



STATUTORY INSTRUMENTS.

S.I. No. 637 of 2024



EUROPEAN UNION (COSMETIC PRODUCTS) (AMENDMENT)
REGULATIONS 2024

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EUROPEAN UNION (COSMETIC PRODUCTS) (AMENDMENT)
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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Regulation (EU) 2017/238 of 10 February 2017¹, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017², Commission Regulation (EU) 2017/1224 of 6 July 2017³, Commission Regulation (EU) 2017/1410 of 2 August 2017⁴, Commission Regulation (EU) 2017/1413 of 3 August 2017⁵, Commission Regulation (EU) 2017/2228 of 4 December 2017⁶, Commission Regulation (EU) 2018/885 of 20 June 2018⁷, Commission Regulation (EU) 2018/978 of 9 July 2018⁸, Commission Regulation (EU) 2018/1847 of 26 November 2018⁹, Commission Regulation (EU) 2019/680 of 30 April 2019¹⁰, Commission Regulation (EU) 2019/681 of 30 April 2019¹¹, Commission Regulation (EU) 2019/698 of 30 April 2019¹², Commission Regulation (EU) 2019/831 of 22 May 2019¹³, Commission Regulation (EU) 2019/1857 of 6 November 2019¹⁴, Commission Regulation (EU) 2019/1858 of 6 November 2019¹⁵, Commission Regulation (EU) 2019/1966 of 27 November 2019¹⁶, Commission Regulation (EU) 2020/1682 of 12 November 2020¹⁷, Commission Regulation (EU) 2020/1683 of 12 November 2020¹⁸, Commission Regulation (EU) 2020/1684 of 12 November 2020¹⁹, Commission Regulation (EU) 2021/850 of 26 May 2021²⁰, Commission Regulation (EU) 2021/1099 of 5 July 2021²¹, Commission Regulation (EU) 2021/1902 of 29 October 2021²², Commission Regulation (EU)

¹ OJ No. L 36, 11.2.2017, p. 37.

² OJ No. L 117, 5.5.2017, p. 1.

³ OJ No. L 174, 7.7.2017, p. 16.

⁴ OJ No. L 202, 3.8.2017, p. 1.

⁵ OJ No. L 203, 4.8.2017, p. 1.

⁶ OJ No. L 319, 5.12.2017, p. 2, as amended by Corrigendum (OJ No. L 326, 9.12.2017, p. 55).

⁷ OJ No. L 158, 21.6.2018, p. 1.

⁸ OJ No. L 176, 12.7.2018, p. 3, as amended by Corrigendum (OJ No. L 183, 19.7.2018, p. 27).

⁹ OJ No. L 300, 27.11.2018, p. 1.

¹⁰ OJ No. L 115, 2.5.2019, p. 3.

¹¹ OJ No. L 115, 2.5.2019, p. 5.

¹² OJ No. L 119, 7.5.2019, p. 66.

¹³ OJ No. L 137, 23.5.2019, p. 29.

¹⁴ OJ No. L 286, 7.11.2019, p. 3.

¹⁵ OJ No. L 286, 7.11.2019, p. 7.

¹⁶ OJ No. L 307, 28.11.2019, p. 15, as amended by Corrigenda (OJ No. L 324, 13.12.2019, p. 80 and OJ No. L 76, 12.3.2020, p. 36).

¹⁷ OJ No. L 379, 13.11.2020, p. 31.

¹⁸ OJ No. L 379, 13.11.2020, p. 34, as amended by Corrigendum (OJ No. L 397, 26.11.2020, p. 30).

¹⁹ OJ No. L 379, 13.11.2020, p. 42.

²⁰ OJ No. L 188, 28.5.2021, p. 44, as amended by Corrigendum (OJ No. L 214, 17.6.2021, p. 68).

²¹ OJ No. L 238, 6.7.2021, p. 29, as amended by Corrigendum (OJ No. L 365, 14.10.2021, p. 46).

²² OJ No. L 387, 3.11.2021, p. 120.

2022/135 of 31 January 2022²³, Commission Regulation (EU) 2022/1176 of 7 July 2022²⁴ and Commission Regulation (EU) 2022/1181 of 8 July 2022²⁵, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Cosmetic Products) (Amendment) Regulations 2024.

(2) The Principal Regulations, the European Union (Cosmetic Products) (Amendment) Regulations 2015 (S.I. No. 512 of 2015), the Regulations of 2016 and these Regulations may be cited together as the European Union (Cosmetic Products) Regulations 2013 to 2024.

2. In these Regulations—

“Principal Regulations” means the European Union (Cosmetic Products) Regulations 2013 (S.I. No. 440 of 2013);

“Regulations of 2016” means the European Union (Cosmetic Products) (Amendment) Regulations 2016 (S.I. No. 317 of 2016);

“Regulations of 2017” means the European Union (Cosmetic Products) (Amendment) Regulations 2017 (S.I. No. 297 of 2017).

3. Regulation 2(1) (as amended by Regulation 3 of the Regulations of 2017) of the Principal Regulations is amended by substituting for the definition of “EU Regulation” the following:

“EU Regulation” means Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009²⁶, as amended by Commission Regulation (EU) No. 344/2013 of 4 April 2013²⁷, Commission Regulation (EU) No. 483/2013 of 24 May 2013²⁸, Commission Regulation (EU) No. 658/2013 of 10 July 2013²⁹, Commission Regulation (EU) No. 1197/2013 of 25 November 2013³⁰, Commission Regulation (EU) No. 358/2014 of 9 April 2014³¹, Commission Regulation (EU) No. 866/2014 of 8 August 2014³², Commission Regulation (EU) No. 1003/2014 of 18 September 2014³³, Commission Regulation (EU) No. 1004/2014 of 18 September 2014³⁴, Commission Regulation (EU) 2015/1190 of 20 July 2015³⁵, Commission

²³ OJ No. L 22, 1.2.2022, p. 2.

²⁴ OJ No. L 183, 8.7.2022, p. 51.

²⁵ OJ No. L 184, 11.7.2022, p. 3.

²⁶ OJ No. L 342, 22.12.2009, p. 59.

²⁷ OJ No. L 114, 25.4.2013, p. 1, as amended by Corrigendum (OJ No. L 142, 29.5.2013, p. 10).

²⁸ OJ No. L 139, 25.5.2013, p. 8.

²⁹ OJ No. L 190, 11.7.2013, p. 38.

³⁰ OJ No. L 315, 26.11.2013, p. 34.

³¹ OJ No. L 107, 10.4.2014, p. 5.

³² OJ No. L 238, 9.8.2014, p. 3, as amended by Corrigendum (OJ No. L 254, 28.8.2014, p. 39).

³³ OJ No. L 282, 26.9.2014, p. 1.

³⁴ OJ No. L 282, 26.9.2014, p. 5.

³⁵ OJ No. L 193, 21.7.2015, p. 115.

Regulation (EU) 2015/1298 of 28 July 2015³⁶, Commission Regulation (EU) 2016/314 of 4 March 2016³⁷, Commission Regulation (EU) 2016/621 of 21 April 2016³⁸, Commission Regulation (EU) 2016/622 of 21 April 2016³⁹, Commission Regulation (EU) 2016/1120 of 11 July 2016⁴⁰, Commission Regulation (EU) 2016/1121 of 11 July 2016⁴¹, Commission Regulation (EU) 2016/1143 of 13 July 2016⁴², Commission Regulation (EU) 2016/1198 of 22 July 2016⁴³, Commission Regulation (EU) 2017/237 of 10 February 2017⁴⁴, Commission Regulation (EU) 2017/238 of 10 February 2017¹, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017², Commission Regulation (EU) 2017/1224 of 6 July 2017³, Commission Regulation (EU) 2017/1410 of 2 August 2017⁴, Commission Regulation (EU) 2017/1413 of 3 August 2017⁵, Commission Regulation (EU) 2017/2228 of 4 December 2017⁶, Commission Regulation (EU) 2018/885 of 20 June 2018⁷, Commission Regulation (EU) 2018/978 of 9 July 2018⁸, Commission Regulation (EU) 2018/1847 of 26 November 2018⁹, Commission Regulation (EU) 2019/680 of 30 April 2019¹⁰, Commission Regulation (EU) 2019/681 of 30 April 2019¹¹, Commission Regulation (EU) 2019/698 of 30 April 2019¹², Commission Regulation (EU) 2019/831 of 22 May 2019¹³, Commission Regulation (EU) 2019/1857 of 6 November 2019¹⁴, Commission Regulation (EU) 2019/1858 of 6 November 2019¹⁵, Commission Regulation (EU) 2019/1966 of 27 November 2019¹⁶, Commission Regulation (EU) 2020/1682 of 12 November 2020¹⁷, Commission Regulation (EU) 2020/1683 of 12 November 2020¹⁸, Commission Regulation (EU) 2020/1684 of 12 November 2020¹⁹, Commission Regulation (EU) 2021/850 of 26 May 2021²⁰, Commission Regulation (EU) 2021/1099 of 5 July 2021²¹, Commission Regulation (EU) 2021/1902 of 29 October 2021²², Commission Regulation (EU) 2022/135 of 31 January 2022²³, Commission Regulation (EU) 2022/1176 of 7 July 2022²⁴ and Commission Regulation (EU) 2022/1181 of 8 July 2022²⁵”.

4. Regulation 9(3) of the Principal Regulations is amended by inserting “and these Regulations” after “the EU Regulation”.

5. Regulations 12 and 13 of the Principal Regulations are amended by inserting “or these Regulations” after “the EU Regulation” in each place where it occurs.

6. Regulation 18 (as amended by Regulation 4 of the Regulations of 2016) of the Principal Regulations is amended—

³⁶ OJ No. L 199, 29.7.2015, p. 22.

³⁷ OJ No. L 60, 5.3.2016, p. 59, as amended by Corrigendum (OJ No. L 17, 21.1.2017, p. 52).

³⁸ OJ No. L 106, 22.4.2016, p. 4.

³⁹ OJ No. L 106, 22.4.2016, p. 7.

⁴⁰ OJ No. L 187, 12.7.2016, p. 1.

⁴¹ OJ No. L 187, 12.7.2016, p. 4.

⁴² OJ No. L 189, 14.7.2016, p. 40.

⁴³ OJ No. L 198, 23.7.2016, p. 10.

⁴⁴ OJ No. L 36, 11.2.2017, p. 12.

- (a) in paragraph (1), by inserting “or these Regulations” after “in conformity with the EU Regulation” in both places where it occurs,
- (b) in paragraph (2)(b), by inserting “or these Regulations” after “requirements of the EU Regulation”, and
- (c) in paragraph (2)(c) and (d), by inserting “or these Regulations” after “in conformity with the EU Regulation” in both places where it occurs.

7. The Regulations of 2017 are revoked.



GIVEN under my Official Seal,
20 November, 2024.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the European Union (Cosmetic Products) Regulations 2013 to give effect to a number of Commission Regulations. These Regulations have the effect of—

- accounting for amendments pertaining to the restrictions in relation to Benzophenone-3 as a UV filter (Commission Regulation (EU) 2017/238 of 10 February 2017),
- accounting for amendments allowing the Commission, at the request of a Member State or on its own initiative, to adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition ‘cosmetic product’ (Commission Regulation (EU) 2017/745 of 5 April 2017),
- accounting for amendments pertaining to the restrictions in relation to Methylisothiazolinone (M.I.) as a preservative in rinse-off products (Commission Regulation (EU) 2017/1224 of 6 July 2017),
- accounting for amendments pertaining to the prohibitions in relation to HICC, Atranol and chloroatranol in cosmetic products (Commission Regulation (EU) 2017/1410 of 2 August 2017),
- accounting for amendments pertaining to the restrictions in relation to non-nano Zinc Oxide as a colorant (Commission Regulation (EU) 2017/1413 of 3 August 2017),
- accounting for amendments pertaining to the restrictions in relation to peanut oil and hydrolysed wheat proteins in cosmetic products (Commission Regulation (EU) 2017/2228 of 4 December 2017),
- accounting for amendments pertaining to the restrictions in relation to Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (MBBT) and MBBT (nano) as UV filters (Commission Regulation (EU) 2018/885 of 20 June 2018),
- accounting for amendments pertaining to the restrictions in relation to *Tagetes minuta* and *Tagetes patula* extracts and oils and prohibitions in relation to *Tagetes erecta* (Commission Regulation (EU) 2018/978 of 9 July 2018),
- accounting for amendments pertaining to the restrictions in relation to O-phenylphenol (OPP), sodium o-phenylphenate, potassium o-phenylphenate and MEA o-phenylphenate as preservatives (Commission Regulation (EU) 2018/1847 of 26 November 2018),
- accounting for amendments pertaining to the restrictions in relation to Phenylene Bis-Diphenyltriazine as a UV filter (Commission Regulation (EU) 2019/680 of 30 April 2019),

- accounting for amendments pertaining to the prohibitions in relation to 2-Chloro-p-Phenylenediamine and its sulfate and dihydrochloride salts when used as a substance in hair dye products, including eyebrow dye products, and eyelash dye products (Commission Regulation (EU) 2019/681 of 30 April 2019),
- accounting for amendments pertaining to the restrictions in relation to Climbazole as an anti-dandruff agent and as a preservative (Commission Regulation (EU) 2019/698 of 30 April 2019),
- accounting for amendments to uniformly implement the prohibition of CMR substances as substances prohibited in cosmetic products and pertaining to restrictions in relation to the use of Trimethylbenzoyl diphenylphosphine oxide, Furfural and Polyaminopropyl biguanide (Commission Regulation (EU) 2019/831 of 22 May 2019),
- accounting for amendments pertaining to the restrictions in relation to the use of three forms of titanium dioxide (nano), coated with either silica and cetyl phosphate, alumina and manganese dioxide, or alumina and triethoxycaprylylsilane as UV filters (Commission Regulation (EU) 2019/1857 of 6 November 2019),
- accounting for amendments pertaining to the restrictions in relation to Hydroxyethoxyphenyl Butanone (HEPB) as a preservative (Commission Regulation (EU) 2019/1858 of 6 November 2019),
- accounting for amendments pertaining to the restrictions in relation to Salicylic acid, including use as a preservative and non-preservative use, and to uniformly implement the prohibition of CMR substances as substances prohibited in cosmetic products (Commission Regulation (EU) 2019/1966 of 27 November 2019),
- accounting for amendments pertaining to the restrictions in relation to the use of 2-hydroxyethyl methacrylate (HEMA) and 11,14-Dioxa-2,9-diazaheptadec-16-enoic Acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester (Di-HEMA Trimethylhexyl Dicarbamate or Di-HEMA TMHDC) in nail products (Commission Regulation (EU) 2020/1682 of 12 November 2020),
- accounting for amendments pertaining to the prohibition in relation to the use of 1,2,4-Trihydroxybenzene, 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid and 4-Amino-3-hydroxytoluene from cosmetic products and restrictions in relation to the use of specific substances in hair dye products (Commission Regulation (EU) 2020/1683 of 12 November 2020),
- accounting for amendments pertaining to use of Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate as a UV filter in cosmetic products (Commission Regulation (EU) 2020/1684 of 12 November 2020),
- accounting for amendments to the prohibition and restriction of CMR substances and restrictions in relation to the use of titanium dioxide in face products, hair aerosol spray products, as a UV filter and as a colourant, the use of salicylic acid in body lotion, eye shadow, mascara,

eyeliner, lipstick and roll-on deodorant, and removing a duplicate entry for Nickel bis(tetrafluoroborate) (Commission Regulation 2021/850 of 26 May 2021),

- accounting for amendments pertaining to the prohibition of the use of deoxyarbutin in cosmetic products and restriction on the use of Dihydroxyacetone in non-oxidative hair dye products and self-tanning products (Commission Regulation (EU) 2021/1099 of 5 July 2021),
- accounting for amendments to uniformly implement the prohibition of CMR substances within the internal market (Commission Regulation (EU) 2021/1902 of 29 October 2021),
- accounting for amendments pertaining to the use of Methyl-N-methylantranilate in cosmetic products (Commission Regulation (EU) 2022/135 of 31 January 2022, and
- accounting for amendments pertaining to restrictions on the use of Benzophenone-3 and Octocrylene when used as UV filters in cosmetic products (Commission Regulation (EU) 2022/1176 of 7 July 2022), and
- accounting for amendments pertaining to the use of certain substances that release formaldehyde in finished cosmetics products by lowering the threshold regarding the requirement to indicate the presence of formaldehyde on the label of such products and to change the specific label warning to “releases formaldehyde” (Commission Regulation (EU) 2022/1181 of 8 July 2022).

These Regulations may be cited as the European Union (Cosmetic Products) (Amendment) Regulations 2024.

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