



2025/877

13.5.2025

COMMISSION REGULATION (EU) 2025/877

of 12 May 2025

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards
the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or
toxic for reproduction**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 15(1) and Article 15(2), fourth subparagraph, thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾ provides for a harmonised classification of substances as carcinogenic, mutagenic or toxic for reproduction (CMR) based on a scientific assessment by the Risk Assessment Committee of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, category 1B or category 2 depending on the level of evidence of their CMR properties.
- (2) Article 15 of Regulation (EC) No 1223/2009 provides that substances which have been classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CMR substances) are to be prohibited from use in cosmetic products. A CMR substance may however be used in cosmetic products where the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph of that Regulation are fulfilled.
- (3) In order to uniformly implement the prohibition of CMR substances within the internal market, to ensure legal certainty, in particular for economic operators and national competent authorities, and to ensure a high level of protection of human health, all CMR substances should be included in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or allowed substances in Annexes III to VI to that Regulation. Where the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph of that Regulation are fulfilled, the lists of restricted or allowed substances in Annexes III to VI to that Regulation should be amended accordingly.
- (4) This Regulation covers substances classified as CMR substances by Commission Delegated Regulation (EU) 2024/197 ⁽³⁾ ('the relevant substances'). Delegated Regulation (EU) 2024/197 will apply from 1 September 2025.
- (5) No request for use in cosmetic products by way of exception has been submitted for the relevant substances.
- (6) The substance 'diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide' (CAS No 75980-60-8), with the International Nomenclature of Cosmetic Ingredients (INCI) name 'Trimethylbenzoyl Diphenylphosphine Oxide', is listed in entry 311 of Annex III to Regulation (EC) No 1223/2009 and is, therefore, allowed for professional use in artificial nail systems with a maximum concentration of 5 %.

⁽¹⁾ OJ L 342, 22.12.2009, p. 59, ELI: <http://data.europa.eu/eli/reg/2009/1223/oj>.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁽³⁾ Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances (OJ L 2024/197, 5.1.2024, ELI: http://data.europa.eu/eli/reg_del/2024/197/oj).

- (7) In light of the classification of 'Trimethylbenzoyl Diphenylphosphine Oxide' as a CMR substance of category 1B (Toxic for Reproduction), that substance should no longer be allowed in cosmetic products. Entry 311 of Annex III to Regulation (EC) No 1223/2009 should, therefore, be deleted and the substance should be included in the list of prohibited substances in Annex II to that Regulation.
- (8) The substance '2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide'(CAS 57966-95-7), with the ISO name 'cymoxanil', which has been classified as Toxic for Reproduction of Category 2 is listed in entry 1580 of Annex II to Regulation (EC) No 1223/2009 and is, therefore, prohibited for use in cosmetic products. However, entry 1580 does not include the additional chemical name '(2E)-2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide' and the CAS number related to that chemical name as referred to in Delegated Regulation (EU) 2024/197. For reasons of clarity and legal certainty, entry 1580 should be adapted so that it has the same content as the corresponding entry in Regulation (EC) No 1272/2008.
- (9) None of the other relevant substances are currently listed in Regulation (EC) No 1223/2009. Consequently, they should be added to the list of substances prohibited in cosmetic products in Annex II to that Regulation.
- (10) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (11) The amendments to Regulation (EC) No 1223/2009 are based on the classifications of the relevant substances as CMR substances and should therefore apply from the same date as those classifications.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II and III to Regulation (EC) No 1223/2009 are amended as follows:

(1) Annex II is amended as follows:

(a) the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1731	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; INCI: Trimethylbenzoyl Diphenylphosphine Oxide	75980-60-8	278-355-8
1732	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	79-94-7	201-236-9
1733	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)- 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane- carboxylate	118712-89-3	405-060-5
1734	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol- 5-ylmethyl)-3-methyl-2-nitroguanidine	210880-92-5	433-460-1
1735	benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl) propan-2-yl]phenolate	577705-90-9	479-100-5
1736	benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene] bis[phenol] (1:1)	75768-65-9	278-305-5
1737	reaction mass of 4,4'-[2,2,2-trifluoro- 1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl) propan-2-yl]phenolate (1:1)	-	-
1738	reaction mass of 4,4'-[2,2,2-trifluoro- 1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene] diphenol (1:1)	-	-
1739	dimethyl propylphosphonate	18755-43-6	242-555-3
1740	dibutyltin maleate	78-04-6	201-077-5
1741	dibutyltin oxide	818-08-6	212-449-1
1742	reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy) methyl)-2-hydroxymethyl butane	-	-
1743	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene] diphenol; bisphenol AF	1478-61-1	216-036-7
1744	benfluralin (ISO); N-butyl-N-ethyl- α,α,α - trifluoro-2,6-dinitro-p-toluidine	1861-40-1	217-465-2

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1745	<i>N,N</i> -dimethyl- <i>p</i> -toluidine	99-97-8	202-805-4
1746	1,4-Benzenediamine, <i>N,N'</i> -mixed Ph and tolyl derivs.	68953-84-4	273-227-8
1747	4-nitrosomorpholine	59-89-2	-
1748	difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1 <i>H</i> -1,2,4-triazole; 3-chloro-4-[(2 <i>RS</i> ,4 <i>RS</i> ;2 <i>RS</i> ,4 <i>SR</i>)-4-methyl-2-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether	119446-68-3	-
1749	4-methylimidazole	822-36-6	212-497-3
1750	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	91-97-4	202-112-7
1751	foramsulfuron (ISO); 2-[[{(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl]-4-formamido- <i>N,N</i> -dimethylbenzamide; 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea	173159-57-4	-'

(b) entry 1580 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1580	cymoxanil (ISO); 2-cyano- <i>N</i> -[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [1]	57966-95-7; [1]	261-043-0; [1]
	(2 <i>E</i>)-2-cyano- <i>N</i> -[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [2]	166900-80-7; [2]	- [2]

(2) in Annex III, entry 311 is deleted.