Risk Management Option Analysis Conclusion Document

Substance Name: tetraphenyl m-phenylene bis (phosphate)

EC Number: 260-830-6

CAS Number: 57583-54-7

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 The RDP is on CoRAP list for an evaluation by France in 2019. It should also be noted that one of its constituent and one of its potential metabolite are on the CoRAP list: - Triphenyl phosphate (constituent) is on the CoRAP 2017 list by UK in particular for potential endocrine disrupting properties concern. - Resorcinol (potential metabolite of the parent compound) is on the CoRAP list 2016 by FI in particular for potential endocrine disrupting properties concern.
	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)	

[2] Please specify the relevant entry.

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes/ EU legislation	☐ Other (provide further details below)

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	x
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Available data on the toxicity of RDP for human health are limited, and are essentially toxicokinetic studies, repeated dose toxicity studies, neurotoxicity studies and developmental and reproductive toxicity studies conducted with the commercial product RDP.

These data showed a possible neurotoxic effect on several species (3 studies in rat and hen), an increase in weight of the adrenal glands, and a possible developmental effect in the rat (a single 2G study available showing a delay in preputial separation and vaginal opening and an increase in weight of the adrenal glands).
Only one toxicity study was conducted with pure RDP. It shows that the exposure of pregnant rabbits by oral gavage from GD6 to GD28 shows fetal malformations at 1000 mg/kg/d.

Data indicate that the production of resorcinol from RDP is possible, but due to the efficiency of phase II metabolic pathways (conjugation), the presence of resorcinol in target tissues should be limited, if any.

The main metabolic pathway of TPP (impurity present up to 5 % in RDP) is hydroxylation

to mono- and di-hydroxylated triphenylphosphate and diphenylphosphate.

For the effects on the environment, RDP is not yet identified as a PBT, but there is a real concern that RDP can meet the PBT criteria, and the available data make it is possible to possibly classify RDP as Aquatic acute tox cat. 1 and Aquatic chronic tox cat. 2.

In summary, the limited data available:
- are in favor of a possible neurotoxic effect of RDP;
- are not in favor of a specific effect of resorcinol as metabolite of RDP;
- are not sufficient to decide on a potential PE effect of RDP
- do not exclude the possibility that certain observed effects are due to the specific action of TPP, which exists as impurity (up to 5%) in RDP used in these studies.
- Are in favour of a real concern about RDP as meeting the PBT criteria and classifying it as acute and chronic toxic aquatic.

The effects described in the few available studies appear to be limited and do not allow conclusions to be drawn about the potential risks of RDP to human health and environmental toxicity. Additional data is required.
It is necessary to include RDP in the CoRAP for evaluation. This is justified by the signals highlighted by the existing data on the possibility of neurotoxic and / or reprotoxic and developmental effects.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor
Substance Evaluation	2019	France