

Directive 75/324/EEC on Aerosol Dispensers and Regulation (EC) No 1272/2008 on classification, labelling and packaging of mixtures – Aerosol dispensers containing a single substance

(Guidance document by the Commission services)¹

At the last meeting of the Working Group of Directive 75/324/EEC on aerosol dispensers (hereinafter ADD) on 4 November 2010, it was discussed how to apply points 2.2 (a) and (b) and 2.3 (b) of the Annex to the ADD in addition to the labelling provisions of Regulation (EC) No 1272/2008 on classification, labelling and packaging of mixtures (hereinafter CLP Regulation), which apply to aerosol dispensers containing a single substance from 1 December 2010.

This note has been prepared by the Commission services in charge of these two pieces of legislation in order to reflect upon the interaction between the labelling requirements in the ADD and the CLP Regulation.

The CLP Regulation applies to substances from 1.12.2010 and to mixtures from 1.06.2015. Aerosol dispensers mainly contain mixtures but there are cases where they contain one single substance. The CLP Regulation will repeal the existing legislation governing the classification, labelling and packaging of dangerous substances (Directive 67/548/EEC) and of mixtures (Directive 99/45/EC) respectively, but only in 2015. Until then, the existing and the new rules will coexist to ensure a smooth transition to the new system. In particular, to ensure that the new information required for substances becomes available for the mixtures containing them. After 2015 only the CLP rules will apply to both substances and mixtures².

This document does not cover aerosol dispensers containing mixtures, since the CLP does not apply to mixtures until June 2015 and by then the ADD will be modified in order to be aligned to the CLP Regulation.

Both, the ADD and the CLP Regulation, contain labelling provisions applicable to aerosol dispensers containing a single substance. Some of these provisions result in a duplication of the same information and therefore in a risk to confuse consumers.

In particular, Article 8 and Annex I, points 2.2 and 2.3 of ADD contain the labelling provisions that apply to aerosol dispensers. Those provisions include:

- Specific labelling provisions that are not covered by any other piece of EU legislation (such as the requirement to affix the symbol '3' – inverted epsilon – certifying conformity with the requirements of the ADD). These provisions are not concerned by this document;

¹ This guidance document does not provide a legally binding interpretation of Directive 75/324/EEC and of Regulation (EC) No 1272/2008. The legally binding text remains that of the legislative documents concerned. However, this document intends to serve as a reference to ensure consistent application of Directive 75/324/EEC by all involved parties.

² For ease of reference the relevant provisions of ADD and CLP are contained in the Annex.

- Provisions which have been copied from Directive 67/548/EEC and reproduced in the ADD (such as the obligation to state ‘flammable’ or ‘extremely flammable’ depending on the properties of the aerosols), and
- Crossed references to Directive 67/548/EEC, in particular the obligation to use the flame symbol, in accordance with the model in Annex II to Directive 67/548/EEC and to bear the safety phrases S2 and S16 laid down in Annex IV to Directive 67/548/EEC.

Directive 67/548/EEC will be in force until 31 May 2015. However, from 1 December 2010, those provisions will only apply for classification purposes. Pursuant to Article 61(3) of the CLP Regulation, the labelling and packaging of substances should be done only according to the CLP Regulation.

As a consequence, from 1st December 2010, the labelling of aerosol dispensers containing a single substance should follow both the CLP Regulation and the ADD. However, as the wording of the Hazard and Precautionary statements of Directive 67/548/EEC has been slightly modified in the CLP Regulation, this would lead to duplication of information with no real additional information for the consumers. Furthermore, keeping the old labelling references mentioned in the ADD would contradict Article 61(3) CLP, affecting its correct implementation and creating, at the same time, legal uncertainty for manufacturers and market surveillance authorities.

Both Article 8 and Annex I, points 2.2 and 2.3 of ADD explicitly mention that the labelling provisions of the ADD shall apply “*without prejudice to other Community Directives, in particular to Directives on dangerous substances and preparations*”.



It results that the ADD imposes the obligation to respect the rules of the chemicals legislation.

As from 1 December 2010, the labelling provisions of Directive 67/548/EEC have been replaced by the corresponding provisions of the CLP Regulation.

Therefore, awaiting the formal adaptation of the references of ADD to the CLP Regulation and the incorporation of the new rules of the CLP Regulation into the ADD, **the labelling provisions of points 2.2(a) and (b) and 2.3(b) of ADD which refer to Directive 67/548/EEC or reproduce provisions of that Directive, should be interpreted as referring or reproducing the corresponding provisions of CLP as provided for in its Annex I, Part 2, section 2.3.3 (see table below).**

Furthermore, according to Article 61(4) of CLP, aerosol dispensers containing a single substance and placed on the market before 1 December 2010 can continue to be labelled in accordance with Directive 67/548/EEC, until 1 December 2012.

Labelling changes for aerosol dispensers containing a single substance:

ADD/75/324/EEC	CLP Regulation (EC) No 1272/2008
	
	Danger
'Flammable' or 'Extremely Flammable'	'Flammable' or 'Extremely Flammable'
Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use	(P251) Pressurised container: Do not pierce or burn, even after use. (P410+412) Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F
(S16) Keep away from sources of ignition – No smoking	(P210) Keep away from heat/sparks/open flames/hot surfaces. – No smoking
Do not spray on a naked flame or any incandescent material	Do not spray on an open flame or other ignition source
(S2) Keep out of the reach of children	Keep out of reach of children (for consumer products)

ANNEX I: LEGAL REFERENCES

Directive 75/324/EEC on Aerosols Dispensers (ADD)

Article 8 (Labelling)

1. 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:
 - (a) the name and address or trade mark of the person responsible for marketing the aerosol dispenser,
 - (b) the symbol '3' (inverted epsilon) certifying conformity with the requirements of this Directive,
 - (c) code markings enabling the filling batch to be identified,
 - (d) the details referred to in points 2.2 and 2.3 of the Annex,
 - (e) the net contents by weight and by volume.
- 1a. Where an aerosol dispenser contains flammable components as defined in point 1.8 of the Annex but the aerosol dispenser is not considered as 'flammable' or 'extremely flammable' according to the criteria set out in point 1.9 of the Annex, 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'.
2. Member States may make the marketing of aerosol dispensers in their territory conditional on the use of their national language or languages for the wording on the label.

Annex I, Points 2.2 and 2.3 : Labelling

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 aerosol is classified as 'flammable' or 'extremely flammable' according to the criteria of point 1.9:
 - the flame symbol, in accordance with the model in Annex II to Directive 67/548/EEC;
 - the indication 'flammable' or 'extremely flammable', depending on the classification of the aerosol as 'flammable' or 'extremely flammable'.

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, any additional operating precautions which alert consumers to the specific dangers of the product; if the aerosol dispenser is accompanied by separate instructions for use, the latter must also reflect such operating precautions;
- (b) Where the aerosol is classified as 'flammable' or 'extremely flammable' according to the criteria of point 1.9, the following warnings:
 - the safety phrases S2 and S16 laid down in Annex IV to Directive 67/548/EEC;
 - 'Do not spray on a naked flame or any incandescent material'.

Regulation (EC) No 1278/2008 on classification, labelling and packaging of substances and mixtures

TITLE II (HAZARD CLASSIFICATION)

Article 14(2)(c): Specific rules for the classification of mixtures

2. A mixture need not be classified for explosive, oxidising, or flammable properties as referred to in Part 2 of Annex I provided that any of the following requirements are met:

- (c) where a mixture is placed on the market in the form of an aerosol dispenser, it satisfies Article 8(1a) of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers.

TITLE III (HAZARD COMMUNICATION IN THE FORM OF LABELLING)

Article 23(c): Derogations from labelling requirements for special cases

The specific provisions on labelling laid down in section 1.3 of Annex I shall apply in respect of the following:

- (c) aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard;

TITLE VII (COMMON AND FINAL PROVISIONS)

Article 61 (transitional provisions)

Article 61(3)

From 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and this Regulation. They shall be labelled and packaged in accordance with this Regulation.

Article 61(4)

By way of derogation from the second subparagraph of Article 62 of this Regulation, substances classified, labelled and packaged in accordance with Directives 67/548/EEC and already placed on the market before 1 December 2010, are not required to be relabelled and repackaged in accordance with this Regulation until 1 December 2012.

Article 62 (Entry into force)

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

Titles II, III and IV shall apply in respect of substances from 1 December 2010 and in respect of mixtures from 1 June 2015.

Annex I, Part 1

1.1.3.7. Aerosols

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.4, 3.8 and 3.9, an aerosol form of a mixture shall be classified in the same hazard category as the non-aerosolised form of the mixture, provided that the added propellant does not affect the hazardous properties of the mixture upon spraying and scientific evidence is available demonstrating that the aerosolised form is not more hazardous than the nonaerosolised form.

1.3.3. Aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard

With regard to the application of section 3.10.4, substances or mixtures classified in accordance with the criteria of sections 3.10.2 and 3.10.3 need not be labelled for this hazard when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.

1.5.2.1.1 (last sentence):

The exemptions for labelling of small packages of aerosols as flammable laid down in Directive 75/324/EEC shall apply to aerosol dispensers.



Annex I, section 2.3. Flammable aerosols (Read full section – only the labelling provisions are copied below)

2.3.3 Hazard Communication

Label elements shall be used for substances or mixtures meeting the criteria for classification in this hazard class in accordance with Table 2.3.2

Table 2.3.2

Label elements for flammable aerosols

Classification	Category 1	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H222: Extremely flammable aerosol	H223: Flammable aerosol
Precautionary Statement Prevention	P210 P211 P251	P210 P211 P251
Precautionary Statement Response		
Precautionary Statement Storage	P410 + P412	P410 + P412
Precautionary Statement Disposal		

Annex I, Part 3

3.10.1.6.3. Classification of aerosol/mist products

Aerosol and mist forms of a substance or a mixture (product) are usually dispensed in containers such as self-pressurised containers, trigger and pump sprayers. The key to classifying these products is whether a pool of product is formed in the mouth, which then may be aspirated. If the mist or aerosol from a pressurised container is fine, a pool may not be formed. On the other hand, if a pressurised container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed, and the contents are available to be swallowed then the classification of the substance or mixture shall be considered.

Annex II, Part 2: Special rules for supplemental label elements for certain mixtures:

“2.11. AEROSOLS:

Note that aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 in the Annex to Directive 75/324/EEC.”

Annex III

H222 Extremely flammable aerosol

H223 Flammable aerosol

P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

P211 Do not spray on an open flame or other ignition source.

P251 Pressurized container: Do not pierce or burn, even after use.

P410 + 412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F.

Annex V

GHS02: Flammable aerosols, hazard categories 1, 2

