Risk Management Option Analysis Conclusion Document

Substance Name: Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
EC Number: 278-355-8
CAS Number: 75980-60-8

Authority: Swedish Chemicals Agency (KemI)
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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

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (herein referred to as TPO) is a member of the organophosphorus compounds, and included in the following EU legislations;

- ECHA's Risk Assessment Committee (RAC) adopted their opinion on a revision of the harmonised classification for TPO from Repr. 2 (H361f) to Repr. 1B (H360Fd) at their 58-meeting (Helsinki, 13 of September 2021). RAC also included the harmonised classification of Skin Sens 1B (H317) for TPO. The opinion by RAC was in line with the proposal of the harmonised classification for TPO by the dossier submitter (Sweden, KemI).

- Due to the harmonised classification for TPO as toxic to reproduction, the substance should not be placed on the market, or used as a substance, as a constituent of other substances, or in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than the relevant specific or generic concentration limit specified in Part 3 of Annex VI in the CLP Regulation (REACH Regulation, Annex XVII, entry 30).

- There is no European Occupational Exposure Limit (OEL) for TPO under Directive 2004/37/EC (Carcinogens and Mutagens Directive, CMD) or Directive 98/24/EC (Chemical Agents Directive, CAD), nor by the Occupational Safety and Health Administration (OSHA) or the American Conference of Governmental Industrial Hygienists (ACGIH).

- However, due to the harmonised classification of TPO as Repr. 1B, the substance is regarded as a *hazardous chemical agent* as defined in the CAD (Article 2b (i)). The provisions in both CAD (Article 4:b) and those in the directive on the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (92/85/EEC, Article 4:1), state that the employer shall assess any risk to the safety and health of workers arising from the presence of such chemical agents and decide what measures should be taken for all activities liable to involve a specific risk. As of March 2022, reprotoxic substances with a harmonized classification in category 1 are also covered by CMD (2022/431/EU, CMRD), which provides stronger requirements on substitution and on minimizing the exposure as compared to e.g., CAD.

- In cosmetic products, TPO is used in nail modelling products. Due to the recent revision of the harmonised classification for TPO as toxic to reproduction (category 1), the substance should be prohibited as a cosmetic ingredient according to Cosmetics Regulation (EC) No 1223/2009 (Article 15). Currently, the TPO has a maximum threshold of 5 % in artificial nail systems and is only allowed for professional use (Opinion by the Scientific Committee on Consumer Safety, SCCS 1528/14).

- TPO is regarded as *hazardous* waste, due to the properties of TPO as toxic to reproduction according the regulation on waste (Directive 2008/98/EC, Annex III, entry H10).

- Organophosphorous compounds have been selected amongst those which present a significant risk to or via the aquatic environment and therefore included in an indicative list in the Water Framework Directive (Directive 2000/60/EC, Annex VIII, entry 2) with related provisions (Directive 2008/105/EC, Directive 2006/11/EC, Directive 2010/75/EU, Regulation 166/2006/EC, Regulation 782/2003/EC).

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)	X
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

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

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

The concern for TPO is mainly due to its properties as toxic to the reproductive system. This was acknowledged by RAC in their recent opinion in which they propose a harmonised classification for TPO as Repr. 1B (H360Fd). Hence, TPO fulfils the criteria as SVHC according to Article 57 (c) of the REACH regulation.

TPO has 29 registrants and 3118 notifications in the C&L inventory. The substance has a wide dispersive use, is manufactured within a high tonnage band (10 000-100 000 tpa) and is used in a large number of products and articles within different sectors. The RCRs for each use are below 1 when all risk reducing measures are taken into account. Industrial workers are considered to be protected by the CMD, that since March 2022 also includes reproductive substance with a harmonised classification in category 1. Consumers are considered to be protected after inclusion of the substance on Annex VI, as the concentration in consumer products will then be < 0.3 %. However, while there is no prima facie evidence for an unacceptable risk connected to the current uses of TPO, there is still a concern related to the exposure of professional workers and it is therefore considered appropriate to initiate regulatory risk management to protect these workers. Based on the above, and since TPO also meets the SVHC Roadmap 2020 relevance criterion, the Swedish CA finds that the most appropriate risk management option is inclusion of TPO in the REACH Candidate list according to Article 57c, for eventual inclusion in Annex XIV.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC identification	February 2023	Member State Sweden