

**NB: Unofficial translation; legally binding texts are those in Finnish and Swedish**

**Ministry of Social Affairs and Health Decree  
on chemical  
classification principles and labelling  
(807/2001)**

Section 1 - *Scope of application*

- (1) This Decree lays down provisions on the classification principles, packaging, and labelling of chemicals referred to in section 19 of the Chemicals Act (744/1989) and sections 5 and 16 of the Chemicals Decree (675/1993).
- (2) Labelling means danger symbols and their names, standard phrases indicating danger(R phrases), standard phrases indicating safety measures(S phrases), and other specific labelling requirements.
- (3) This Decree applies to preparations which have been classified as dangerous under section 3, 4 or 5 and contain at least one substance classified as dangerous.
- (4) This Decree also applies to preparations that are not classified but for which a safety data sheet must be drawn up under section 17 of the Chemicals Act or the packaging of which must be equipped with safety closures or a tactile warning of danger, or the packaging of which must be labelled as laid down in Appendix 3.
- (5) All dangerous substances must be taken into account when classifying a preparation as dangerous, with special consideration given to the following:

- 1) substances included in the list of dangerous substances (list of substances)
- 2) dangerous substances included in the list of new substances
- 3) dangerous substances that have been classified independently by the manufacturer, importer or distributor on the basis of section 6 of the Chemicals Decree
- 4) new dangerous substances for which a notification has been submitted but which have not yet been entered in the list of new substances
- 5) new dangerous substances for which a reduced notification has been submitted
- 6) new dangerous substances that have been classified and labelled as required in section 8 of the Ministry of Social Affairs and Health Decision on the notification procedure for new substances (1642/1993).

## Section 2 - *Testing methods*

When determining the properties of a chemical for the purpose of classification, the chemical must be tested according to approved testing methods in the form in which it is to be placed on the market. Plant protection products referred to in the Pesticides Act may also be tested for the purpose of classification using other internationally recognized methods as is laid down in the pesticides legislation.

## Section 3 - *Classification of flammable and explosive chemicals*

- (1) The flammability and explosiveness of a chemical are assessed for the purpose of classification by

determining the flammable and explosive properties using tests referred to in section 2 or other similar investigations. Chemicals are classified on the basis of test results and other research data as laid down in Appendix 1.

- (2) The flammability or explosiveness of a preparation (mixture) does not need to be tested if:
- 1) the preparation contains no flammable or explosive substances and, based on information available to the manufacturer, the preparation poses no such risk; or
  - 2) the preparation has been placed on the market as an aerosol and it is the manufacturer's opinion that the aerosol does not pose a flammability risk as provided in legislation on aerosols.
- (3) Exemptions from application of the testing methods are laid down in Appendix 2.1, item 1, of this Decree.
- (4) When tests cannot be conducted to determine flammability and explosiveness, the calculation methods listed in Appendix 2.1, item 2, of this Decree will apply to classification of the preparation.

#### Section 4 - *Classification of chemicals dangerous to health*

- (1) The health hazards of chemicals (substances and preparations) are assessed for the purpose of classification by determining the properties that cause danger to health using the testing methods referred to in section 2 or with other similar investigations. Chemicals are classified on the

basis of test results and other research data as provided in Appendix 1.

- (2) Preparations are classified primarily in accordance with the conventional method described in Appendix 2.2. However, if the list of substances includes specified concentration limits for a substance for the purpose of classification, these limits must be applied instead of those determined in Appendix 2.2.
- (3) In the case of preparations tested to determine their health hazards, the test results are used in classification unless the hazardous effects are carcinogenic, mutagenic or toxic to reproduction. In these cases, the conventional method described in Appendix 2.2 will apply to the classification.
- (4) Animal tests referred to in section 2 may be used to test preparations for the purpose of classification only if the party placing the preparation on the market can scientifically prove that the properties of the preparation that are dangerous to health cannot be appropriately indicated using a conventional method or existing animal test results. Animal tests must be justified and allowed under the provisions of animal protection legislation on animal experiments. The requirements that apply to tests of plant protection products referred to in the Pesticides Act are laid down in the pesticides legislation.
- (5) All health risks of a preparation under Appendix 1 must be assessed either on the basis of test results or using a conventional method.
- (6) An exemption may be made from classification determined on the basis of test results or a

conventional method and the preparation classified on the basis of effects that endanger human health, provided that these effects can be proven by:

- 1) epidemiological study results or case histories as provided in Appendix 1 regarding individual cases; or
  - 2) statistical data provided by a poison information centre or on occupational diseases.
- (7) Conventional methods may not be used for classification if the preparation has mutually weakening or enhancing effects that are known. In such cases, classification of the preparation will take these effects into account.

#### Section 5 - *Classification of chemicals dangerous for the environment*

- (1) The environmental hazards of chemicals (substances and preparations) must be assessed for the purpose of classification by determining their environmentally hazardous properties using tests referred to in section 2 or other similar investigations. Chemicals are classified on the basis of test results and other research data as provided in Appendix 1.
- (2) Preparations will be primarily classified in accordance with the conventional method described in Appendix 2.3. However, if the list of substances includes specific concentration limits for a substance for the purpose of classification, these limits must be used instead of those laid down in Appendix 2.3.
- (3) In the case of preparations that have been tested to determine their environmental hazards, the test

results must be used in classification as provided in Appendix 2.3.

- (4) Animal tests must be justified and allowed under the provisions of animal protection legislation on animal experiments. The requirements that apply to tests of plant protection products referred to in the Pesticides Act are laid down in the pesticides legislation.

*Section 6 - Reassessment of the classification of a tested dangerous preparation*

- (1) Preparations with known compositions that have been assessed and classified as flammable and explosive on the basis of test results need not be retested for the purpose of classification when their composition is altered if it can be scientifically justified that their classification as flammable and explosive would not change.
- (2) When preparations with known compositions have been assessed and classified as dangerous to health or the environment on the basis of test results, the dangers to health or the environment must be reassessed on the basis of new test results or a conventional method if:

- 1) the manufacturer alters the concentration of one or more dangerous components of the original composition more than is allowed in the following table:

Original concentration range of component	Tolerance margin of original concentration
Concentration $\leq$ 2.5%	$\pm$ 30%
2.5%<concentration $\leq$ 10%	$\pm$ 20%
10%<concentration $\leq$ 25%	$\pm$ 10%

25%<concentration<=100% ±5%

- 2) the manufacturer alters the composition by replacing or adding one or more components, irrespective of the classification of the substance.
- (3) Reassessment of a preparation whose composition has been altered can only be avoided if it can be scientifically proven that a new test would not lead to reclassification.
- (4) This provision does not apply to plant protection products referred to in the Pesticides Act.

*Section 7 - Minimum concentrations of substances dangerous to health and the environment in preparations*

- (1) Substances dangerous to health and the environment must be taken into account in the classification of a preparation if their minimum concentration is as indicated in the table below. The substances must also be taken into account when they are present as additives or impurities in a preparation:

Dangerousness	Relevant concentrations in gaseous preparations vol/vol %	other preparations weight/weight %
Very toxic	>= 0.02	>= 0.1
Toxic	>= 0.02	>= 0.1
Carcinogenic, Cat. 1 or 2	>= 0.02	>= 0.1
Mutagenic, Cat. 1 or 2	>= 0.02	>= 0.1
Toxic for reproduction. Cat. 1 or 2	>= 0.02	>= 0.1
Harmful	>= 0.2	>= 1
Corrosive	>= 0.02	>= 1
Irritating	>= 0.2	>= 1
Sensitizing	>= 0.2	>= 1
Carcinogenic, Cat. 3	>= 0.2	>= 1
Mutagenic, Cat. 3	>= 0.2	>= 1
Toxic for reproduction, Cat. 3	>= 0.2	>= 1
Dangerous for the environment N		>= 0.1

Dangerous for the environment  $\geq 0.1$

Ozone

Dangerous for the environment  $\geq 1$

- (2) If the list of substances or Appendices 2.2, 2.3 or 3 to this Decree provide that concentrations lower than those given in the table above apply, these must be observed instead of the concentration limits specified in the table above.

#### Section 8 - *Taking dangerous properties into account*

All dangerous properties of substances contained in a preparation must be taken into account when classifying the preparation and selecting its labelling. The classification of a preparation and its labelling must be selected on accordance with its most seriously dangerous properties.

#### Section 9 - *Content of package labelling*

- (1) Section 16 of the Chemicals Decree lays down provisions on the labelling of packaging for dangerous chemicals.
- (2) Danger symbols, their names, R and S phrases and other special markings to be placed on the packaging are selected on the basis of the chemical's classification under sections 3, 4 and 5 and in accordance with the selection criteria laid down in Appendices 1, 2.1, 2.2, 2.3, 3 and 4.
- (3) Any labelling placed on the packaging of a preparation must include the names of substances that exceed the following limits given for the purpose of classification in the list of substances or the tables of Appendix 2.2:



- 1) the concentration limits determined in 1 and 1a for acute toxicity (including the minimum limit for classification Xn)
  - 2) the concentration limits determined in 4 and 4a for corrosiveness (including the minimum limit for classification Xn).
- (2) However, the names of substances on whose account a preparation has been classified in one or more of the following risk groups must always be entered on the package labelling:
- 1) carcinogenic substances of Cat. 1, 2 or 3;
  - 2) mutagenic substances of Cat. 1, 2 or 3;
  - 3) substances toxic to reproduction of Cat. 1, 2 or 3;
  - 4) substances that are very toxic, toxic or harmful on the basis of their irreversible effects, other than death, from a single exposure;
  - 5) substances that are toxic or harmful on the basis of serious irreversible effects from repeated or long-term exposure;
  - 6) sensitizing substances.
- (3) The names of substances given on packaging must be the names stated in the list of substances or, in the case of substances not included in the list of substances, internationally accepted chemical names.
- (4) The names of substances on whose account a preparation is classified under the following risk classes need not be entered on the packaging:
- 1) explosive
  - 2) oxidizing
  - 3) extremely flammable
  - 4) highly flammable

- 5) flammable
- 6) irritant
- 7) dangerous for the environment,

unless the preparation is classified as dangerous on the basis of other properties of the substance.

- (5) In the case of packaging for strong perfumes intended for the perfume industry, only the name of the sensitizing substance that is deemed to be the principal sensitizing substance of the preparation containing the perfume need be entered on the packaging.
- (6) Chemical names may be entered on the packagings of natural products in a form indicating the origin of the natural product.
- (7) A maximum of four names of substances hazardous to health contained in a preparation may normally be entered on the packaging.
- (8) A maximum of six R phrases may generally be entered on packaging. Combined phrases are considered a single phrase. However, more than 6 R phrases must be used on the packaging when the various dangerous properties of the chemical are not otherwise apparent.
- (9) R phrases R12 'Erittäin helposti syttyvä. Extremt brandfarligt.' (Extremely flammable) or R11 'Helposti syttyvä. Mycket brandfarligt.' (Highly flammable) do not need to be entered on the packaging if they replicate the name of the danger symbol.

- (10) A maximum of 6 S phrases may generally be entered on packaging. Combined phrases are considered a single phrase.
- (11) A separate safety guidance must be added to packaging if, due to the shape or size of the packaging or other special reason, it is impossible to enter S phrases on the packaging itself or on some other package.
- (11) Danger symbols and their names are laid down in Appendix 2 of the Ministry of Social Affairs and Health Decree on the list of dangerous substances. R phrases are listed in Appendix 3 of the Ministry of Social Affairs and Health Decree on the list of substances, and S phrases in Appendix 4 of the same Decree.

Section 10 - *Chemicals with several dangerous properties*

- (1) If a chemical has several properties on whose account a number of danger symbols are required to be placed on its packaging, only the danger symbols indicating the most serious dangers and their names are to be placed on the packaging, in a manner that indicates the danger to health, danger for the environment or flammability or explosiveness. Other dangerous properties must be indicated with R phrases.
- (2) When a chemical hazardous to health is marked with the danger symbol
- 1) T+, the symbols T, Xn, C and Xi may be omitted;
  - 2) T, the symbols Xn, C and Xi may be omitted, unless specified otherwise in the list of substances;
  - 3) Xn, the symbol Xi may be omitted;

- 4) C, the symbols Xi and Xn may be omitted.
- (3) When a chemical that is flammable and explosive is marked with the danger symbol E, the symbols O, F+ and F may be omitted.

#### Section 11 - *Labelling small packages*

- (1) When the contents of the packaging of a dangerous substance are no more than 125ml and if the substance is classified as an irritant, highly flammable, flammable or oxidizing, R or S phrases need not be entered on the packaging. This also applies to the same volume of harmful substances not sold to the general public.
- (2) When the contents of the packaging of a dangerous preparation are no more than 125ml and if
- 1) the preparation is classified as dangerous for the environment, highly flammable, oxidizing or an irritant using the danger symbol N, excluding irritant preparations for which R phrase 41 is required, R or S phrases need not be entered on the packaging;
  - 2) the preparation is classified as flammable or dangerous for the environment without the danger symbol N, R phrases must be entered but S phrases may be omitted.
- (3) Other markings must be made on packaging irrespective of the packaging size.

#### Section 12 - *Exemptions from the requirements on labelling and packaging*

- (1) Appendix 4 to this Decree specifies the preparations classified as dangerous under this Decree to which requirements concerning the safety or labelling of packaging do not apply on the basis of risk assessment.
- (2) Labelling may be omitted from the packaging of a preparation under section 16 of the Chemicals Decree and under this Decree, or packaging may be labelled in another appropriate way if the content of the packaging of a preparation which is harmful, extremely flammable, highly flammable, flammable, an irritant or oxidizing is so small that there is no cause to suspect the handling of the preparation to pose a danger to health.
- (3) The packaging of a preparation that is explosive, very toxic, toxic, sensitizing, carcinogenic, mutagenic or toxic to reproduction or the environment may be labelled in some other appropriate way if it is too small to be labelled as required under section 16 of the Chemicals Decree or under this Decree, provided that there is no cause to suspect the handling of the preparation to cause a danger to health or the environment.
- (4) In the case of unusual labelling, only the danger symbols and their names referred to in this Decree and the R and S phrases may be used.
- (5) The requirements on the safety and labelling of packaging referred to in this Decree do not apply to explosives.

#### Section 13 - *Special provisions on labelling*

Special labelling used on the packaging of chemicals are specified in Appendix 3.

Section 14 - *Labelling of packaging*

- (1) The labelling referred to in section 16 of the Chemicals Decree must be entered on labels which are attached to or printed on the packaging.
- (2) Labels must be attached firmly to at least one side of the packaging so that the labelling can be read horizontally when the packaging is upright.
- (3) Labels must have the following measurements:

Packaging volume	Measurements (mm)
Maximum 3l	minimum 52 x 74
More than 3l, but maximum 50l	minimum 74 x 105
More than 50l, but maximum 500l	minimum 105 x 148
More than 500l	minimum 148 x 210
- (4) Each danger symbol must cover at least one tenth of the surface area of the label but may not be smaller than 1 cm<sup>2</sup>. The entire surface of a label must be attached to the packaging of the chemical.
- (5) In addition to the information referred to in section 16 of the Chemicals Decree, additional information on dangers and safety may be included on labels when needed.
- (6) Labels and their appearance must be such that danger symbols and their backgrounds are clearly distinguishable. Danger symbols must be printed in black on an orange-yellow background. The text on labels must be clearly distinguishable from its background, and its size and layout must be such that it is easily readable. The text must be written in Finnish and Swedish. Text may also be included in other languages, provided that the requirements of size and form of the label are met.

- (7) Labelling is deemed to meet the requirements of this Decree if
- 1) the outer package containing one or more individual chemical packages has been labelled as required by regulations on the transport of dangerous substances, and the interior packages as required by this Decree;
  - 2) the packaging of the chemical has been labelled as required by regulations on the transport of dangerous substances and the information referred to in section 16 of the Chemicals Decree has been entered on it, with the exception of the danger symbols referred to in this Decree and their names and the volume of the preparation content intended for retail; however, danger symbols and their names must be entered on the packaging of preparations classified as dangerous to the environment when a corresponding symbol is not required under transport regulations;
  - 3) labelling on mobile gas containers meets the requirements laid down in Appendix 1, items 7.1 and 7.2, of this Decree.
- (8) Danger markings required on chemical packaging that are valid in Sweden and issued for the purpose of implementing the chemicals legislation of the European Community may be used, when necessary, in place of the Swedish-language danger markings of the same meaning in use in Finland.

*Section 15 - Keeping information for supervision purposes*

- (1) The manufacturer or importer of a chemical or the party responsible for its placement on the market or supply for use, must, for supervision purposes,

keep information that has been used in

- 1) the classification of the chemical and the selecting of labelling;
- 2) drawing up a safety data sheet;
- 3) ensuring that packaging is safe.

Section 16 - *Entry into force*

- (1) This Decree enters into force on October 1, 2001. The provisions of this Decree must be applied no later than August 1, 2002. However, section 2 on testing methods must be applied as of October 1, 2001.
- (2) Notwithstanding subsection 1, the provisions of this Decree must be applied to plant protection products referred to in the Pesticides Act and biocidal products referred to in the Chemicals Act by August 1, 2004, at the latest.