

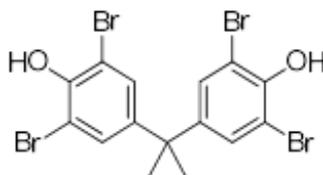
RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

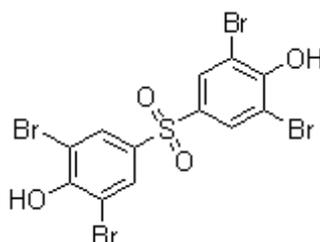
for

**Tetrabromobisphenol A (TBBPA), TBBPA derivatives,
Tetrabromobisphenol S (TBBPS) and TBBPS derivatives**

EC number: 201-236-9
CAS number: 79-94-7



Substance name: Tetrabromobisphenol S (TBBPS)
EC number: 254-551-9
CAS number: 39635-79-5



Member State: Denmark

Dated: August 2014, Final version

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The Danish EPA has conducted a survey of all substances listed on the Danish List of Unwanted Substances (LOUS). Access to the surveys carried out so far can be found at the following link:

http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/

The main reason for the inclusion in LOUS is that "*Certain brominated flame retardants are either persistent or can be degraded to persistent compounds, bioaccumulative or toxic.*"

The survey carried out for brominated flame retardants provides an overview of the use and the environmental and human health aspects of the substances. The results of the survey have been used as the main background information for this RMO assessment.

Brominated flame retardants have in common that they contain bromine and are used to prevent the ignition of plastic materials and textiles. TBBPA is mainly used as a reactive and additive flame retardant in plastics. It is the additive use causing a challenge.

This RMO assessment could in principle have been divided into two separate for TBBPA and TBBPS with corresponding derivatives respectively. The survey uncovered a lack of data for TBBPS and especially its derivatives. This together with the structural similarity between TBBPA and TBBPS is making a joint assessment of the two substances and their derivatives relevant.

A harmonised CLP classification has been agreed upon for TBBPA due to its toxicity to organisms in the aquatic environments. Otherwise, TBBPA, TBBPA derivatives, TBBPS or TBBPS derivatives are not individually addressed by any EU or Danish legislation.

TBBPA is on the List of Chemicals for Priority Action of the Oslo/Paris convention OSPAR (for the Protection of the Marine Environment of the North-East Atlantic).

According to the COM Recommendation 2008/454/EC on risk reduction measures for the environment for TBBPA competent authorities should lay down conditions for installations concerned in order to operate according to BAT and local emission should be controlled by national rules.

The COM communication 2008/C 152/02 on results of the risk evaluation and the risk reduction strategies for TBBPA concluded that there is a need for further information and testing regarding the aquatic and terrestrial ecosystem. It also concluded some specific measures regarding compounding and conversion sites for ABS (acrylonitrile-butadiene-styrene resins) where TBBPA is used as an additive flame retardant.

However, the implementation of the specific measures and the measures in the COM recommendation is expected to sufficiently reduce the concentration in the aquatic and terrestrial ecosystem and to eliminate the need for further information requirements.

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Substance evaluation	X
Harmonised classification and labelling	?
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	X
No need for regulatory follow-up action	

A harmonised CLP classification has been agreed upon for TBBPA due to its toxicity to organisms in the aquatic environments. Otherwise, TBBPA, TBBPA derivatives, TBBPS or TBBPS derivatives are not individually addressed by any EU. Globally, TBBPA is still the main BFR, accounting for about 40% of total global production and mainly used as reactive flame retardants in printed circuit boards for electronic equipment. About 95% of the consumption in the EU is as reactive flame retardants thereby being incorporated into the polymer structure and thus not present *per se* in the final products. The remaining 5% was used as additive BFR and therefore causing a challenge. Data from 2011 are indicating TBBPA having endocrine disrupting properties and recent findings may further support this. Other data indicate that TBBPA may have PBT like properties of equivalent concern as PBT. Lack of data for TBBPA derivatives, TBBPS and TBBPS derivatives is also objective for further risk management.

The following combination of risk management options is suggested:

1. The currently most appropriate risk management option for TBBPA is CoRAP inclusion followed by substance evaluation with a focus on potential endocrine disrupting properties and PBT like properties having equivalent concern as PBT.
2. If ongoing EFSA assessment of endocrine effects from low dose exposure of bisphenol A concludes that those effects are present Denmark is planning to initiate a study on the debromination which TBBPA undergo under anaerobic conditions forming bisphenol A and the possible TBBPA derivatives break down to bisphenol A as well as TBBPS and TBBPS-BDBPE to form bisphenol S.

Based on the results from the study the need to feed TBBPA and TBBPA derivatives into the substance evaluation of bisphenol A can be considered (and TBBPS into the bisphenol S evaluation). It can also be considered to ask for further data on degradation into bisphenol A in a TBBPA evaluation.

Germany has performed a substance evaluation for bisphenol A in 2012 and Belgium has informed that it will perform a substance evaluation for bisphenol S in 2014. Belgium's initial concerns are potential endocrine disruptor, potentially toxic for reproduction and PBT.

3. Moreover, Denmark is considering using QSAR to establish data on the environmental hazards in order to consider harmonised classification for the derivatives.
4. Denmark is planning to conduct a study on the possibility of assessing the hazard of brominated flame retardants (including substances covered in this RMO) as

group and subsequently, if warranted, consider restriction of the whole group as hazardous substances under the Electrical and electronic equipment (RoHS) directive.

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