



Brussels, **XXX**
[...] (2024) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**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)

COMMISSION REGULATION (EU) .../...

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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 products¹, 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 Council² 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.

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>).

- (4) This Regulation covers substances classified as CMR substances by Delegated Regulation (EU) 2024/197³ ('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 %.
- (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) 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.

³ Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 2024/197, 5.1.2024, ELI: http://data.europa.eu/eli/reg_del/2024/197/oj).

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,

For the Commission
The President
Ursula von der Leyen



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[...] (2024) XXX draft

ANNEX

ANNEX

to the

Commission Regulation (EU) .../...

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council
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mutagenic or toxic for reproduction**

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
'X [OP: please replace with the next consecutive number]	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	278-355-8
X [OP: please replace with the next consecutive number]	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	79-94-7	201-236-9
X [OP: please replace with the next consecutive number]	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	118712-89-3	405-060-5
X [OP: please replace with the next consecutive number]	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	210880-92-5	433-460-1
X [OP: please replace with the next consecutive number]	benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate	577705-90-9	479-100-5
X [OP: please replace with the next consecutive number]	benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	75768-65-9	278-305-5
X [OP: please replace with the next consecutive number]	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)	-	-
X [OP: please replace with the next consecutive number]	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]bis[phenol] (1:1)	-	-

X [OP: please replace with the next consecutive number]	dimethyl propylphosphonate	18755-43-6	242-555-3
X [OP: please replace with the next consecutive number]	dibutyltin maleate	78-04-6	201-077-5
X [OP: please replace with the next consecutive number]	dibutyltin oxide	818-08-6	212-449-1
X [OP: please replace with the next consecutive number]	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	-	-
X [OP: please replace with the next consecutive number]	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF	1478-61-1	216-036-7
X [OP: please replace with the next consecutive number]	benfluralin (ISO); <i>N</i> -butyl- <i>N</i> -ethyl- α,α,α -trifluoro-2,6-dinitro- <i>p</i> -toluidine	1861-40-1	217-465-2
X [OP: please replace with the next consecutive number]	<i>N,N</i> -dimethyl- <i>p</i> -toluidine	99-97-8	202-805-4
X [OP: please replace with the next consecutive number]	1,4-Benzenediamine, <i>N,N'</i> -mixed Ph and tolyl derivs.	68953-84-4	273-227-8
X [OP: please replace with the next consecutive number]	4-nitrosomorpholine	59-89-2	-
X [OP: please replace with the next consecutive number]	difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether	119446-68-3	-
X [OP: please replace with the next consecutive number]	4-methylimidazole	822-36-6	212-497-3

number]			
X [OP: please replace with the next consecutive number]	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	91-97-4	202-112-7
X [OP: please replace with the next consecutive number]	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] (2 <i>E</i>)-2-cyano- <i>N</i> -[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [2]	57966-95-7; [1] 166900-80-7; [2]	261-043-0; [1] - [2]’

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