Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 21,214, 28 ta' Marzu, 2024
Taqsima B

L.N. 77 of 2024

PRODUCT SAFETY ACT
(CAP. 427)

Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2024

IN EXERCISE of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister responsible for consumer affairs, 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, 2024, 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) The scope of these regulations is to transpose Commission Delegated Directive (EU) 2023/1437 of 4 May 2023 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 mercury in melt pressure transducers for capillary rheometers under certain conditions and Commission Delegated Directive (EU) 2023/1526 of 16 May 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in vitro diagnostic medical devices

(3) These regulations shall be deemed to have come into force on the 1st of February 2024.

Amends Schedule IV to the principal regulations.

2. Schedule IV to the principal regulations shall be amended as follows:

(a) immediately after item 41 thereof, there shall be added the following new item:

"41a. Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in *in vitro* diagnostic medical devices for

the analysis of creatinine and blood urea nitrogen in whole blood. Applies to category 8 and expires on 31 December 2023."; and

(b) immediately after item 48 thereof, there shall be added the following new item:

"49. Mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1,000 bar. Applies to category 9 and expires on 31 December 2025.".

Amends Schedule VIII to the principal regulations.

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

(a) immediately after the item "Commission Delegated Directive (EU) 2023/171 of 28 October 2022 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium as an anticorrosion agent in gas absorption heat pumps**********.", there shall be added the following new items:

"- Commission Delegated Directive (EU) 2023/1437 of 4 May 2023 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 mercury in melt pressure transducers for capillary rheometers under certain conditions**********.

- Commission Delegated Directive (EU) 2023/1526 of 16 May 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in vitro diagnostic medical devices**********."; and

(b) immediately after the footnote "********** Applicable as from 1st September 2023.", there shall be added the following new footnote:

"********** Applicable as from 1st February 2024."

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