Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,794, 25 ta' Frar, 2022

Taqsima B

L.N. 93 of 2022

PRODUCT SAFETY ACT (CAP. 427)

Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2022

IN EXERCISE of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister for Tourism and Consumer Protection, on the advice of the Director General (Technical Regulations), has made the following regulations:-

Citation, scope and commencement.

1. (1) The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2022, 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.

(2) These regulations transpose:

(a) Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices;

(b) Commission Delegated Directive (EU) 2021/1979 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils; and

(c) Commission Delegated Directive (EU) 2021/1980 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or

dialysate fluids.

(3) These regulations shall be deemed to have come into force on 21 July 2021.

Amends Schedule IV to the principal regulations.

2. In Schedule IV to the principal regulations, immediately after item 44 thereof, there shall be added the following three new items:

"45. Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. Expires on 21 July 2028.

46. Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils. Expires on 1 January 2024.

47. Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. Expires on 21 July 2028.".

Amends Schedule VIII to the principal regulations.

3. Immediately after the item "Commission Delegated Directive (EU) 2021/884 of 8 March 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems********." in Schedule VIII to the principal regulations, there shall be added the following new items:

"- Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices*********.

- Commission Delegated Directive (EU) 2021/1979 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic

resonance imaging (MRI) detector coils*********.

- Commission Delegated Directive (EU) 2021/1980 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids*********.

********* Applicable as from 21st July, 2021.".

VERŻJONI ELETTRONIKA

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