

L.N. 391 of 2010**PRODUCT SAFETY ACT
(CAP. 427)****Cosmetic Products (Amendment) (No. 2) Regulations, 2010**

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Prime Minister has, on the advice of the Malta Standards Authority, made the following regulations:-

1. The title of these regulations is the Cosmetic Products (Amendment) (No. 2) Regulations, 2010, and they shall be read and construed as one with the Cosmetic Products Regulations, 2004, hereinafter referred to as “the principal regulations”. Citation.
L.N. 424 of 2004.

2. (1) Reference number 207 of regulation 3(a) and regulation 4 of these regulations shall apply as from 1st March, 2011. These regulations implement the provisions of Commission Directive 2010/3/EU of 1 February 2010 amending, for the purpose of adaptation to technical progress, Annexes III and VI to Council Directive 76/768/EEC concerning cosmetic products. Commencement and scope.

(2) Reference numbers 208 and 209 of regulation 3(a) and regulation 3(b) of these regulations, except the obligations concerning the labelling set out in column (f) of reference number 208, shall apply as from 1st December, 2010. This regulation implements the provisions of Commission Directive 2010/4/EU of 8 February 2010 amending, for the purpose of adaptation to technical progress, Annex III to Council Directive 76/768/EEC concerning cosmetic products.

(3) After 1st November 2011 no cosmetic products which fail to comply with the obligations concerning the labelling set out in column (f) of reference number 208 of regulation 3(a) of these regulations shall be placed on the market. After 1st November 2012 no cosmetic products which fail to comply with the obligations concerning the labelling set out in column (f) of

reference number 208 of regulation 3(a) of these regulations, shall be sold or disposed of to the final consumer.

Amends the Third
Schedule to the
principal regulations.

3. The Third Schedule to the principal regulations shall be amended as follows:

(a) In the table set out in Part 1, the following reference numbers 207, 208 and 209 shall be inserted immediately after reference number 206:

Reference Number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
“207	Ethyl Lauroyl Arginate HCl (INCI) (*) Ethyl-N ^a -dodecanoyl-L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	(a) soap (b) anti-dandruff shampoos (c) deodorants, not in form of spray	0,8 %	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	
208	1-(beta-Aminoethyl)amino-4-(beta-hydroxyethyl)oxy-2-nitrobenzene and its salts HC Orange No 2 CAS No 85765-48-6 EINECS 416-410-1	Hair dye substance in non-oxidative hair dye products	1,0 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	 <p>Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if:</p> <ul style="list-style-type: none"> — You have a rash on your face or sensitive, irritated and damaged scalp. — You have ever experienced any reaction after colouring your hair. — You have experienced a reaction to a

					temporary “black henna
209	2-[(2-methoxy-4-nitrophenyl)amino]ethanol and its salts 2-Hydroxyethylamino-5-nitroanisole CAS No 66095-81-6 EINECS 266-138-0	Hair dye substance in non-oxidative hair dye products	0,2 %	— Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
(*) For use as a preservative, see Fifth Schedule, Part 1, entry No 58.”.					

(b) In Part 2, the entries relating to reference numbers 26 and 29 shall be deleted.

Amends the Fifth Schedule to the principal regulations.

4. In Part 1 of the Fifth Schedule to the principal regulations, the following reference number 58 shall be inserted immediately after reference number 57:

Reference Number	Substance	Maximum authorised concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
“58	Ethyl Lauroyl Arginate HCl (INCI) (*) (**) Ethyl-N ^α -dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	0,4%	Not to be used in lip products, oral products and spray products.	
(**) For other uses than preservatives, see Third Schedule, Part I, entry No 207.”.				

