

ORDINANCE
on classification, packaging and labelling of existing and new chemical substances and preparations
(*)

CHAPTER ONE
GENERAL PROVISIONS

Article 1

This Ordinance regulates:

1. the terms and conditions for classification, packaging and labelling of existing and new chemical substances, preparations and products;
2. requirements for packaging and labelling of existing and new chemical substances, preparations and products;
3. additional requirements for placing on the market of dangerous chemical substances and preparations intended for professional use.

Article 2

A producer and importer placing on the market chemical substance, preparation and product is obliged:

1. to obtain all the accessible data on the properties of the chemical substance, preparation and product needed for its classification;
2. to classify it on the basis of its physico-chemical, toxicological and ecotoxicological properties in one or more of the categories of danger set in Article 2 of the Law on Protection against Harmful Impact of Chemical Substances, Preparations and Products (LPHICSPP);
3. to package and label it in accordance with the category of danger defined after classification.

CHAPTER TWO
TERMS AND CONDITIONS FOR CLASSIFICATION, PACKAGING AND LABELLING OF EXISTING AND
NEW CHEMICAL SUBSTANCES, PREPARATIONS AND PRODUCTS

Section I
Classification of Chemical Substances

Article 3

- (1) Chemical substances which are not included in Annex No.1 are classified in one or more of the categories of danger set in Article 2 of the LPHICSPP on the basis of their physico-chemical, toxicological and ecotoxicological properties in accordance with the criteria set in Annex No.2.
- (2) Tests on chemical substances for determination of their physico-chemical, toxicological and ecotoxicological properties are conducted in accordance with the methods laid down in Annex No.3.
- (3) Tests under paragraph (2) are conducted in compliance with the principles of Good Laboratory Practice.

Article 4

- (1) Manufacturers or importers of dangerous substances which appear in the Annex No.4 but which have not yet been introduced into Annex No.1 are obliged to make themselves aware of the information available concerning the properties of these substances and on the basis of this information to package and provisionally label them following the rules laid down in Sections II and III hereto.
- (2) When for the chemical substances included in Annex No.4 test data exist which have been generated by methods other than those laid down in Article 3, paragraph (2) the use of such data for the

(*)Adopted with Council of Ministers' Decree No 316/20.12.2002, published in the State Gazette No.5/17.01.2003, in force as of 01.01.2004. This Ordinance transposes Directive 67/548/EEC, as last amended by Directive 2001/59/EC, Directive 99/45/EC, as last amended by Directive 2001/60/EC and Directive 91/155/EC, as last amended by Directive 2001/58/EC. Following the amendments to the Law (LPHICSPP) amendments to this Ordinance are in process of drafting.

purposes of classification and the need to conduct new tests according to Article 3, paragraph 2 are decided on a case-by-case basis taking into account the need to minimise testing on vertebrate animals.

Article 5

The presence of dangerous chemical substances as impurities must be taken into account in the classification of chemical substances, as far as the concentration(s) of the latter exceed the concentration limits specified in Article 20.

Section II Packaging of Dangerous Chemical Substances

Article 6

Dangerous chemical substances are packaged in accordance with the requirements of Article 6 of LPHICSPP.

Article 7

Child-resistant fastenings and tactile warning of danger under Article 6, point 5 and 6 of LPHICSPP must also conform to the requirements laid down in Annex No.5.

Section III Labelling of Dangerous Chemical Substances

Article 8

Dangerous chemical substances are labelled in accordance with the requirements of Article 7, paragraph (1) of LPHICSPP and Annex No.2, and the following particulars must be put on the label in addition:

1. name of the dangerous chemical substance under one of the designations given in Annex No.1;
2. name of the dangerous chemical substance under Annex No.4 or 6, or other internationally recognised designation, when the substance is not yet listed in Annex No.1;
3. EC № under Annexes No.4 and 6, when allocated;
4. The words “EC label” must be written for the substances listed in Annex No.1.

Article 9

(1) For the dangerous chemical substance listed in Annex No.1 danger symbols and indications of the danger set in Article 7, paragraph (1), point 4 of LPHICSPP must be given on the label of the substance in accordance with Annex No.1.

(2) For dangerous substances not yet appearing in Annex No.1 the danger symbols and indications of danger are assigned according to the rules laid down in Annex No.2.

(3) The design of the danger symbols must comply with Annex No.7.

(4) When more than one danger symbol and indication of the danger are assigned to a dangerous chemical substance they must appear on the label in accordance with the following rules:

1. the obligation to indicate the symbol and indication T+ or T makes the symbols and indications Xi, Xn and C optional, unless Annex No.1 provides otherwise;
2. the obligation to indicate the symbol and indication C makes the symbols and indications Xi and Xn optional;
3. the obligation to indicate the symbol and indication E makes the symbols and indications F and O optional.

Article 10

(1) For the dangerous chemical substance listed in Annex No.1 standard risk phrases (R-phrases) under Article 7, paragraph (1), point 5 of LPHICSPP must be given on the label of the substance in accordance with Annex No.1.

(2) For dangerous substances not yet appearing in Annex No.1 R-phrases are assigned according to the rules laid down in Annex No.2.

(3) The wording of the R-phrases must comply with that laid down in Annex No.8.

Article 11

- (1) For the dangerous chemical substance listed in Annex No.1 standard safety advices (S-phrases) under Article 7, paragraph (1), point 6 of LPHICSPP must be given on the label of the substance in accordance with Annex No.1.
- (2) For dangerous substances not yet appearing in Annex No.1 S-phrases are assigned according to the rules laid down in Annex No.2.
- (3) The wording of the S-phrases must comply with that laid down in Annex No.9.

Article 12

R-phrases and S-phrases need not be given on the label where the package of the dangerous chemical substance does not contain more than 125 ml and when the substance is classified as:

1. “irritant”, “highly flammable”, “flammable” and “oxidising”;
2. “harmful” and is not intended for sale to the general public.

Article 13

- (1) The label must be firmly affixed to one or more surfaces of the packaging in contact with the chemical substance so that its particulars can be read horizontally when the package is set down normally.
- (2) The dimensions of the label are given in Annex No.10, Table 1.
- (3) Each symbol of danger must cover at least one-tenth of the surface area of the label but not be less than 1 cm².

Article 14

- (1) The placement and the size of the label’s particulars must be such that the information stands out clearly from its background and is indelible and legible, and in conformity with Annex No.2.
- (2) The colour and presentation of the label or, the information on the package must be such that the danger symbol and its background stand out clearly.

Article 15

- (1) A label is not required where the particulars are clearly shown on the package itself and in accordance with the requirements of Article 13 and 14.
- (2) Where the type or the size of the package does not permit labelling, the package must be accompanied by a leaflet conforming to the requirements of this Section.

Article 16

Labelling requirements are deemed to be satisfied when:

1. in the case of an outer package containing one or more inner packages, 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 this Ordinance;
2. in the case of a single package, it is labelled in accordance with international rules on the transport of dangerous substances and with Article 7, paragraph (1), points 3, 5 and 6 of LPHICSPP, and Article 8, points 1 and 3 of this Ordinance, as well as in the cases under point 8 of Annex No.2.

Article 17

Requirements for labelling and packaging do not apply to munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

CHAPTER THREE CHEMICAL PREPARATIONS

Section I Classification of Chemical Preparations

Article 18

Chemical preparations are classified in one or more of the categories of danger set in Article 2 of LPHICSPP on the basis of their physico-chemical, toxicological and ecotoxicological properties in

accordance with the criteria set in Annex No.2, when the preparation contains at least one dangerous chemical substance.

Article 19

Physico-chemical, toxicological and ecotoxicological properties of the chemical preparation are determined when it contains:

1. a dangerous chemical substance listed in Annex No.1;
2. a chemical substance under Annex No.4, provisionally classified as dangerous and labelled in accordance with Article 4, paragraph (1);
3. a dangerous chemical substance under Annex No.6;
4. a dangerous chemical substance notified in accordance with the Ordinance on the terms and conditions for notification of new chemical substances, adopted with Council of Ministers' Decree № 137/2002 (State Gazette 67/2002), but not yet included in Annex No. 6;
5. a chemical substance which is not subject to notification in accordance with Article 8, paragraph (2), points 2, 3 and 4 of LPHICSPP but which has been classified as dangerous and provisionally packaged and labelled in accordance with Chapter II.

Article 20

(1) Dangerous substances constituents of a preparation, whether they are present as impurities or additives, are taken into consideration for the classification when their concentrations are equal to, or greater than, those defined in Annex No.10, Table 2.

(2) When the concentrations of the dangerous chemical substances are lower than the concentration limits given in Annex No.10, Table 2, for the purposes of classification of the chemical preparation the values given in Annex No.1 or Annex No.11, or Annex No.12 are taken into consideration, unless otherwise specified in Annex No.13.

Article 21

(1) Physico-chemical properties of the chemical preparations are determined in accordance with:

1. Annex No.3, unless for the plant protection products other internationally recognised methods are acceptable in accordance with the Ordinance on the authorisation of plant protection products, adopted with Council of Ministers' Decree № 213/2002 (State Gazette 93/2002);

2. Annex No.14 where the methods under point 1 are not appropriate.

(2) The determination of the explosive, oxidising, extremely flammable, highly flammable, or flammable properties is not necessary provided that:

1. none of the constituents possesses such properties and that, on the basis of the information available, the preparation is unlikely to present hazards of this kind;

2. in the event of a change in the composition of a preparation of known composition, scientific data indicate that a reassessment of the hazards will not lead to a change in classification;

3. the results of the tests show that under the normal use aerosols will not lead to ignition.

Article 22

(1) Toxicological properties of the chemical preparations are determined in accordance with:

1. conventional method under Annex No.12, and/or

2. Annex No. 3, unless for the plant protection products other internationally recognised methods are acceptable in accordance with the Ordinance on the authorisation of plant protection products.

(2) Producer and importer applies the methods set in paragraph (1), point 2 where:

1. it can be scientifically proved that the toxicological properties of the preparation cannot correctly be determined by the method outlined in paragraph (1), point 1;

2. existing test results on animals are not sufficient for the determination of toxicological properties.

(3) When any of the toxicological properties of the chemical preparation is not determined by the method outlined in paragraph (1), point 2, they shall be assessed in accordance with the method outlined in paragraph (1), point 1.

(4) Where a toxicological property has been established on the basis of both the methods outlined in paragraph (1), points 1 and 2, the results from the methods outlined in paragraph (1), point 2, must be

used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic for reproduction properties for which only the method outlined in paragraph (1), point 1 must be used.

(5) Where it can be demonstrated:

1. by epidemiological and scientifically valid studies as or by statistically backed health experience, that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph 1, the preparation must be classified according to its effects on man;
2. that, on the basis of the effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, the potentiation effect must be taken into account in classifying the preparation;
3. that, on the basis of the effects such as antagonism, a conventional assessment would underestimate the toxicological hazard, the presence of antagonism must be taken into account in classifying the preparation.

Article 23

(1) For the chemical preparations classified in accordance with Article 22, paragraph (1), point 2, with the exception of plant protection products, new tests of toxicological properties by the methods outlined in either Article 22, paragraph (1), points 1 and 2 are performed whenever:

1. changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with Annex No.10, Table 3;
2. changes of composition involving the substitution or addition of one or more constituents are introduced by the manufacturer.

(2) The tests under paragraph 1 do not apply where there is valid scientific data for considering that the new tests will not result in a change of classification.

Article 24

(1) Ecotoxicological properties of the chemical preparations are determined in accordance with:

1. conventional method under Annex No.11;
2. Annex No. 3, in accordance with Annex No.11, part C, unless for the plant protection products other internationally recognised methods are acceptable in accordance with the Ordinance on the authorisation of plant protection products.

(2) Where an ecotoxicological property has been established on the basis of both the methods outlined in paragraph (1), points 1 and 2, the results from the methods outlined in paragraph (1), point 2, must be used for classifying the preparation.

Article 25

(1) For the chemical preparations classified in accordance with Article 24, paragraph (1), point 2, with the exception of plant protection products, new tests under Article 24, paragraph (1) are performed whenever:

1. changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the Annex No.10, Table 4;
2. changes of composition involving the substitution or addition of one or more constituents are introduced by the manufacturer.

(2) The tests under paragraph 1 do not apply where there is valid scientific data for considering that the new tests will not result in a change of classification.

Article 26

Laboratory tests of the preparations must be conducted in accordance with the principles of Good Laboratory Practice and in the form in which the preparation is placed on the market.

Section II Packaging of Dangerous Chemical Preparations

Article 27

Dangerous chemical preparations must be packaged in accordance with the requirements set in Article 6 of LPHICSPP.

Article 28

(1) The packaging of dangerous chemical preparations, placed on the market for sale to the general public must not have:

1. either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or
2. a presentation and/or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.

(2) Containers which contain certain chemical preparations covered by Annex No.15 must be fitted with child-resistant fastenings and/or carry a tactile warning of danger.

(3) Child-resistant fastenings and tactile warnings of danger must conform to the requirements set in Annex No.5.

Article 29

Requirements of Article 27 and 28 also apply to the preparations which have not been classified as dangerous but nevertheless may present a specific hazard.

Section III Labelling of Dangerous Chemical Preparations

Article 30

(1) Dangerous chemical preparations must be labelled in accordance with the requirements set in Article 8 of LPHICSPP and Annex No.13, and the following particulars must also appear on the label:

1. the chemical name of the substance/substances listed in Annex No.1 which are present in the preparation;
2. an internationally recognised name of the dangerous substance/substances present in the preparation, where the substance is not listed in Annex No.1.

(2) The name of the substance/substances which have given rise to the classification of the preparation in one or more of the following danger categories must be given on the label:

1. carcinogen (categories 1, 2 and 3);
2. mutagen (categories 1, 2 and 3);
3. toxic for reproduction (categories 1, 2 and 3);
4. very toxic, toxic or harmful due to non-lethal effects after a single exposure;
5. toxic or harmful due to severe effects after repeated or prolonged exposure;
6. sensitising.

(3) For preparations classified as very toxic, toxic and harmful, only the chemical names of the substances classified as very toxic, toxic and harmful present in the preparation in concentrations equal to, or greater than, the lowest limit (limit X_n) laid down in Annex No.1 or, failing that – laid down in Annex No.12, have to be shown on the label.

(4) For preparations classified as corrosive, only the chemical names of the substances classified as corrosive present in the preparation in concentrations equal to, or greater than, the lowest limit (limit X_n) laid down in Annex No.1 or, failing that – laid down in Annex No.12, have to be shown on the label.

(5) The wording: "To avoid risks to man and the environment, comply with the instructions for use" must be given on the label of plant protection products.

Article 31

(1) The name of any substance which leads to the classification of the preparation in the following danger categories shall not be given on the label:

1. explosive;
 2. oxidising;
 3. extremely flammable;
 4. highly flammable;
 5. flammable;
 6. irritant;
 7. dangerous for the environment.
- (2) Paragraph (1) does not apply where the dangerous chemical preparation is labelled in accordance with Article 30, paragraphs 2, 3 and 4.

Article 32

- (1) A maximum of four chemical names shall suffice to identify the substances primarily responsible for the toxicological properties which have given rise to the classification and the choice of the corresponding R-phrases.
- (2) If necessary, more than four chemical names may be given.

Article 33

- (1) The danger symbols and indications of danger shall be assigned in accordance with Annex No.2 and on the basis of the evaluation of hazards carried out in accordance with Annexes No.11, 12 and 14.
- (2) The design of the danger symbols must comply with Annex No.7.
- (3) When more than one danger symbol and indication of the danger are assigned to a dangerous chemical preparation they must appear on the label in accordance with the following rules:
1. the obligation to indicate the symbol and indication T+ or T makes the symbols and indications Xi, Xn and C optional, unless Annex No.1 provides otherwise;
 2. the obligation to indicate the symbol and indication C makes the symbols and indications Xi and Xn optional;
 3. the obligation to indicate the symbol and indication E makes the symbols and indications F and O optional;
 4. the obligation to indicate the symbol and indication E makes the symbols and indications Xn and Xi optional.

Article 34

- (1) The standard risk phrases (R-phrases) set in Article 7, paragraph (1), point 5 of LPHICSPP shall be assigned in accordance with Annex No.8.
- (2) R-phrases shall be assigned in accordance with the criteria laid down in Annex No.2 and on the basis of the evaluation of the hazards carried out in accordance with Annexes No.11, 12 and 14.
- (3) A maximum of six R-phrases shall suffice to describe the principal hazards associated with use of the preparation which falls within more than one danger category.
- (4) If necessary, more than six R-phrases may be given.
- (5) Each combined R-phrase listed in Annex No.8 shall be regarded as a single phrase.
- (6) The R-phrases “extremely flammable” or “highly flammable” need not be given where the corresponding symbols and indications of danger are put on the label in accordance with Article 33.

Article 35

- (1) The standard safety advices (S-phrases) set in Article 7, paragraph (1), point 6 of LPHICSPP shall be assigned in accordance with Annex No.9.
- (2) S-phrases shall be assigned in accordance with the criteria laid down in Annex No.2 and on the basis of the evaluation of the hazards carried out in accordance with Annexes No.11, 12 and 14.
- (3) A maximum of six S-phrases shall be given on the label of a preparation which falls within more than one danger.
- (4) If necessary, more than six S-phrases may be given.
- (5) Each combined S-phrase listed in Annex No.9 shall be regarded as a single phrase.

(6) Where the type or the size of the package does not permit to include the S-phrases on the label or package itself, the package shall be accompanied by a leaflet containing safety advices on the use of the preparation.

Article 36

Where the package of the dangerous chemical preparation does not contain more than 125 ml and when the preparation is classified as:

1. “highly flammable”, “oxidising”, “irritant”, with the exception of those to which R41 has been assigned, or have been classified as “dangerous for the environment” and assigned the indication N, R- and S-phrases need not to be given;
2. “flammable” or “dangerous for the environment” and not assigned the indication N, only R-phrases need to be given.

Article 37

Requirements of Article 13, 14 and 16 shall also apply to the labelling chemical preparations.

Article 38

Where the type or the size of the package does not permit labelling, the package must be accompanied by a leaflet conforming to the requirements of this Section.

Article 39

Preparations which have not been classified as dangerous but nevertheless may present a specific hazard must be labelled in accordance with Article 7, paragraph (1), points 1 and 3 of LPHICSPP and Annex No.13 hereto.

Article 40

Exceptions from the requirements laid down in Sections II and III are allowed for:

1. munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect;
2. preparations defined in Annex No.2, point 9.3, which, in the form in which they are placed on the market, do not present any risk to the human health or to the environment;
3. preparations defined in Annex No.5, classified in accordance with Article 21, 22 and 24, where in the form in which they are placed on the market do not present any risk to the human health or to the environment.

Section IV

Additional Requirements for Placing on the Market of Dangerous Chemical Substances and Preparations Intended for Professional Use

Article 41

- (1) Manufacturer and importer of dangerous chemical substances and preparations is obliged to provide free of charge a safety data sheet set out in Annex No.16;
- (2) The safety data sheet shall be prepared upon a request of a professional user providing proportionate information for preparations not classified as dangerous but containing in an individual concentration of 1 % for non-gaseous preparations and 0,2 % for gaseous preparations at least:
 1. one substance posing health or environmental hazards; or
 2. one substance for which an exposure limit for the air in the workplace is set in the Ordinance No.13 from 1992 for the concentration limits in the air of the workplace (State Gazette No.81/1992).

Article 42

- (1) Safety data sheet shall be provided when the substance or preparation is first supplied to the professional user.
- (2) If any new information regarding safety and protection of the human health and the environment becomes available, the manufacturer or importer must prepare a revised version of the safety data sheet.
- (3) The new version must be provided free of charge to all former recipients who received the substance or preparation within the preceding 12 months.

Article 43

The safety data sheet is supplied on paper or electronically, in Bulgarian language and in the language of origin.

Article 44

(1) The safety data sheet need not be supplied where dangerous substances or preparations placed on the market for sale to the general public are furnished with sufficient information to enable users to take the necessary measures as regards the protection of health and safety.

(2) In the cases covered by paragraph (1) a safety data sheet must be supplied at the request of a professional user.

Article 45

Requirements of this Section and Annex No.16 are also applied to the preparations which have not been classified as dangerous but nevertheless may present a specific hazard.

ADDITIONAL PROVISION

§ 1. Within the meaning of this Ordinance:

1. "Information available" is any information existing in the scientific literature or in any other sources of specialised information, including electronic ones.

2. "EINECS" is 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.

3. "ELINCS" is the European List of Notified Substances.

4. "Indication of danger" is the letter mark of the danger symbol from Latin alphabet and it's corresponding Bulgarian meaning, as follows:

- E - експлозивен (explosive);
- F - силно запалим (highly flammable);
- T - токсичен (toxic);
- C - корозивно действащ (corrosive);
- Xi - дразнещ (irritant);
- Xn - вреден (harmful);
- N - опасен за околната среда (dangerous for the environment);
- T + - силно токсичен (very toxic);
- F + - изключително запалим (extremely flammable);
- O - оксидиращ (oxidising).

The Latin letter from the indication is not obligatory to be given on the label.

5. "Professional user" is any natural or legal person, registered in accordance with the Trade law or exercising a free-lance profession within the meaning of Personal Income Tax Act who uses and/or places on the market chemical substances, preparations and products.

6. "Placing on the market" is making available a chemical substance or preparation, whether in return for payment or free of charge, for distribution and/or use.

7. "R-phrases" are standard phrases indicating the special risks arising from the dangers involved in using the substance, preparation or product.

8. "S-phrases" are standard phrases giving advices relating to the safe use of the substance, preparation or product.

9. "Danger symbol" is a graphic image printed in black on an orange-yellow background.

FINAL PROVISIONS

§ 2. This Ordinance is adopted on the basis of Article 5, paragraph (2) of the Law on Protection against Harmful Impact of Chemical Substances, Preparations and Products.

§ 3. The Ordinance shall enter into force on 1 January 2004.

§ 4. Annexes to this Ordinance shall be published as Addendum to the State Gazette.

Note: As translation of the Annexes to the Ordinance is not included in this text, please refer to the table below which shows the correspondence to the Annexes of the relevant Directives.

Annexes to the Ordinance on classification, packaging and labelling of existing and new chemical substances, preparations and products	Corresponding Annex of Directive 67/548/EEC or Directive 99/45/EC
Annex I	Annex I, Directive 67/548
Annex II	Annex VI, Directive 67/548
Annex III	Annex V, Directive 67/548
Annex IV	EINECS
Annex V	Annex IX, Directive 67/548
Annex VI	ELINCS
Annex VII	Annex II, Directive 67/548
Annex VIII	Annex III, Directive 67/548
Annex IX	Annex IV, Directive 67/548
Annex X	Tables with concentration limits from both directives
Annex XI	Annex III, Directive 99/45
Annex XII	Annex II, Directive 99/45
Annex XIII	Annex V, Directive 99/45
Annex XIV	Annex I, Directive 99/45
Annex XV	Annex IV, Directive 99/45
Annex XVI	Annex to Directive 91/155 (as last amended by 2001/59)