Annex XV report

PROPOSAL FOR 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

Submitted by: Sweden Date: February 2023

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ABBREVIATIONS

AC: Article Category ATP: Adaptation to Technical and Scientific Progress of the CLP Regulation CLH: Harmonised Classification and Labelling ERC: Environmental Release Category PC: Product Category PROC: Process Category RAC: ECHA's Risk Assessment Committee SVHC: substance of very high concern

PROPOSAL FOR 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 proposed to be 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, which is anticipated to be published before the summer of 2023.

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.

PART I

Justification

1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance	identity
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EC number:	278-355-8	
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:

H₂C

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	CAS	Classif	ication		Labelling		Spec.	Notes
	x No	name		Νο	Hazard Class and Category Codes	Hazard statement codes	Pictogram, Signal Word Codes	Hazard statement codes	Suppl. Hazard stateme nt code	Conc. Limits, M- factors and ATEs ⁴	
Current Annex VI entry	015- 203- 00-X	diphenyl(2,4, 6- trimethylbenz oyl)phosphine 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)phosphine 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 classification
and 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, which is anticipated to be published before the summer of 2023.

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(2,4,6trimethylbenzoyl)phosphine oxide as Repr. 1B (H360Fd⁵). The revised harmonised classification of the substance is included in ATP 21, which is anticipated to be published before the summer of 2023.

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'.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3: Registration status

From the ECHA dissemination site ⁶				
Registrations	 Full registrations (Art. 10) Intermediate registration(s) (Art. 17 and/or 18) 			

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications ⁷
Number of aggregated notifications	41
Total number of notifiers	3126

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁸	10,000-100,000 t/pa
Tonnage information from public sources other than registration dossiers (if available) ⁹	Sweden: 19.5 t/pa Denmark: 2.0 t/pa

⁶ Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide <u>Substance Information - ECHA (europa.eu)</u> (12 December 2022)

⁷ C&L Inventory database, <u>http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database</u> (accessed *12 December 2022*)

⁸ Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide <u>Substance Information - ECHA (europa.eu)</u> (12 December 2022)

⁹ Nordic product register database (SPIN) from 2019. <u>http://spin2000.net/</u> (accessed 16 June 2022)

9. Information on uses of the substance

Substance info card (ECHA website)¹⁰

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is used in photo-chemicals, inks and toners, coating products, adhesives and sealants, polymers and fillers, putties, plasters, and modelling clay. The substance can also be found in materials based on fabrics, textiles and apparels (e.g., clothing, mattresses, curtains, carpets, or textile toys), paper (e.g., tissues, feminine hygiene products, nappies, books, magazines, or wallpaper) and plastics (e.g., food packaging and storage, toys, or mobile phones). The different uses of the substance are specified in Table 6.

Product register data

According to the Nordic product register database (SPIN) from 2019, the technical uses of the preparations include activator, catalyst, surfactant, pigment, UV-absorbent and "unspecified function". The industrial use of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide includes:

- Manufacture of chemicals and chemical products
- Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
- Printing and reproduction of recorded media
- Publishing, printing and reproduction of recorded media

	Uses	Registered use	Use <u>likely</u> to be in the scope of Authorisation
Uses as intermediate	-	-	-
	Industrial manufacture of coatings and inks PROC 1-3, 5, 8a, 8b, 9, 15. ERC 2, 3.	Yes	Yes
	Formulation of the chemical PROC 1-3, 5, 8a, 8b, 9. ERC 2. PC 30.		
Formulation	Formulation of preparations PROC 1-3, 5, 8a, 8b, 9. ERC 2.		
or repacking	Formulation of preparations containing photoinitiator TPO PROC 1-3, 5, 8a, 8b, 15. ERC 2.		
	Formulation of Inks/Ink-/3DP-Components PROC 5, 8b, 9, 28. ERC 2. PC 15, 18, 26, 32, 35.		
	Formulation of ink PROC 1, 3, 5, 8a, 8b, 9. ERC 2, 3. PC 18.		

Table 6: Uses

¹⁰ <u>https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.071.211</u>

ANNEX XV – IDENTIFICATION OF DIPHENYL(2,4,6-TRIMETHYLBENZOYL)PHOSPHINE

	 Formulation of preparations (mixtures) containing photoinitiator TPO PROC 1-3, 5, 7, 8a, 8b, 9, 10, 13, 15, 21. ERC 2. Formulation of coatings and inks PROC 1-3, 8a, 8b, 9, 15. ERC 2, 3. Industrial formulation of preparations containing the photoinitiator PROC 1-3, 5, 8a, 8b, 9, 15. ERC 2. PC 0, 9a, 18. Formulation of inks, coatings and adhesives PROC 1-3, 5, 8a, 8b, 9. ERC 2. PC 1, 9a, 9b, 18, 32. Formulation or re-packing – industrial manufacture of coatings and inks PROC 1-3, 8a, 8b, 9, 15. ERC 2, 3. PC 30. Mixing or blending in batch processes for formulation of preparations PROC 5. 		
	ERC 2. PC 30. Industrial application of coatings and inks PROC 7, 8b, 9, 10, 13. ERC 5, 6d. PC 18. Industrial use of the photoinitiator resulting in inclusion into a matrix, including application in coatings, adhesives, inks, fiber sizing	Yes	Yes
Uses at industrial	PROC 1, 2, 5, 7, 8a, 8b, 10, 13, 21, 24. ERC 5, 6d. PC 0, 9a, 18. Industrial use resulting in inclusion into (or onto) a matrix PROC 1-5, 7, 8a, 8b, 10, 13, 15, 21. ERC 5. PC 1, 9a, 9b, 18, 30, 32. Industrial use of process regulators for polymerisation PROC 3, 4, 8a, 8b.		
sites	ERC 6d. PC 30. Industrial use of process regulators for polymerisation in production of resins, rubbers, polymers PROC 3, 4, 8a, 8b. ERC 6d.		
	Use of Inks/ink-/3DP-components PROC 3, 8b, 9, 14, 28. ERC 4, 5. PC 15, 18, 26, 32, 35.		
	1 PROC 1-3, 5, 8a, 8b, 10, 13, 15. ERC 5. Use of ink bottles		
	PROC 1. ERC 5. PC 18.		

ANNEX XV – IDENTIFICATION OF DIPHENYL(2,4,6-TRIMETHYLBENZOYL)PHOSPHINE OXIDE AS SVHC

	Use of inks/ink-/3DP-components	Yes	Yes
	PROC 3, 8a, 8b, 10, 14, 28.	162	Tes
	ERC 8a, 8c. PC 15, 18, 26, 32, 35.		
	Wide dispersive indoor use of reactive substances in open systems PROC 2, 3, 5, 8a, 10. ERC 8c. PC 1, 9a, 9b, 18, 32.		
	Professional use in coatings/inks/toners/paints PROC 5, 8a, 8b, 10. ERC 8c.		
	Wide dispersive use into or onto a matrix PROC 2, 3, 5, 8a, 8b, 10, 11, 13, 14, 21, 24. ERC8c, 8f. PC 1, 9a, 9b, 18, 30, 32.		
	Wide dispersive outdoor use into or onto a matrix PROC 8b, 14. ERC 8f. PC 30.		
	Professional application in inks/coatings/paints/toners PROC 5, 8a, 8b, 9, 10. ERC 8c. PC 9a, 18.		
Uses by	Professional application in inks and coatings PROC 8b, 9, 10. ERC 8c. PC 18.		
professional workers	Professional application of coatings and inks PROC 10, 13. ERC 8c.		
	Professional use of photoinitiator TPO PROC 2, 3, 5, 8a, 8b, 10, 11, 13. ERC 8c. PC 0.		
	Professional use of photoinitiator TPO in printing inks PROC 2, 3, 8a, 8b, 10, 11, 13. ERC 8c.		
	Professional use of TPO in printing inks PROC 2, 3, 5, 8a, 8b, 10, 11, 13. ERC 8c.		
	Professional use of photoinitiator TPO resulting in inclusion into a matrix PROC 2, 3, 5, 8a, 8b, 10, 11, 13. ERC 8c.		
	Wide dispersive indoor use of processing aids in open systems PROC 8b, 14. ERC 8f. PC 1.		
	Widespread use by professional workers – Professional application of coatings and inks PROC 10, 13. ERC 8c.		
	Wide dispersive indoor use (professional) of photoinitiator resulting in inclusion into a matrix, including application in coatings, adhesives, and inks		
	PROC 2, 3, 5, 8a, 8b, 10, 11, 13, 21, 24.		

	ERC 8c.		
	Use of ink bottles by professional workers PROC 1. ERC 8c. PC 18.		
Consumer uses	Use of ink bottles by consumers ERC 8c. PC 18.	Yes	No
	Industrial use resulting in inclusion into a matrix PROC 1, 2, 5, 7, 8a, 8b, 10, 13, 15. ERC 10a, 11a, 12a. Article used by workers.	Yes	Yes
	Use of articles PROC 21. ERC 11a. AC 5, 8, 13. Article used by workers.		
Article service life	Article service of articles produced or treated with ink/coatings used by workers PROC 21. ERC 10a, 12a. Article used by workers.		
	Wide dispersive outdoor use into or onto a matrix PROC 8b, 14. ERC 10a. Article used by workers.		
	Wide dispersive use into or onto a matrix PROC 2, 3, 5, 8a, 10. ERC 11a. Article used by workers		

10. Information on structure of the supply chain

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is registered by 28 active registrants/suppliers from nine countries through joint submission. In total, 3 126 companies have notified the substance in the C&L inventory indicating that the substance is handled by many individuals at many sites. The overall conclusion is that diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide may be used by a medium-to-high number of actors EU-wide.

There is no information available on downstream user reports or PPORD notifications.

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is manufactured/imported in large quantities (10,000-100,000 tpa) and used in a large number of products within different sectors.

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is also used by actors in five out of six lifecycle stages (formulation, use at industrial sites, use by professional workers, consumer use, and article service life) for its use in a variety of products (see section 9). However, the uses of the substance seem to be limited to its function as a photo-initiator, indicating a low diversity with regard to the technical function. Together, this illustrates that diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is a substance for which exposure is expected to be widely spread.

In summary, diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide has wide dispersive uses covering both:

- widespread use, i.e., industrial use, professional use, consumer use and articles service life.
- high potential for worker exposure through, for example, PROC 10 (roller application or brushing), PROC 11 (non-industrial spraying), and PROC 13 (treatment of articles by dipping and pouring).

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

There is to our knowledge no information on substances with similar hazard and use profiles on the Candidate List.

11.2 Alternatives

There is to our knowledge no information on alternative substances. Further research is required to determine whether structurally similar substances, found in the ECHA registration database, are alternative substances.

11.3 Existing EU legislation

- 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 currently classified in the hazard class toxic for reproduction category 2 (H361f). In 2021, RAC adopted its opinion on a revision of the current harmonised classification of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide to Repr. 1B (H360Fd). The revised harmonised classification of the substance is included in ATP 21, which is anticipated to be published before the summer of 2023.
- When the harmonised classification of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide as Repr. 1B has entered into force, 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).
- Organophosphorous compounds have been selected amongst those which present a significant risk to or via the aquatic environment and, therefore, they are 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).
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is regarded as *hazardous* waste due to the properties of TPO as toxic to reproduction according to the Waste Directive 2008/98/EC (Annex III, entry H10).
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is listed in the Swiss Ordinance of the FDHA (Federal Department of Home Affairs) on materials and articles

intended to come into contact with foodstuffs with a specific migration limit of 0.05 mg/kg food.

- In cosmetic products, diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is used in nail modelling products. Due to the recent revision of the harmonised classification of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (Repr. 1B), the substance will become prohibited as a cosmetic ingredient according to Cosmetics Regulation (EC) No 1223/2009 (Article 15). Currently, the substance 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).
- There is no European Occupational Exposure Limit (OEL) for diphenyl(2,4,6trimethylbenzoyl)phosphine oxide under Directive 2004/37/EC (CMD, Carcinogens and Mutagens Directive) or Directive 98/24/EC (CAD, Chemical Agents Directive). Still, the substance meets the criteria for classification within a hazard class as laid down in the CLP regulation (Article 3) and thereby regarded as a *hazardous chemical agent* as defined in the CAD, CMD/CMRD and 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).

11.4 Previous assessments by other authorities/ongoing regulatory activities

The only ongoing regulatory activity is the CLH process for inclusion of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide on ATP 21.

REFERENCES

References for Part I

- 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. https://echa.europa.eu/documents/10162/86e7e3f1-725b-2412-59bb-c1fe04529e0c

References for Part II

- C&L Inventory database, <u>http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database</u> (accessed 12 December 2022).
- 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-2412-59bbc1fe04529e0c</u>
- ECHA (2022): <u>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</u>. Information on registered substances, published on ECHA's website <u>https://www.echa.europa.eu/web/guest/substance-information/-</u>/substanceinfo/100.071.211 (accessed on 12 December 2022).
- EU (1992). Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (10th individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), OJ L 348.

- EU (1998). Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (14th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), L 131/11.
- EU (2000). Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, L 327/1.
- EU (2003). Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships, L 115/1.
- EU (2004). Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (6th individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), OJ L 158.
- EU (2006). Directive 2006/11/EC of the European Parliament and of the Council of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, L 64/52.
- 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 (2006). Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC, L 33/1.
- 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.
- EU (2008). Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, L 348/84.EU (2004). Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version). Official Journal of the European Union, L158: 50-76.

- EU (2008). Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. L 312/3.
- EU (2009). Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 as regards of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII. Official Journal of the European Union, L164: 7-31.
- EU (2010). Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), L 334/17.
- EU (2014). Opinion by the Scientific Committee on Consumer Safety, SCCS 1528/14. Opinion on trimethylbenzoyl diphenylphosphine oxide (TPO). SCCS adopted this opinion at its 5th plenary meeting of 27 March 2014. ISSN 1831-4767.
- EU (2022). Directive 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
- SPIN (2019): Nordic product register database (SPIN) from 2019. <u>http://spin2000.net/</u> (accessed 16 June 2022).