Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether

List No. 926-564-6

CAS RN 1179964-22-7

Evaluating Member State: Germany

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Evaluating Member State Competent Authority

BAuA
Federal Institute for Occupational Safety and Health
Division 5 - Federal Office for Chemicals
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund, Germany

Year of evaluation in CoRAP: 2016

Before concluding the substance evaluation, a Decision to request further information was issued on12 April 2018.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether ("TBBPA-PO-nBGE", 'the Substance') was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB
- Potential endocrine disruptor
- Exposure of environment

During the evaluation, long-term aquatic toxicity was identified as an additional concern by the evaluating Member State Competent Authority (eMSCA).

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The European Chemical Agency (ECHA) issued a compliance check (CCH) decision on 25 April 2016 requiring information on the identity of the Substance.[2] On 22 October 2020 ECHA issued a testing proposal evaluation (TPE) decision requiring a sub-chronic toxicity study and a pre-natal developmental toxicity study with the Substance by the deadline of 29 April 2022.[3]

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the Substance has led the evaluating Member State to the following conclusions, as summarised in Table 1 below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	x

[2] CCH decision on the Substance dated 25 April 2016: https://echa.europa.eu/documents/10162/1ba6ee28-f4d8-9345-31f6-b0c99b4fb804
[3] TPE decision on the Substance dated 22 October 2020 https://echa.europa.eu/documents/10162/ad31f0da-54d7-de4e-1ca6-cf08dd56fb06

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Not applicable.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

4.1.3. Restriction

Not applicable.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	x
Actions by the registrants to ensure safety, as reflected in the registration dossiers (e.g., change in supported uses, applied risk management measures, etc.)	

Currently the available information does not suggest that the Substance fulfils the PBT/vPvB criteria according to REACH Annex XIII or the criteria for ED identification according to Article 57f. Should new information become available on the Substance itself or its degradation products or constituents suggesting a potential to fulfil either of these criteria, this conclusion will be revisited.

5.2. Other actions

Currently, no regulatory follow-up is foreseen at EU-level. However, conclusion on possible regulatory follow-up awaits the results of the compliance check once initiated as requested by the eMSCA.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Table 3

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
Initiate Compliance Check	Ongoing process – compliance check draft decision submitted to the concerned registrant on 17 November 2022	ECHA

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

The Substance was originally selected for substance evaluation in order to clarify concerns on:

- Suspected PBT/vPvB

- Potential endocrine disruptor

- Exposure of environment

During the evaluation, long-term aquatic toxicity was identified as an additional concern by the eMSCA.

Table 4

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome / conclusion**
PBT/vPvB	Concern refuted. Based on the results of an OECD 305 fish feeding study, the Substance does not fulfil the B criterion according to Annex XIII.
Endocrine disrupting (ED) properties for the environment	Concern refuted. Based on the Substance's composition, 2,2,6,6-tetrabromo-4,4-isopropylidenediphenol (TBBPA, EC No 201-236-9)[4] is not a constituent or impurity. No data on the ED properties of the Substance itself with regard to the environment are available.
Exposure of the environment	Concern refuted. As the Substance has a relatively high tonnage (100 to 1000 t/a) and uses include wide dispersive outdoor and indoor use with inclusion into or onto a matrix there is a likelihood of environmental exposure. However, according to the registrant, the use of the Substance is designed in such way that a release to the environment is unlikely. No further action necessary.
Additionally evaluated endpoints	
Long-term aquatic toxicity	Concern unresolved. As the Substance is poorly water soluble and only short-term toxicity tests on aquatic organisms are available, long-term toxicity data on aquatic organisms are missing. The data gap persists and should be addressed in a compliance check.

[4] TBBPA is currently undergoing SEV (eMSCA DK) based on a concern for endocrine disruption. This also gave rise to the initial concern for ED for the Substance. An SVHC dossier to identify TBBPA as an SVHC based on its classification as a carcinogen according to Article 57a) REACH has been submitted in August 2022 by the NO CA.

7.2. Procedure

In this substance evaluation, environmentally relevant endpoints have been considered; human health aspects have not been considered. The evaluation was based on the content of the registration dossier. A dossier update from July 2016, i.e., during the initial assessment period, has been considered.

The registrant had provided further data on the substance composition in 2016 indicating that TBBPA is not a relevant constituent of the UVCB. Later in October 2016, a meeting took place with the registrant. Following, the registrant provided data on uses.

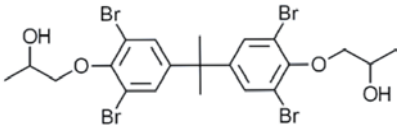
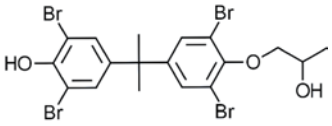
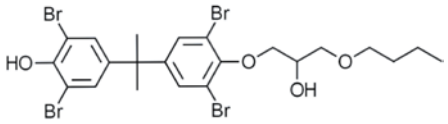
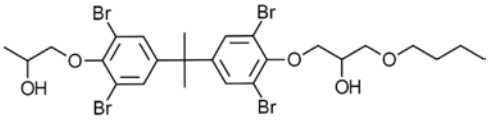
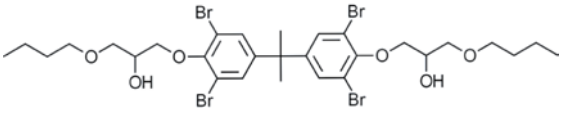
7.3. Identity of the substance

Table 5

SUBSTANCE IDENTITY	
Public name:	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether
EC/list number:	926-564-6
CAS number:	1179964-22-7
Index number in Annex VI of the CLP Regulation:	N/A
Molecular formula:	n.a. (UVCB)
Molecular weight range:	ca. 190 – 900 g/mol
Synonyms:	Tetrabromo-BPA + nBGE + PO (N 8424-2)

Type of substance: UVCB
Structural formula: n.a. (registered as UVCB – see table below for representative structures of constituents)

Table 6

Constituents of TBBPA- PO-nBGE			
No.	**Constituent**	**IUPAC name**	**Structural formula**
1	TBBPA+2PO	1-(2,6-dibromo-4-{1-[3,5-dibromo-4-(2-hydroxypropoxy)phenyl]-1-methylethyl}phenoxy)-2-propanol	
2	TBBPA+PO	2,6-dibromo-4-{1-[3,5-dibromo-4-(2-hydroxypropoxy)phenyl]-1-methylethyl}phenol	
3	TBBPA+nBGE	2,6-dibromo-4-{1-[3,5-dibromo-4-(3-butoxy-2-hydroxypropoxy)phenyl]-1-methylethyl}phenol	
4	TBBPA+nBGE+PO	3-butoxy-1-(2,6-dibromo-4-{1-[3,5-dibromo-4-(2-hydroxypropoxy)phenyl]-1-methylethyl}phenoxy)-2-propanol	
5	TBBPA+2nBGE	3-butoxy-1-(2,6-dibromo-4-{1-[3,5-dibromo-4-(3-butoxy-2-hydroxypropoxy)phenyl]-1-methylethyl}phenoxy)-2-propanol	
6	unknown	-	-

7.4. Physico-chemical properties

Table 7

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	visual inspection: colourless, solid
Vapour pressure	calculated [OECD Guideline 104]: ▫ 0.00092 Pa at 20 °C ▫ 0.0014 Pa at 25 °C ▫ 0.011 Pa at 50 °C
Water solubility	OECD TG 105 (Water Solubility; flask method); with modifications according to OECD TG 120 (Solution/Extraction Behaviour of Polymers in Water): The water solubility of the test item was determined as < 0.0051 g/L at 20°C for both test concentrations (100 mg/L and 1000 mg/L).
Partition coefficient n-octanol/water (Log K_{ow})	OECD TG 117 (Partition Coefficient (n-octanol / water), HPLC Method): The test item is a complex reaction product. The chromatogram of the test item showed a mixture of 7 peaks corresponding to 7 fractions. ▫ Log P_{ow}: 4.5 - 6.9 (40°C, pH 7.0; peaks with an area > 1 % were integrated) ▫ Log P_{ow}: 4.8 (40°C, pH 7.0; Area % weighed Log Pow for all peaks of the test item)
Granulometry	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the Substance is marketed or used in a non-solid or granular form.
Stability in organic solvents and identity of relevant degradation products	In accordance with column 1 of REACH Annex IX, a study does not need to be conducted, as the stability of the Substance is not considered critical.
Dissociation constant	From the registration dossier: “The dissociation constant of the substance is affected by its constituent tetrabromobisphenol A. The dissociation constants for Tetrabromobisphenol A are estimated to be pKa1 of 7.05 and pKa2 of 6.33. Two other constituents do not contain any chemical moiety being capable to dissociate.“ (Remark: Tetrabromobisphenol A (EC no. 201-236-9) is not a constituent of the evaluated UVCB substance but is regarded as representative for the Substance due to its structural similarity.) A pKa of 9.73 at 20 °C is used for chemical safety assessment (CSA) in the registration.
Relative density	1.72

7.5. Manufacture and uses

7.5.1. Quantities

Table 8

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☒ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

The Substance is used for manufacturing foams for isolation panels, isolation foams, metal panels, in foam for insulating tubes and pipes, cables, jointing. It reacts with isocyanate oligomers producing those foams.

According to the registrant, there are only industrial and professional uses. The supply chain is rather small.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

The Substance is not listed in Annex VI CLP. Additionally, there is currently no CLH proposal for the Substance.

TBBPA (EC / List. No 201-236-9), one of the starting materials for the Substance, has a harmonised classification as

Aquatic Acute 1	H400
Aquatic Chronic 1	H410

in Annex VI CLP. Additionally, a CLH proposal to add the classification

Carc. 1B	H350

to the Annex VI entry for TBBPA has been submitted by the NO CA. The Risk Assessment Committee (RAC) supports this proposal.[5]

7.6.2. Self-classification

- In the registration*:*

  Not classified.

- Additional hazard classes notified among the aggregated self-classifications in the C&L Inventory:

  Aquatic Chronic 3 H412

[5] CLH process on TBBPA on the ECHA website: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e184330ec8

7.7. Environmental fate properties

7.7.1. Degradation

Biodegradation of the Substance was determined with 0% in 28 days (ready biodegradation study according to EU method C.4-D similar to OECD TG 301F) and 4% in 28 days (inherent biodegradation in a study according to OECD TG 302C measured as O_2 consumption) in two tests contained in the registration dossier. The eMSCA concludes that the Substance is not biodegradable.

7.7.2. Environmental distribution

7.7.3. Bioaccumulation

Aquatic bioaccumulation

The Substance, which is registered as a UVCB, includes six identified main constituents. Based on QSAR predictions, the log K_{ow} values range between 4.5 and 6.9. Therefore, the identified constituents fulfil the screening criterion for B.

Table 9

CONSTITUENTS OF THE SUBSTANCE AND THEIR PROPERTIES			
Constituent No.	**Experimental log K_{OW}**	**BCF[1]**	**Water Solubility [mg/L][2]**
1	4.5	240	0.22
2	4.8	378	0.005
3	5.5	1097	0.0003
4	5.7	1487	0.00001
5	6.9	9205	0.000009
6	5.9	485-1234[3]	0.2-1[3]

[1] calculated using QSAR BCFBAW [2] calculated using QSAR WSKOW [3] experimental value

In the substance evaluation decision, an OECD TG 305 study was required, which was conducted as dietary exposure study using rainbow trout (*O. mykiss*) as test organisms and the whole Substance as test material.

Since no bioaccumulation of the test item was observed and in order to be sure not to miss a late bioaccumulation event, the uptake phase lasted 36 days. However, no bioaccumulation was determined for the five constituents measured. Most measurements were below the limit of detection and some data points below the limit of quantification. Since no bioaccumulation had occurred it was decided to skip the depuration phase and to terminate the study.

In conclusion, the OECD TG 305 dietary exposure study revealed that none of the five constituents of the UVCB with log K_{ow} > 4.5 accumulated in fish and thus, the eMSCA concludes the test substance is not bioaccumulative.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

The registration dossier of the Substance contains three short-term studies covering three trophic levels.

Table 10

AVAILABLE STUDIES ON AQUATIC TOXICITY			
Organism		**result**	**Comment**
Fish (*Danio rerio*)	LL_{50} (96 h)	>100 mg/L	Nominal, WAF, Limit test
Invertebrates (*Daphnia magna*)	EL_0 (48 h)	>100 mg/L	Nominal, WAF, Limit test
Algae (*Desmodesmus subspicatus*)	E_rL_{50} (72 h) NOE_rL (72 h)	>100 mg/L ≥100 mg/L	Nominal, WAF, Limit test

7.8.1.1. Fish

An acute toxicity test according to OECD TG 203 and EU method C.1 with *Danio rerio* showed no effect up to the limit concentration of 100 mg/L after 96 hours. A Water Accommodated Fraction (WAF) was used and the DOC was determined to quantify the test concentrations. The test is valid without restriction.

Despite the fact that the Substance is poorly water-soluble and the REACH regulation Annex VIII section 9.1.3 column 2 concludes that “long-term aquatic toxicity study on fish (Annex IX, section 9.1.6) shall be considered if the Substance is poorly water soluble”, there is no long-term toxicity test with fish available.

7.8.1.2. Aquatic invertebrates

The acute toxicity test according to EU method C.2 with *Daphnia magna* showed no effect up to the limit concentration of 100 mg/L after 48 hours. A Water Accommodated Fraction (WAF) was used and the DOC was determined. The test is valid without restriction.

Despite the fact that the Substance is poorly water-soluble and the REACH regulation Annex VII section 9.1.1 column 2 concludes that “long-term aquatic toxicity study on *Daphnia* (Annex IX, section 9.1.5) shall be considered if the Substance is poorly water soluble”, there is no long-term toxicity test with aquatic invertebrates available.

7.8.1.3. Algae and aquatic plants

The limit test with the algae *Desmodesmus subspicatus* according to EU method C.3 and OECD TG 201 showed no effect up to 100 mg/L after 72 hours. A Water Accommodated Fraction (WAF) was used and the DOC was determined. The test is valid without restriction.

7.8.1.4. Sediment organisms

No data available.

7.8.1.5. Other aquatic organisms

No data available.

7.8.2. Terrestrial compartment

No data available.

7.8.3. Microbiological activity in sewage treatment systems

The test according to EU method C.11 and OECD TG 209 with a mixed population of aquatic microorganisms (activated sludge) from a domestic sewage treatment plant showed 11.11% respiration inhibition at the highest concentration of 1000 mg/L after 3 hours. An EC_{50} of > 1000 mg/L and an EC_{10} of 856.5 mg/L was determined.

7.8.4. PNEC derivation and other hazard conclusions

There were no effects in the acute toxicity tests with fish, daphnia and algae observed up to 100 mg/L. No long-term toxicity data are available.

7.8.5. Conclusions for classification and labelling

The Substance is poorly water soluble, not readily biodegradable and the log K_{ow} is above 4. Long-term toxicity data is only available for one trophic level (algae). Therefore, the eMSCA recommends that a self-classification as Aquatic Chronic 4 is applied in the registration.

7.9. Human Health hazard assessment

Not part of the substance evaluation.

7.10. Assessment of endocrine disrupting (ED) properties

Based on the Substance's composition, TBBPA (EC No 201-236-9) which is currently also undergoing substance evaluation due to potential ED properties and gave rise to the intial concern for the Substance, is not a constituent or impurity. No data on the ED properties of the Substance itself with regard to the environment are available.

Based on the available information, the eMSCA considers that the concern for endocrine disruption of the Substance in the environment is clarified.

7.11. PBT and vPvB assessment

All available data on persistence, bioaccumulation and toxicity of the Substance were assessed in a Weight of Evidence approach by the eMSCA.

1) Persistence

The Substance is not readily biodegradable (0% degradation within 28 days) and therefore fulfils the screening criteria for P and vP. Simulation tests are not available; in order to definitively conclude on P or vP an additional simulation test would be necessary. However, the eMSCA does not consider this a priority to be pursued under the substance evaluation process.

2) Bioaccumulation

The measured octanol-water partition coefficient (log K_{ow}) of the constituents are in the range from 4.5 and 6.9. An OECD TG 305 study was conducted with dietary exposure using rainbow trout (*O. mykiss*) as test organisms. No bioaccumulation was determined for none of the five constituents tested. Most measurements were below the limit of detection (LOD) and some data points were below the limit of quantification (LOQ).

In conclusion, the OECD TG 305 dietary exposure study revealed that none of the five UVCB constituents with log K_{ow} > 4.5 accumulated in fish and thus, the test substance is not bioaccumulative.

3) Toxicity

Long-term aquatic toxicity data for fish or daphnia are not available. Therefore, a comparison with the Annex XIII criteria regarding the T_{eco}-criterion is not possible. No indications regarding a potential fulfilment of the T_{HH}-criterion are available in the registration although the evaluation was focussed on the environmental data.

4) Overall conclusion

Overall, based on present information, the eMSCA concludes that the Substance is not bioaccumulative and consequently not a PBT-substance.

7.12. Exposure assessment

7.12.1. Human health

Not part of this substance evaluation.

7.12.2. Environment

According to the registration dossier, some exposure of the environment is likely based on ERC descriptions. According to the Registrant, there is negligible exposure of the Substance to the environment; the Substance reacts with isocyanate oligomers for manufacturing insulation foams, however, TBBPA is not detectable in those foams. Since the scope of this substance evaluation is on PBT, no detailed exposure assessment was conducted by the eMSCA.

7.12.3. Combined exposure assessment

Not part of this substance evaluation.

7.13. Risk characterisation

Not part of this substance evaluation.

7.14. References

The information given in the registration dossier was assessed.

7.15. Abbreviations

BCF	Bioconcentration factor
CCH	Compliance check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DMEL	Derived minimum effect level
DNEL	Derived no-effect level
DOC	Dissolved organic carbon
EC	Effect concentration
ED	Endocrine disruptor
EL	Effect level
eMSCA	Evaluating member state competent authority
NOAEL	No observed adverse effect level
LL	Lethal level
LOD	Level of detection
LOQ	Level of quantification
Log K_{ow}	Octanol-water partitioning coefficient
OECD	Organisation for economic co-operation and development

PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
QSAR	Quantitative structure activity relationship
SEv	Substance evaluation
SVHC	Substance of very high concern
UVCB	Unknown or variable composition, complex reaction products or biological materials
WAF	Water accommodated fraction