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Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,489, 27 ta' Ottubru, 2015
Taqsima B

L.N. 347 of 2015

PRODUCT SAFETY ACT
(CAP. 427)

Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2015

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2015, and these regulations shall be read and construed as one with the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, hereinafter referred to as "the principal regulations". S.L.427.57

Implementation.

2. (1) These regulations implement the following European Union legislation:

(a) Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices;

(b) Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems; and

(c) Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

(2) These regulations shall apply to equipment falling under the scope of the principal regulations.

(3) Regulation 3 shall apply as from the 22nd July 2019.

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Substitutes Schedule II of the principal regulations.

3. Schedule II to the principal regulations shall be substituted by the following:

"Schedule II

Restricted substances referred to in regulation 4(1) and maximum concentration values tolerated by weight in homogeneous materials

Lead (0,1 %)

Mercury (0,1 %)

Cadmium (0,01 %)

Hexavalent chromium (0,1 %)

Polybrominated biphenyls (PBB) (0,1 %)

Polybrominated diphenyl ethers (PBDE) (0,1 %)

Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)

Butyl benzyl phthalate (BBP) (0,1 %)

Dibutyl phthalate (DBP) (0,1 %)

Diisobutyl phthalate (DIBP) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.

The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.".

Amends Schedule IV of the principal regulations.

4. The following points shall be added to the list in Schedule IV of the principal regulations:

"41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric

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and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases. Expires on 31 December 2018.

42. Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation. Expires on 30 June 2019.".

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