Risk Management Option Analysis Conclusion Document

Substance Name: 2,2’,4,4’-tetrabromodiphenyl ether (BDE-47)

EC Number: -

CAS Number: 5436-43-1

Authority: France

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA		☐ Risk Management Option Analysis (RMOA) other than this RMOA
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[2]
Harmonised C&L		☐ Annex VI (CLP) (see section 3.1)
Processes under other EU legislation		☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009
		☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation		☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
		☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)		☐ Assessment
		☒ In relevant Annex

[2] Please specify the relevant entry.

Other processes/ EU legislation	☐ Other (provide further details below)

Tetrabromodiphenyl ether listed in Annex I Part A of Regulation (EU) No 757/2010 of 24 August 2010 - amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants ("POP") as regards Annexes I and III.

The "POP" Regulation contains provisions regarding production, placing on the market and use of chemicals, management of stockpiles and wastes, and measures to reduce unintentional releases of POPs. Furthermore, Member States must set up emission inventories for unintentionally produced POPs, national implementation plans (NIPs) and monitoring and information exchange mechanisms.

As stated in Annex I Part A, for the purposes of this entry, Article 4(1)(b) shall apply to concentrations of Tetrabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles.

By way of derogation, the production, placing on the market and use of the following shall be allowed:

(a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of tetrabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;

(b) electrical and electronic equipment within the scope of Directive 2002/95/EC of the European Parliament and Council (repealed by Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment).

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	x
No action needed at this time	

3. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Article 58(7) of REACH states that "substances for which all uses have been prohibited under Title VIII or by other Union legislation shall not be included in Annex XIV". Although the POP Convention and the POP Regulation do not necessarily prohibit "all uses" (since there can be exemptions for certain specified uses), it is clear that REACH should neither depart from nor duplicate the rules fixed by the POP Regulation. Therefore, if a substance that is already regulated under the POP Regulation (EC) is included in Annex XIV to REACH, authorisations may only be granted under REACH in relation to uses exempted under the POP Regulation.

According to the European Commission[3], in principle, any risks related to the exempted uses of that substance should be addressed though adaptation to technical progress under the POP Regulation and, therefore, the REACH authorisation requirement should only be superimposed on the provisions of the POP Regulation if there are good reasons for doing so. For BDE-47, exempted uses relate to recycled materials (concentration up to 0.1%) and uses in electrical and electronic equipment that are managed by Directive 2011/65/EU.

Regarding the Environment, the water framework directive 2000/60/EC is an EU directive which commits EU Member States to achieve good qualitative and quantitative status of all water bodies. In this framework the EQS (Environmental quality standards) in water for the PBDE is extremely low, with a maximum of 0.5 ng/L for the sum of the 6 most identified PBDE (BDE 28, 47, 99, 100, 153 et 154). These EQS implies that management options has to be taken up to avoid the occurrence of these PBDE in water.

As the substance is not registered and already regulated in the POP Convention, no further action is recommended in the framework of REACH Regulation.

Some uses are however exempted of the POP regulation, such as recycled materials (concentration up to 0.1%) and uses of BDE-47 in electrical and electronic equipment (that are managed by Directive 2011/65/EU).

In order to have information on the exposure levels of European population, BDE-47 was included in the European program for biomonitoring HBM4U as part of the 1st priority list[4]. One objective for that chemical group is a meta-analysis of existing HBM data to identify time trends in exposure and possible regional differences, and also to inform on whether current regulatory structure can effectively lead to decreases in human exposure. Depending on the outome of this program, further action may be considered (including exempted uses of the POP regulation).

As BDE-47 has been identified in some media, the French Authorities recommends also the derivation of human reference values (both internal and external) in order to assess health risk of exposed population.

[3] Common understanding paper. Ref. Ares(2014)2334658 - 14/07/2014.
[4] Prioritized substance group: Flame retardants. Source: https://www.hbm4eu.eu/the-substances/flame-retardants/.