test was conducted with nominal concentrations in the range 0.0078–1.0 mg/L. Test condition deviations from the guideline and concentrations not analytically verified, as well as no consideration for the surfactant behaviour of the Substance, do not allow to conclude on the toxicity effect in algae.

Based on the available information in the dossier it is not possible to draw a conclusion on the potential T properties of the Substance.

1.2 Potential exposure

According to the information you submitted in all registration dossiers, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 10 – 100 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used in lubricant additives and functional fluids. It is used by industrial workers and professionals as intermediate not under strictly closed conditions and as a functional fluid in open systems, outdoors. The substance can be released to the environment as emissions from manufacturing plants, industrial and professional facilities using the Substance. Therefore exposure to environment cannot be excluded.

1.3 Identification of the potential risk to be clarified

Based on all information available in the registration, the Substance may be a PBT/vPvB substance.

The information you provided on manufacture and uses demonstrates a potential for environmental exposure.

Based on this hazard and exposure information the Substance poses a potential risk to the environment.

As explained in Section 1.1. above, the available information is not sufficient to conclude on the potential hazard, in particular on the P/vP, B/vB and T properties. Consequently further information is needed to clarify the potential risk related to PBT/vPvB properties.

1.4 Further risk management measures

If the Substance is confirmed as meeting the P, B and T or vP and vB criteria it can be identified as a PBT/vPvB. The evaluating MSCA will analyse the options to manage the risk(s) and will assess the need for:

- further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 57 of REACH;
- a subsequent authorisation or a restriction of the Substance. This would lead to stricter risk management measures than those currently in place, such as minimisation of emissions.

2. How to clarify the potential risk

2.1 Development of the testing strategy

Using a tiered-testing strategy and in accordance with ECHA Guidance R.11, ECHA considers that the P concern must first be clarified. Further testing to clarify the B and T concern may be requested in a future Substance Evaluation decision.

The result will constitute the first tier in a testing strategy to conclude on PBT properties. The evaluating MSCA will review the information you will submit as an outcome of the first tier of the testing strategy, and evaluate whether further information is still needed to clarify the potential risk for PBT properties.

2.2 Request A.1 (Ready biodegradability (test method: Closed bottle test, OECD TG 301 D)

a) Aim of the study

The aim of the testing requested is:

- to allow a conclusion on ready biodegradability of the Substance.

Testing for Ready biodegradability with Closed bottle test, OECD TG 301 D is considered appropriate for the following reasons:

- results from submitted OECD TG 301 B were not conclusive;
- based on the Substance intrinsic properties (cationic surfactant) adsorption to test vessels is expected. Glass surfaces offer negatively charged hydroxyl groups which can bind with cationic test chemicals such as surfactants. This type of adsorptive loss could reduce the available exposure concentration (OECD, 2018);
- the OECD TG 301 D design is adequate for adsorbing substances and is considered to be a more suitable test design for the Substance than the OECD TG 301 B. In this guideline the test substance concentration is low (2-10 mg/L) and therefore possible toxicity to the inoculum is minimised. It is noted that the Substance has a 3h EC_{10} of 18 mg/L from a respiration inhibition test (according to OECD TG 209) and therefore the OECD TG 301 D can be considered as technically feasible without inducing significant toxicity to the inoculum. Additionally, the smaller volume of the vessels (<300 mL) and the lowest inoculum concentration (10^4-10^6 cells/L) are also more suitable for minimising adsorption.

In your comments to the original draft decision, you conclude that adsorption of the Substance to the glass surface of the testing equipment or the activated sludge is possible, as observed in the second OECD TG 301 B study ([redacted], 2012). You point out that in OECD TG 301, methods B and D are both suitable for adsorbing substances and that test concentration in OECD TG 301 B can be reduced to 10 mg TOC/L at which no inhibition of the degradation activity of the microbial community was observed in [redacted], 2016 test. The lower concentration of the inoculum and the smaller volume of the test vessels according to OECD TG 301 D would reduce the probability of the presence and the number of microbes in the assay.

ECHA considers that the OECD TG 301 D test is a compromise to address potential adsorption, low solubility and concentration issues. Method D has a smaller volume of the vessels and lower inoculum concentration which is considered more suitable to minimise and avoid adsorption and the lower test substance concentration (2-10 mg/L) minimises the toxicity to the inoculum. In conclusion, ECHA considers that this is a more suitable testing strategy than the OECD TG 301 B tests.

b) Specification of the requested study

Test material and concentration

The test must be performed at a concentration within the concentration range in the guideline, i.e. 2-10 mg/L. Additionally, you must consider the instructions regarding difficult to test substances, established in ECHA Guidance R.7b.

The test must include a sterile control containing no inoculum and a sterile control with (sterilized) inoculum, both prepared and treated similarly to the test vessels, to verify whether there are losses from the test system due to adsorption or even volatilisation. The maintenance of the test substance concentrations, in sterile controls, must be verified during the test with analytical determinations.

Additionally, the measurement of test substance concentrations must be performed in all test vessels.

The chemical analysis must be conducted at least on days 0, 1, 7, 14 and 28 and with at least three replicates for each day.

In your comments to the original draft decision, you noted that specific chemical analysis is not required according to OECD TG 301 B or D and that OECD TG 301 mentions that specific chemical analysis can be used to assess primary degradation. You also argued that, as ultimate degradation is the key parameter for assessing ready biodegradability, specific chemical analysis has no added value and that the idea of a stable exposure concentration is not an issue in biodegradability testing according to OECD TG 301.

ECHA acknowledges that degradation is the key parameter, however the potential behavioural characteristics of the Substance such as adsorption, cationic surfactant or even volatilisation were taken into account to support the request for analytical determinations.
Analytical determinations of the Substance will help the interpretation of the study results and allow to calculate primary degradation that can be used to conclude on not P/vP, if necessary.

Test enhancement

The test can only be enhanced by extending the test duration, up to 60 days. The possibility to enhance the test should only be used to compensate the poor bioavailability of adsorptive substances to the degrading microorganisms which could limit its degradation rate, however it should not induce additional adaptation of the inoculum (according to ECHA Guidance R.7b).

Modifications included in Appendix R.7.9-3 (Testing the Biodegradability of Poorly Water Soluble Substances) from ECHA Guidance R.7b could be used, if deemed necessary by technical reasons, duly justified in the study report.

Accounting for nitrification

Since the Substance contains nitrogen, according to OECD TG 301 D corrections for the uptake of oxygen by nitrification must be considered. Therefore the indications in paragraphs 14, 21 and 24 of the test guideline must be followed.

In your comments to the original draft decision, you noted that nitrification is relevant for OECD TG 301 D, but not for OECD TG 301 B as the latter method detects biodegradation by means of CO_2 evolution. Therefore, you concluded that an OECD TG 301 B is more suitable for a nitrogen-containing substance like bis(2-ethylhexyl)amine than a respirometric method as OECD TG 301 D.

ECHA agrees that accounting for nitrification is only relevant in methods based on oxygen consumption for substances containing nitrogen. Corrections for uptake of oxygen by any nitrification occurring should be made, as indicated in test guideline. It is considered that the need for nitrification correction does not make the OECD TG 301 D unsuitable for a nitrogen-containing substance.

Inoculum origin

Effluent from a municipal waste water treatment plant (WWTP) must be used as inoculum. To prevent any type of adaptation, the source WWTP must not receive releases from sites using the Substance or structurally similar substances. The WWTP must be located in a rural area to exclude adaptation.

ECHA Guidance R.7b, states that "*An inoculum is considered adapted not only if special arrangements were made with the aim to adapt the inoculum to the substance but also if the inoculum used was previously exposed to the substance or structurally similar substances*".

Preparation of test flasks

It is recommended that the test vessels are treated with a suitable technique for passivation of the glass surface of the vessel, e.g. silylation, for preventing the adsorption of the Substance to the glass surface.

As the test substance is a cationic surfactant, adsorption to the test vessel is expected. The chosen passivation technique must avoid a false positive impact on test results and would be justified in the study report.

To address the missing information identified above, the OECD TG 301 D requested will allow to have screening information on biodegradation, which is required to conclude on the ready biodegradability of the Substance. In case the result from the requested study does not allow to verify the non-persistent nature of the Substance, further higher-tier tests may be requested in a follow-up decision. This may include simulation tests on degradation, in order to confirm whether P/vP properties are of concern for the Substance.

Request for the full study report

You must submit the full study report which includes:

- a complete rationale of test design
- interpretation of the results
- information on microbial cell density of the inoculum (in cells/mL)
- access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis, and to efficiently clarify the potential hazard for the PBT/vPvB properties for the Substance.

c) Alternative approaches and how the request is appropriate to meet its objective

The request is:

- Appropriate, because the test is suitable and necessary to obtain information which will allow clarifying whether the Substance fulfils the screening P/vP criteria;
- The possible alternative tests on OECD TG 301 series would not generate the same

level of information due to the Substance cationic surfactant behaviour. Additionally performing a ready biodegradability test is less onerous than performing a biodegradation simulation test.

2.3 References relevant to the requests (which are not included in the registration dossier)

Armitage J.M., Erickson R.J., Luckenbach T, Ng C.A., Prosser R.S., Arnot J.A., Schirmer K., Nichols J.W. (2017). Assessing the bioaccumulation potential of ionizable organic compounds: curret knowledge and research priorities. Environmental Toxicology and Chemistry, 36 (4): 882–897.

Arnot J.A., Gobas F. (2006). A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms, Environmental Reviews, 14(4):257-297.

EBS (2013). We'll clarify it for you! 135 years of sewage disposal in Mannheim. Eigenbetrieb Stadtenwässerung Mannheim. PDF file. Retrieved from: https://www.mannheim.de/sites/default/files/institution/1035/we_ll_clarify_it_for_you.pdf

EBS (2019). EBS Mannheim – Wastewater Department City of Mannheim. Eigenbetrieb Stadtenwässerung Mannheim. PDF file. Retrieved from: https://www.mannheim.de/sites/default/files/2019-09/20.09.19_EBS-Pr%C3%A4sentation%20EN.pdf

ECETOC (2014). Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH). EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS. Special Report No. 18.

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.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

OECD (2018). Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals. Series on Testing and Assessment No. 23 second edition, OECD Environment, Health and Safety Publications, Paris.

Appendix B: Procedure

This decision does not imply that the information you submitted in your registration dossier(s) are in compliance with the REACH requirements. ECHA may still initiate a compliance check on your dossiers.

12-month evaluation

- Due to initial grounds of concern for PBT/vPvB, and for exposure of enviroment the Member State Committee agreed to include the Substance (EC No 203-372-4, CAS RN 106-20-7) in the Community rolling action plan (CoRAP) to be evaluated in 2019. Portugal is the competent authority ('the evaluating MSCA') appointed to carry out the evaluation.

- In accordance with Article 45(4) of REACH, the evaluating MSCA carried out its evaluation based on the information in the registration dossier(s) you submitted on bis(2-ethylhexyl)amine and on other relevant and available information.

- The evaluating MSCA completed its evaluation considering that further information is required to clarify the following concerns: PBT/vPvB

- Therefore, it submitted a draft decision (Article 46(1) of REACH) to ECHA on 16 March 2020.

Decision-making

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

For the purpose of this decision-making, dossier updates made after the date the draft of this decision was notified to you (Article 50(1) of REACH) will not be taken into account.

(i) Registrant(s)' commenting phase

ECHA received your comments and forwarded them to the evaluating MSCA.

The evaluating MSCA took your comments into account (see Appendix A). The request was not amended.

You agreed with the request to conduct the OECD TG 301 D test needed to clarify the PBT/vPvB concern. However you did not agree with the analytical verification in the study design.
You proposed to perform 2 additional studies according to OECD TG 301 B.

(ii) Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision .

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s).

You provided comments on the draft decision. Your comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 52(2) and Article 51(5).

(iii) MSC agreement seeking stage

The Member State Committee reached a unanimous agreement in its MSC-75 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of REACH.

After the deadline set in this decision has passed, the evaluating MSCA will review the information you will have submitted and will evaluate whether further information is still needed to clarify the potential risk, according to Article 46(3) of REACH. Therefore, a subsequent evaluation of the Substance may still be initiated after the present substance evaluation is concluded.

Appendix C: Technical Guidance to follow when conducting new tests for REACH purposes

Test methods, GLP requirements and reporting

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.

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.

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].

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*

   a) 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.
   b) The reported composition must include all constituents of each Test Material and their concentration values.

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 "How to prepare registration and PPORD dossiers"[3].

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