L.N. 145 of 2002

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Aerosol Dispensers Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and commencement.

1.1. The title of these regulations is the Aerosol Dispensers Regulations, 2002.

1.2. These regulations shall become operative on the 1st July, 2002:

Provided that the requirements to provide information to the European Commission referred to in regulation 7.3 of these regulations shall come into force on such date as the Minister responsible for Consumer Affairs, after consultation with the Malta Standards Authority, may prescribe.

Scope.

2.1. These regulations shall apply to aerosol dispensers as defined in regulation 3 of these regulations, with the exception of those with a maximum capacity of less than 50 ml, and those with a maximum capacity greater than that specified in points 3.1, 4.1.1, 4.2.1, 5.1 and 5.2 respectively of the Annex of the Directive, which is set out in the Schedule hereto.

Definitions.

3.1. For the purposes of these regulations, the following definitions shall apply:

3.1.1. "The Directive" means Council Directive 75/324/EEC[1] on the approximation of the laws of the Member States relating to aerosol dispensers, as amended by Commission Directive 94/01/EEC[2].

1 OJ No. L 147, 09-06-75, p. 40.
2 OJ No. L 023, 28-01-94, p. 28.

3.1.2. "Aerosol dispenser" means any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state.

3.1.3. "OJ" means the Official Journal of the European Communities.

3.1.4. "Manufacturer" means the person who is primarily responsible for the design and construction of the aerosol dispenser so that it complies with the requirements of these regulations;

3.1.5. "Local authorised representative" means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.6. "Importer" means any person who places aerosol dispensers from a foreign country on to the Maltese market so that he supplies such aerosol dispensers on the first occasion that they are supplied in Malta;

3.1.7. "Person who supplies aerosol dispensers" means wholesalers, distributors, retailers etc;

3.1.8. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly;

3.1.9. "Responsible person" in relation to aerosol dispensers means:

3.1.9.1. the manufacturer thereof;

3.1.9.2. the manufacturer's local authorised representative; or

3.1.9.3. where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the aerosol dispensers on the local market.

3.1.10. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

4.1. The provisions of these regulations are applicable to all imported aerosol dispensers as well as to those manufactured for the local market. Applicability.

4.1.1. No person may construct, import, place on the market or put into service any aerosol dispensers which do not comply with the provisions of these regulations.

5.1. The responsible person shall affix the symbol '3' (inverted epsilon) to aerosol dispensers, as proof that they satisfy the requirements of these regulations and the Annex of the Directive, which is set out in the Schedule hereto. General requirements.

5.2. Without prejudice to other Community Directives, in particular to Directives on dangerous substances and preparations, each aerosol dispenser or, where particulars cannot be put on the aerosol dispenser due to its small dimensions (maximum capacity of 150 ml or less) a label attached thereto must bear the following particulars in visible, legible and indelible characters:

5.2.1. The name and address or trade mark of the person responsible for marketing the aerosol dispenser,

5.2.2. The symbol '3' (inverted epsilon) certifying conformity with the requirements of these regulations,

5.2.3. Code and markings enabling the filling batch to be identified,

5.2.4. The details referred to in points 2.2 and 2.3 of the Annex of the Directive, which is set out in the Schedule hereto,

5.2.5. The net contents by weight and by volume.

5.3. The wording on the label of aerosol dispensers being placed on the local market should be made in either the Maltese or the English language.

5.4. All necessary measures shall be taken to prevent the use on aerosol dispensers of markings or inscriptions which might be confused with the symbol '3' (inverted epsilon).

5.5. Where the responsible person is in possession of test results or other data, showing that although those aerosol dispensers have flammable contents they do not present any risk of ignition under normal or reasonably foreseeable conditions of use, he may on his own

responsibility decide not to apply the provisions of points 2.2 (b) and 2.3 (b) of the Annex, which is set out in Schedule I hereto.

5.5.1. He shall make a copy of such documents available to the Member States.

5.5.2. In such a case the quantity of flammable material contained in the aerosol dispenser must be stated clearly on the label, in the form of the following legible and indelible wording: *"X % by mass of the contents are flammable"*.

Free movement.

6.1. The marketing of any aerosol dispenser which complies with the requirements of these regulations, may not, for reasons related to the requirements laid down in these regulations and the Annex of the Directive, which is set out in the Schedule I hereto, be refused, prohibited or restricted.

Withdrawal and prohibition from market.

7.1. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations.

7.2. If the Director of Consumer Affairs notes, on the basis of a substantive justification, that one or more aerosol dispensers, although complying with the requirements of these regulations, represent a hazard to safety or health, it may provisionally prohibit the sale of the dispenser or dispensers in Malta or subject it or them to special conditions.

7.2.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

7.2.2. The Director of Consumer Affairs shall immediately inform the Consumer and Industrial Goods Directorate[3] of the Malta Standards Authority, stating the grounds for its decision.

7.3. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission and the other Member States of any measures taken in pursuance of regulation 7.2 of these regulations.

3 L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

Schedule

Based on the Annex of the Directive

1. DEFINITIONS

1.1. Pressures

'Pressures' means the internal pressures in bars (relative pressures).

1.2. Test pressure

'Test pressure' means the pressure to which an unfilled aerosol dispenser container may be subjected for 25 seconds without any leakage being caused or, in the case of metal or plastic containers, any visible or permanent distortion except as allowed under point 6.1.1.2 of this Schedule.

1.3. Bursting pressure

'Bursting pressure' means the minimum pressure which causes the aerosol dispenser container to burst or rupture.

1.4. Total capacity of the container

'Total capacity of the container' means the volume in millimetres of an open container up to the rim of the opening.

1.5. Net capacity

'Net capacity' means the volume in millimetres of a filled and closed aerosol dispenser.

1.6. Volume of the liquid phase

'Volume of liquid phase' means the volume of the non-gaseous phases in the filled and closed aerosol dispenser.

1.7. Test conditions

'Test conditions' means the values of the test and bursting pressures exerted hydraulically at 20 °C (± 5 °C).

1.8. Flammable contents

'Flammable contents' means the substances and preparations corresponding to the criteria laid down for the categories "extremely flammable", "highly flammable" and "flammable" and listed in Annex VI to Council Directive 67/548/EEC[4].

The flammability and flash point of the contents of the container shall be determined using the specific methods described in Part A of Annex V to the abovementioned Directive.

2. GENERAL PROVISIONS

2.1. Construction and equipment

2.1.1. The filled aerosol dispenser must be such that, under normal conditions of use and storage, it complies with the provisions of this Schedule.

2.1.2. The value must enable the aerosol to be virtually hermetically sealed under normal conditions of storage or transport and must be protected, for example by means of a protective cap, against any unintentional opening and any deterioration.

2.1.3. There must be no possibility that the mechanical resistance of the aerosol dispenser can be impaired by the action of the substances contained in it, even during prolonged storage.

2.2. Labelling

Without prejudice to the Directives relating to the classification, packaging and labelling of dangerous substances and preparations, particularly as regards danger to health and/or the environment, any aerosol dispenser must visibly bear the following legible and indelible marking:

(a) *Whatever its contents*: "Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use."

(b) *Where the contents are flammable within the meaning of point 1.8*: the flame symbol where appropriate, the indication that the substances and/or preparations contained in the aerosol dispenser, including the propellant, are flammable and the relevant risk phrases determined in accordance with the criteria in points 2.2.3, 2.2.4 or 2.2.5 of Annex VI to Directive 67/548/EEC and, as regards the flame symbol and the indication of danger, in accordance with the provisions of Annex II to the abovementioned Directive.

4 OJ No. L 196, 16-08-67, p. 01.

2.3. Special statements concerning use

Without prejudice to the Directives relating to the classification, packaging and labelling of dangerous substances and preparations, particularly as regards danger to health and/or the environment, any aerosol dispenser must visibly bear the following legible and indelible wording:

(a) *Whatever its contents*: the additional operating precautions which alert consumers to the specific dangers of the product;

(b) *Where the contents are flammable*, the following warnings:

- "Do not spray on a naked flame or any incandescent material."
- "Keep away from sources of ignition - No smoking."
- "Keep out of the reach of children".

3. SPECIAL PROVISION FOR METAL AEROSOL DISPENSERS

3.1. Capacity

The total capacity of these containers may not exceed 1 000 ml.

3.1.1. *Test pressure of containers*

(a) For containers filled with a pressure of less than 6.7 bars at 50 (C, the test pressure must be equal to at least 10 bars.

(b) For containers filled at a pressure equal to or greater than 6.7 bars at 50°C, the test pressure must be 50% higher than the internal pressure at 50 °C.

3.1.2. *Filling*

At 50 °C the pressure in the aerosol dispenser must not exceed 12 bars, whatever kind of gas is used for filling.

3.1.3. *Volume of the liquid phase*

The volume of the liquid phase at 50 °C must not exceed 87 % of the net capacity. However, for containers with a concave base which becomes convex before bursting, the volume of the liquid phase at 50 °C may be as much as 95 % of the net capacity.

4. SPECIAL PROVISIONS FOR GLASS AEROSOL DISPENSERS

4.1. Plastic coated or permanently protected containers

Containers of this type may be used for filling compressed, liquefied or dissolved gas.

4.1.1. *Capacity*

The total capacity of such containers may not exceed 220 ml.

4.1.2. *Coating*

The coating must be a protective envelope of plastic or other suitable material, intended to prevent the risk of flying particles of the glass if the container is accidentally broken, and must be so designed that there are no flying particles of glass if the filled aerosol dispenser, brought to a temperature of 20°C, is dropped from a height of 1.8 m onto a concrete floor.

4.1.3. *Test pressure of container*

(a) Containers used for filling with compressed or dissolved gas must resist a test pressure equal to at least 12 bars.

(b) Containers used for filling with liquefied gas must resist a test pressure equal to at least 12 bars.

4.1.4. *Filling*

(a) Aerosol dispensers filled with compressed gas shall not be required to withstand a pressure of more than 9 bars at 50 °C.

(b) Aerosol dispensers filled with dissolved gas shall not be required to withstand a pressure of more than 8 bars at 50 °C.

(c) Aerosol dispensers containing liquefied gas or mixtures of liquefied gas shall not be required to withstand, at 20 °C, at pressure higher than those shown in the following table:

Total capacity	Percentage weight of liquefied gas in the total mixture		
	20%	50%	80%
50 to 80 ml	3.5 bars	2.8 bars	2.5 bars
< 80 to 160 ml	3.2 bars	2.5 bars	2.2 bars
< 160 to 220 ml	2.8 bars	2.1 bars	1.8 bars

This table shows the pressure limits permitted at 20 °C in relation to the percentage of gas.

Pressure limits for percentages of gas not shown in the table shall be extrapolated from it.

4.1.5. *Volume of the liquid phase*

At 50 °C, the volume of the liquid phase of a filled aerosol dispenser must not exceed 90 % of the net capacity.

4.2. Unprotected glass containers

Aerosol dispensers using unprotected glass shall be filled exclusively with liquefied or dissolved gases.

4.2.1. *Capacity*

The total capacity of these containers may not exceed 150 ml.

4.2.2. *Test pressure of the container*

The test pressure of the container must be equal to at least 12 bars.

4.2.3. *Filling*

(a) Aerosol dispensers filled with dissolved gas shall not be required to withstand a pressure of more than 8 bars at 50 °C.

(b) Aerosol dispenser containing liquefied gas shall not be required to withstand, at 20 °C, pressure in excess of those shown down in the following table:

Total capacity	Percentage by weight of liquefied gas in the total mixture		
	20%	50%	80%
50 to 70 ml < 70 to 150 ml	1.5 bar 1.5 bar	1.5 bar 1.5 bar	1.25 bar 1 bar

This table shows the pressure limits permitted at 20 °C in relation to the percentage of liquefied gas.

Pressure limits for percentages of gas not shown in the table shall be extrapolated from it.

4.2.4. *Volume of liquid pressure*

At 50 °C, the volume of the liquid phase an aerosol dispenser filled with liquefied or dissolved gas must not exceed 90 % of the net capacity.

5. SPECIAL PROVISION APPLYING TO PLASTIC AEROSOL DISPENSERS

5.1. Plastic aerosol dispensers which may splinter on bursting shall be treated in the same way as unprotected glass aerosol dispensers.

5.2. Plastic aerosol dispensers which cannot splinter on bursting shall be treated in the same way as glass aerosol dispensers with a protective coating.

6. TESTS

6.1. Test requirements to be guaranteed by the person responsible for marketing

6.1.1. *Hydraulic test on empty containers*

6.1.1.1. Metal, glass or plastic aerosol dispensers must be able to withstand a hydraulic pressure test as laid down in points 3.1.1, 4.1.3 and 4.2.2 of this Schedule.

6.1.1.2. Metal containers showing asymmetrical or major distortions or other similar faults shall be rejected. A slight symmetrical distortion of the base or one

affecting the profile of the upper casing shall be allowed provided that the container passes the bursting test.

6.1.2. *Bursting test for empty metal containers*

The person responsible for marketing must ensure that the bursting pressure of containers is at least 20% higher than the test pressure laid down.

6.1.3. *Dropping test for protected glass containers*

The manufacturer must ensure that the containers satisfy the test requirements laid down in point 4.1.2 of this Schedule.

6.1.4. *Individual inspection of filled aerosol dispensers*

6.1.4.1. (a) Each filled aerosol dispenser shall be immersed in a bath of water. The temperature of the water and the period of immersion must be such as to enable:

– the contents of the aerosol dispenser to reach a uniform temperature of 50 °C or

– the pressure in the aerosol dispenser to reach that exerted by its contents at a uniform temperature of 50 °C.

(b) Any aerosol dispenser showing visible permanent distortion or a leak must be rejected.

6.1.4.2. However, any test system enabling a result equivalent to that of the water bath method to be obtained may be used by the person responsible for marketing, on his own responsibility and with the agreement of the Committee referred to in Article 6 of the Directive.

6.2. Examples of inspection tests which may be carried out by Member States

6.2.1. *Test on unfilled containers*

The test pressure shall be applied for 25 seconds on five containers selected at random from a homogeneous batch of 2 500 unfilled containers, i.e. manufactured from the same materials by the same continuous batch manufacturing process, or from a batch constituting one hour's production.

If any of these containers does not pass the test, ten additional containers shall be drawn at random from the same batch and put through the same test.

If any one of these aerosols containers does not pass the test, the whole batch shall be unsuitable for use.

6.2.2. *Tests on filled aerosol dispensers*

Air and water-tightness inspection test shall be carried out by immersing a representative number of filled aerosol dispensers in a bath of water. The temperature of the bath and the period of immersion must be such as to enable the contents of the aerosol dispenser to attain a uniform temperature of 50°C during the time required to ensure that there is no bursting or rupture.

Any batch of aerosol dispensers which does not pass these tests must be considered unsuitable for use.

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