Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,475, 1 ta' Settembru, 2020
Taqsima B

L.N. 361 of 2020

PRODUCT SAFETY ACT
(CAP. 427)

Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2020

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:-

Title and commencement.

1. (1) The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment No. 2) Regulations, 2020, 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) Regulations 4(c) and 5 shall apply from 1st September 2020 and regulations 3, 4(a) and 4(b) shall apply from 1st April 2021.

Scope and applicability.

2. (1) The scope of these regulations is to implement the following European Union legislation:

(a) Commission Delegated Directive (EU) 2020/360 of 17 December 2019 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 lead in platinized platinum electrodes used for certain conductivity measurements;

(b) Commission Delegated Directive (EU) 2020/361 of 17 December 2019 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 anti-corrosion agent of the carbon steel cooling system in absorption refrigerators;

(c) Commission Delegated Directive (EU) 2020/364 of 17 December 2019 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 cadmium in certain radiation tolerant video camera tubes;

(d) Commission Delegated Directive (EU) 2020/365 of 17 December 2019 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 lead in solders and termination finishes used in certain hand-held combustion engines; and

(e) Commission Delegated Directive (EU) 2020/366 of 17 December 2019 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 lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

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

Amends Schedule III to the principal regulations.

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

(a) item 9 thereof shall be substituted by the following:

"9	Hexavalent chromium as an anti-corrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75% by weight in the cooling solution	Applies to categories 8, 9 and 11 and expires on: — 21 July 2021 for categories 8 and 9 other than *in vitro* diagnostic medical devices and industrial monitoring and control instruments, — 21 July 2023 for category 8 *in vitro* diagnostic medical devices, — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.

9(a)-I	Up to 0,75% hexavalent chromium by weight, used as an anti-corrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators (including minibars) designed to operate fully or partly with electrical heater, having an average utilised power input <75W at constant running conditions	Applies to categories 1-7 and 10 and expires on 5 March 2021.
9(a)-II	Up to 0,75% hexavalent chromium by weight, used as an anti-corrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators: — designed to operate fully or partly with electrical heater, having an average utilised power input ≥75W at constant running conditions, — designed to fully operate with non-electrical heater.	Applies to categories 1-7 and 10 and expires on 21 July 2021.";

(b) item 41 thereof shall be substituted by the following:

"41	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (*))	Applies to all categories and expires on: — 31 March 2022 for categories 1 to 7, 10 and 11; — 21 July 2021 for categories 8 and 9 other than *in vitro* diagnostic medical devices and industrial monitoring and control instruments; — 21 July 2023 for category 8 *in vitro* diagnostic medical devices; — 21 July 2024 for category 9 industrial monitoring and control instruments.

(*) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1). ".

Amends Schedule IV to the principal regulations.

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

(a) item 37 thereof shall be substituted by the following:

"37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:

(a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1mS/m and 5mS/m) in laboratory applications for unknown concentrations;

(b) measurements of solutions where an accuracy of +/– 1% of the sample range and where high corrosion resistance of the electrode are required for any of the following:

(i) solutions with an acidity <pH 1;

(ii) solutions with an alkalinity >pH 13;

(iii) corrosive solutions containing

halogen gas;

(c) measurements of conductivities above 100mS/m that must be performed with portable instruments.

Expires on 31 December 2025. ";

(b) item 41 thereof shall be substituted by the following:

"41. Lead as a thermal stabiliser 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 blood and other body fluids and body gases. Expires on 31 March 2022."; and

(c) immediately after item 43 thereof, there shall be added the following new item:

"44. Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy. Applies to category 9. Expires on 31 March 2027. ".

5. The following items shall be appended to the list in Schedule VIII to the principal regulations:

Amends Schedule VIII to the principal regulations.

- Commission Delegated Directive (EU) 2020/360 of 17 December 2019 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 lead in platinized platinum electrodes used for certain conductivity measurements******.

- Commission Delegated Directive (EU) 2020/361 of 17 December 2019 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 anti-corrosion agent of the carbon steel cooling system in absorption refrigerators******.

- Commission Delegated Directive (EU) 2020/364 of 17 December 2019 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 cadmium in certain radiation tolerant video camera tubes*****.

- Commission Delegated Directive (EU) 2020/365 of 17 December 2019 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 lead in solders and termination finishes used in certain hand-held combustion engines******.

- Commission Delegated Directive (EU) 2020/366 of 17 December 2019 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 lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases******.

*****Applicable as from 1st September, 2020.

******Applicable as from 1st April, 2021.

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