

L.N. 306 of 2008

**PRODUCT SAFETY ACT
(CAP. 427)**

The Dangerous Substances Regulations, 2008

IN exercise of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister of Finance, the Economy and Investment has, on the advice of the Malta Standards Authority, made the following regulations:-

1. The title of these regulations is the Dangerous Substances Regulations, 2008. Title.

2. (1) These regulations concern the classification, packaging and labelling of substances dangerous to man or the environment, where such substances are placed on the market. Applicability.

(2) These regulations shall not apply to the following preparations in the finished state, intended for the final user:

(a) medicinal products for human or veterinary use, as defined in Directive 65/65/EEC, as last amended by Directive 87/21/EEC;

(b) cosmetic products defined by Directive 76/768/EEC, as last amended by Directive 86/199/EEC;

(c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC and 78/319/EEC;

(d) foodstuffs;

(e) animal feedingstuffs;

(f) pesticides;

(g) radioactive substances as defined by Directive 80/836/EEC ;

(h) other substances or preparations for which a European Community notification or approval procedures exist and for which requirements are equivalent to those laid down in these regulations.

(3) In addition, these regulations shall not apply to:

(a) the carriage of dangerous substances by rail, road, inland waterway, sea or air; and

(b) substances in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Definitions.

3. (1) In these regulations, the following definitions shall apply, unless the context otherwise requires:

“the Directive” shall mean Council Directive 67/548/EEC¹ on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended by the following Directives:

- (i) Directive 71/144/EEC (OJ L 074, 29.3.1971, p.15)
- (ii) Directive 73/146/EEC (OJ L 167, 25.6.1973, p.1)
- (iii) Directive 75/409/EEC (OJ L 183, 14.7.1975, p.22)
- (iv) Directive 76/907/EEC (OJ L 360, 30.12.1976, p.1)
- (v) Directive 79/370/EEC (OJ L 088, 7.4.1979, p.1)
- (vi) Directive 79/831/EEC (OJ L 259, 15.10.1979, p.10)
- (vii) Directive 80/1189/EEC (OJ L 366, 31.12.1980, p.1)
- (viii) Directive 81/957/EEC (OJ L 351, 7.12.1981, p.5)
- (ix) Directive 82/232/EEC (OJ L 106, 21.4.1982, p.18)
- (x) Directive 83/467/EEC (OJ L 257, 16.9.1983, p.1)
- (xi) Directive 84/449/EEC (OJ L 251, 19.9.1984, p.1)
- (xii) Directive 86/431/EEC (OJ L 247, 1.9.1986, p.1)
- (xiii) Directive 87/432/EEC (OJ L 239, 21.8.1987, p.1)
- (xiv) Directive 88/490/EEC (OJ L 259, 19.9.1988, p.1)
- (xv) Directive 90/517/EEC (OJ L 287, 19.10.1990, p.37)
- (xvi) Directive 91/410/EEC (OJ L 228, 17.8.1991, p.67)
- (xvii) Directive 91/632/EEC (OJ L 338, 10.12.1991, p.23)
- (xviii) Directive 92/32/EEC (OJ L 154, 5.6.1992, p.1)
- (xix) Directive 92/37/EEC (OJ L 154, 5.6.1992, p.30)
- (xx) Directive 93/21/EEC (OJ L 110, 4.5.1993, p.20)
- (xxi) Directive 93/72/EEC (OJ L 258, 5.6.1992, p.30)
- (xxii) Directive 92/37/EEC (OJ L 154, 16.10.1993, p.29)
- (xxiii) Directive 93/101/EEC (OJ L 013, 15.1.1993, p.1)
- (xxiv) Directive 92/105/EEC (OJ L 294, 30.11.1993, p.21)
- (xxv) Directive 94/69/EC (OJ L 381, 31.12.1994, p.1)

¹ OJ No L 196, 16.8.1967, p.1

- (xxvi) Directive 96/54/EC (OJ L 248, 30.9.1996, p.1)
- (xxvii) Directive 96/56/EC (OJ L 236, 18.9.1996, p.35)
- (xxviii) Directive 97/69/EC (OJ L 343, 13.12.1997, p.19)
- (xxix) Directive 98/73/EC (OJ L 325, 16.11.1998, p.1)
- (xxx) Directive 98/98/EC (OJ L 335, 30.12.1998, p.1)
- (xxxi) Directive 99/33/EC (OJ L 199, 30.7.1999, p.57)
- (xxxii) Directive 2000/32/EC (OJ L 136, 8.6.2000, p.1)
- (xxxiii) Directive 2000/33/EC (OJ L 136, 8.6.2000, p.90)
- (xxxiv) Directive 2001/59/EC (OJ L 225, 21.8.2001, p.1)
- (xxxv) Directive 2004/73/EC (OJ L 152, 29.04.2004, p. 1)
- (xxxvi) Directive 2006/102/EC (OJ L 363, 20.12.2006)
- (xxxvii) Directive 2006/121/EC (OJ L 396, 30.12.2006, p. 850);

Provided that references to Annexes VII A, VII B, VII C, VII D and VIII in the Directive shall be construed as references to the corresponding Annexes VI, VII, VIII, IX, X and XI of Regulation (EC) No 1907/2006.

“EINECS” means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981;

“placing on the market” means the making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

“preparations” means mixtures or solutions composed of two or more substances;

“substances” means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

(2) The following are “dangerous” within the meaning of these regulations:

(a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

(b) oxidizing substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

(c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

(d) highly flammable substances and preparations:

(i) substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

(ii) solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

(iii) liquid substances and preparations having a very low flash-point, or

(iv) substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable substances and preparations: liquid substances and preparations having a low flash-point;

(f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

(k) sensitizing substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

(o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment.

4. Tests on substances carried out within the framework of these regulations shall be conducted according to the requirements of Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency² and according to the requirements set in Regulation (EC) No 440/2008³ of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006.

Testing and assessment of the properties of substances.

5. (1) Substances shall be classified on the basis of their intrinsic properties according to the categories laid down in regulation 4(2) of these regulations. In the classification of substances, impurities shall be taken into account as far as any concentration of the latter exceeds the concentration limits specified in regulation 6(4) of these regulations and in regulation 7 of the Dangerous Substances and Preparations Regulations of 2007 (L.N. 10 of 2007).

Classification.

² OJ L 396, 30.12.2006, p. 1

³ OJ L142, 31.05.2008, p. 1

(2) The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI of the Directive, save where contrary requirements for dangerous preparations are specified in separate provisions.

(3) Annex I of the Directive contains the list of substances classified in accordance with the principles outlined in regulations 6(1) and 6(2), together with their harmonized classification and labelling.

(4) The dangerous substances listed in Annex I of the Directive shall, where appropriate, be characterized by concentration limits or any other parameter enabling an assessment to be made of the health or environmental hazard of preparations containing the said dangerous substances or substances containing other dangerous substances as impurities.

Duties of the
Competent
Authority.

6. Substances cannot be placed on the market on their own or in preparations unless they have been packaged and labelled in accordance with regulations 9 to 12 of these regulations and with the criteria in Annex VI of the Directive, and, for registered substances, in accordance with the information obtained through the application of Articles 12 and 13 of Regulation (EC) No 1907/2006, save in the case of preparations where provisions exist in other Directives.

Obligation to carry
out investigations.

7. Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I of the Directive shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in regulations 9 to 12 of these regulations and the criteria in Annex VI of the Directive.

Packaging.

8. (1) Dangerous substances cannot be placed on the market unless their packaging satisfies the following requirements:

(a) it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;

(b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;

(c) packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

(e) every container of whatever capacity, containing substances sold or made available to the general public and labelled “very toxic”, “toxic” or “corrosive”, as defined in these regulations, must have a child-resistant fastening and a tactile warning of danger;

(f) every container, of whatever capacity, containing substances sold or made available to the general public and labelled “harmful”, “extremely flammable” or “highly flammable” as defined in these regulations must bear a tactile warning of danger.

(2) The technical specifications relating to the devices referred to in regulations 9(1)(e) and 9(1)(f) are to be found in points A and B of Annex IX to the Directive.

9. (1) Dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements. Labelling.

(2) Every package shall show clearly and indelibly the following:

(a) the name of the substance under one of the designations given in Annex I of the Directive. If the substance is not yet listed in Annex I of the Directive, the name shall be given using an internationally recognized designation;

(b) the name and full address including the telephone number of the person established in the European Community who is responsible for placing the substance on the market whether it be the manufacturer, the importer or the distributor;

(c) danger symbols, when laid down, and indication of the danger involved in the use of the substance. The design of the danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II of the Directive. The symbol shall be printed in black on an orange-yellow background. The danger symbols and indications of danger to be used for each substance shall be those indicated in Annex I of the directive. For dangerous substances not yet appearing in Annex I of the Directive the danger symbols and indications of danger shall be assigned according to the rules laid down in Annex VI of the Directive.

When more than one danger symbol is assigned to a substance:

(i) the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I provides otherwise,

(ii) the obligation to indicate the symbol C makes the symbol X optional,

(iii) the obligation to indicate the symbol E makes the symbol F and O optional;

(d) standard phrases (R-phrases) indicating the special risks arising from the dangers involved in using the substance. The wording of those R-phrases shall comply with that laid down in Annex III of the Directive. The R-phrases to be used for each substance shall be as indicated in Annex I of the Directive. For dangerous substances not yet appearing in Annex I of the Directive the R-phrases to be used shall be assigned according to the rules laid down in Annex VI of the Directive;

(e) standard phrases relating to the safe use of the substance (S-phrases). The wording of these S-phrases shall comply with that laid down in Annex IV of the Directive. The S-phrases to be used for each substance shall be as indicated in Annex I of the Directive. For dangerous substances not yet appearing in Annex I of the Directive, the S-phrase to be used shall be assigned according to the rules laid down in Annex VI of the Directive;

(f) the EC number, when allocated. The EEC number shall be obtained from the EINECS or from the list referred to in Article 21(1) of the Directive. In addition, as regards substances appearing in Annex I of the Directive, the label shall also include the words "EC label".

(3) In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of R-phrases and S-phrases need not be given where the package does not contain more than 125 ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

(4) Indications such as "non-toxic", "non-harmful" or any other similar indications must not appear on the label or packaging of substances subject to these regulations.

Implementation of
labelling
requirements.

10. (1) Where the particulars required by regulation 10 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

Capacity of the package	Dimension (in millimetres)
not exceeding 3 litres	at least 52 _ 74
greater than 3 litres but not exceeding 50 litres	at least 74 _ 105
greater than 50 litres but not exceeding 500 litres	at least 105 _ 148
greater than 500 litres	at least 148 _ 210

Each symbol shall cover at least one-tenth of the surface area of the label but not be less than 1 cm². The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provisions of the information required by these regulations and if necessary of any supplementary health or safety indications.

(2) A label is not required where the particulars are clearly shown on the package itself, as specified in regulation 11(1).

(3) The colour and presentation of the label - or, in the case of regulation 11(2), of the package - shall be such that the danger symbol and its background stand out clearly.

(4) The information required on the label under regulation 11 shall stand out clearly from its background and shall be of such size and spacing as to be easily read. Specific provisions regarding the presentation and dimensions of this information laid down in Annex VI of the Directive shall be observed.

(5) Dangerous substances may only be placed on the market if they are labelled in at least one of the official languages of Malta.

(6) For the purpose of these regulations, labelling requirements shall be deemed to be satisfied:

(a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous substances and the inner package or packages are labelled in accordance with these regulations;

(b) in the case of a single package:

(i) if such a package is labelled in accordance with international rules on the transport of dangerous substances and with regulations 10(2)(a), (b), (d), (e) and (f), and

(ii) where appropriate, for particular types of packaging such as mobile gas cylinders, in accordance with the specific requirements referred to in Annex VI of the Directive.

Where dangerous substances do not leave the territory of Malta, labelling which complies with national rules instead of with international rules on the transport of dangerous substances may be permitted.

Exemptions from labelling and packaging requirements.

11. Regulations 9, 10 and 11 shall not apply to the provisions governing munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

Advertisement.

12. Any advertisement for a substance which belongs to one or more of the categories referred to in regulation 4(2) shall be prohibited if no mention is made therein of the category or categories concerned.

Free movement clause.

13. Substances which comply with the requirements of these regulations, on grounds relating to notification, classification, packaging or labelling within the meaning of the Directive, may not be prohibited, restricted or impeded from being placed on the market.

Safeguard clause.

14. Where, in the light of new information, the competent authority has justifiable reasons to consider that a substance, which has been accepted as satisfying the requirements of these regulations, nevertheless constitutes a danger for man or the environment, by reason of classification, packaging or labelling which is no longer appropriate, it may temporarily reclassify or, if necessary, prohibit the placing on the market of that substance or subject it to special conditions.

Revokes L.N. 318 of 2001.

15. The Dangerous Substances (Notification) Regulations, 2001 are hereby revoked.