

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

SUPPORT DOCUMENT FOR IDENTIFICATION OF

DIPHENYL(2,4,6-TRIMETHYLBENZOYL)PHOSPHINE OXIDE AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS TOXIC FOR REPRODUCTION (ARTICLE 57C) PROPERTIES This document has been prepared according to template: TEM-0049.04

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ABBREVIATIONS

ATP: Adaptation to Technical and Scientific Progress of the CLP Regulation CLH: Harmonised Classification and Labelling RAC: ECHA's Risk Assessment Committee SVHC: substance of very high concern

IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

EC Number: 278-355-8

CAS Number: 75980-60-8

• The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B¹.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is covered by index number 015-203-00-X of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 2 (H361f²). In 2021, the Risk Assessment Committee (RAC) adopted its opinion on the proposal for harmonised classification and labelling (CLH) of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as Repr. 1B (H360Fd²) by consensus³. The revised harmonised classification of the substance is included in ATP 21.

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

• Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance: Yes

 $^{^{\}rm 1}$ Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

² H361f: 'Suspected of damaging fertility'; H360Fd: 'May damage fertility. Suspected of damaging the unborn child'.

³ RAC opinion, adopted 16 September 2021, CLH-O-0000007023-85-01/F.

Justification

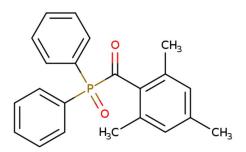
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	278-355-8
	270 333 0
EC name:	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
CAS number:	75980-60-8
IUPAC names:	 (Diphenylphosphinyl)-(2,4,6- trimethylphenyl)methanone (mesitylcarbonyl)(diphenyl)phosphine oxide 2,4,6-Trimethylbenzoyldiphenylphosphine oxide diphenyl(2,4,6-trimethylbenzoyl)phosphineoxide diphenylphosphoryl-(2,4,6- trimethylphenyl)methanone Phosphine oxide, diphenyl(2,4,6-trimethylbenzoyl)
Index number in Annex VI of the CLP Regulation	015-203-00-X
Molecular formula:	$C_{22}H_{21}O_2P$
Molecular weight range:	348.38
Synonyms:	 Methanone, (diphenylphosphinyl)(2,4,6- trimethylphenyl)-

Structural formula:



1.2 Composition of the substance

Name: Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Description: Organic

Substance type: Mono-constituent

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

1.5 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

2. Harmonised classification and labelling

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is covered by Index number 015-203-00-X in part 3 of Annex VI to the CLP Regulation as follows:

	Inde		EC No	o CAS No	Classification		Labelling			Spec.	Notes
	x No				Hazard Class and Category Codes	Hazard statemen t codes	Pictogram, Signal Word Codes	Hazard statement codes	Suppl. Hazard stateme nt code	Conc. Limits, M- factors and ATEs ⁴	
Annex VI entry (May 2023)	015- 203- 00-X	diphenyl(2,4, 6- trimethylbenz oyl)phosphin e oxide	278- 355- 8	759 80- 60-8	Repr. 2	H361f	GHS08 Wng	H361f			
Revised Annex IV entry. RAC opinion 2021	015- 203- 00-X	diphenyl(2,4, 6- trimethylbenz oyl)phosphin e oxide	278- 355- 8	759 80- 60-8	Skin Sens. 1B Repr. 1B	H317 H360Fd	GHS07 GHS08 Dgr	H317 H360Fd			

Table 2: Classification according to Annex VI, Table 3 (list of harmonised classificationand labelling of hazardous substances) of Regulation (EC) No 1272/2008

⁴ Acute Toxicity Estimate

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

4. Human health hazard assessment

In 2010, ECHA's Risk Assessment Committee (RAC) adopted its opinion on a harmonised classification of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as Repr. 2 (H361f). The substance was placed on the 3rd ATP to the CLP regulation (Annex VI).

Since then, the registrant has provided more toxicity studies according to the minimum information required at 100 to 1000 tonnage band according to the REACH regulation.

In 2021, RAC adopted its opinion on the proposal for harmonised classification and labelling (CLH) of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as Repr. 1B (H360Fd) at its 58th meeting by consensus (RAC, 2021). RAC also adopted its opinion on the proposal for CLH as Skin Sens. 1B (H317). The revised harmonised classification of the substance is included in ATP 21.

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is covered by index number 015-203-00-X of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 2 (H361f⁵). In 2021, RAC adopted its opinion on the proposal for harmonised classification and labelling (CLH) of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as Repr. 1B (H360Fd⁵). The revised harmonised classification of the substance is included in ATP 21

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

• Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

⁵ H361f: 'Suspected of damaging fertility'; H360Fd: 'May damage fertility. Suspected of damaging the unborn child'.

References

- EU (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.
- EU (2007). Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L136: 3-280.
- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide. EC Number: 278-355-8. CAS Number: 75980-60-8. CLH-O-0000007023-85-01/F. Adopted 16 September 2021. <u>https://echa.europa.eu/documents/10162/86e7e3f1-725b-2412-59bb-</u> <u>c1fe04529e0c</u>