Ordinance on Protection against Dangerous Substances and Preparations

(Chemicals Ordinance, ChemO)

of 18 May 2005 (Status as of 1 February 2009)
Please note: this translation does not yet include the amendments of 1 December 2010!

The Swiss Federal Council,

based on the Chemicals Act of 15 December 2000 (ChemA)[1],
on Article 26 paragraph 3, Article 29, Articles 30*a*-30*d*, Article 38 paragraph 3, Article 39 paragraph 1, Article 41 paragraph 3, Article 44 paragraphs 2 and 3, Article 46 paragraphs 2 and 3, Article 48 paragraph 2 and Article 63 paragraph 2 of the Federal Act of 7 October 1983 on the Protection of the Environment (EPA)[2],
and on Article 9 paragraph 2 letter c, Article 27 paragraph 2 and Article 48 paragraph 2 of the Water Protection Act of 24 January 1991[3],
and in implementation of the Federal Act of 6 October 1995[4] on Technical Barriers to Trade,

ordains:

Title 1: General Provisions

Art. 1 Aim and scope

[1] This Ordinance regulates:

a. the determination and assessment of dangers and risks that substances and preparations may pose to human life and health and to the environment;

b. the conditions under which substances and preparations that may endanger people or the environment are placed on the market;

c. the handling of substances and preparations that may endanger people or the environment;

d. the way in which data relating to substances and preparations is processed by the enforcement authorities.

AS **2005** 2721
[1] SR **813.1**
[2] SR **814.01**
[3] SR **814.20**
[4] SR **946.51**

[2] This Ordinance applies to biocidal products and plant protection products insofar as they are referred to in the Ordinance of 18 May 2005[5] on Biocidal Products or the Ordinance of 18 May 2005[6] on Plant Protection Products.

[3] This Ordinance applies to radioactive substances and preparations, excluding effects attributable to the radioactive nature of these substances and preparations.

[4] Only Articles 7 to 10, 13 to 15 and 95 apply to cosmetic products[7] and only with regard to environmental protection and classification or evaluation in relation to risks to the environment.

[5] This Ordinance does not apply to:

a. the transport of substances and preparations by road, rail, water, air or pipelines;

b.[8] the transit of substances and preparations under customs supervision provided that they do not undergo any processing or transformation;

c. substances and preparations in the form of finished products ready for supply to the end consumer that fall into the following categories:

1. foodstuffs as defined by Article 3 of the Foodstuffs Act of 9 October 1992[9],
2. medicinal products as defined by Article 4 paragraph 1 letter a and medical devices as defined by Article 4 paragraph 1 letter b of the Therapeutic Products Act of 15 December 2000[10],
3. animal feedstuffs as defined by Article 2 paragraph 1 of the Feedstuffs Ordinance of 26 May 1999[11];

d. weapons as defined by Article 4 paragraph 1 and ammunition as defined by Article 4 paragraph 4 of the Weapons Act of 20 June 1997[12];

e. substances, preparations and objects which are waste according to Article 7 paragraph 6 of the EPA.

[6] Only Article 49 applies to substances and preparations that are imported, relabelled and then exported.[13]

Art. 2 Definitions

[1] By way of clarification of the definitions given in the Chemicals Act, in this Ordinance:

5 SR **813.12**
6 SR **916.161**
7 Expression in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821). This change has been made throughout the text.
8 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
9 SR **817.0**
10 SR **812.21**
11 SR **916.307**
12 SR **514.54**
13 Inserted by No. I of the Ordinance of 28 February 2007, in force since 1 April 2007 (AS **2007** 821).

a. *substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability 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;

b. …[14]

c.[15] *manufacturer* means

1. any natural or legal person domiciled in Switzerland or with a registered office or branch in Switzerland, who manufactures, extracts or imports substances, preparations or objects in a professional or commercial capacity.
2. Also deemed to be a manufacturer is any person who obtains substances, preparations or objects in Switzerland and supplies them on a commercial basis, without altering their composition:
   - under his own name, without specifying the name of the original manufacturer,
   - under his own trade name,
   - in packaging other than that intended by the original manufacturer, or
   - for some other purpose.
3. If a person arranges for the manufacture of a substance, preparation or object in Switzerland by a third party, this person is deemed to be the sole manufacturer if he is domiciled or has a registered office or branch in Switzerland.

[2] In addition, in this Ordinance:

a.[16] *object* means an article, consisting of one or more substances or preparations, which during production is given a special shape, surface or design which determines its end use function to a greater degree than does its chemical composition;

b. *existing substance* means any substance listed in EINECS[17] of 15 June 1990[18];

14 Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).

15 Amended in accordance with No. I of the Ordinance of 28 February 2007, in force since 1 April 2007 (AS **2007** 821).

16 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1. Feb. 2009 (AS **2009** 401).

17 European inventory of existing commercial chemical substances.*
* Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1. Feb. 2009 (AS **2009** 401).

18 OJ C 146 A of 15.6.1990, p.1, corrected in OJ C 54 of 1.3.2002, p. 13). The EINECS inventory can be consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; it can also be accessed on the Internet at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ein.*
* Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

c. *polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising:
   1. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and
   2. less than a simple weight majority of molecules of the same molecular weight; these molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. The term "monomer unit" means the reacted form of a monomer substance in a polymer;

d.[19] *intermediate* means a substance manufactured and used solely for chemical processing during which it is transformed into one or more other substances;

e. *secondary product* means any substance formed by chemical or biochemical transformation during the storage, use or disposal of a substance or preparation;

f. *classification* means the classification of substances on the basis of the hazardous properties defined in Articles 4 to 6 and indication of special risks (R phrases) listed in Annex 1, numbers 2.1 and 2.2;

g. *sole representative* means any natural or legal person that is authorised by a manufacturer whose domicile or registered office is located abroad to notify a substance in Switzerland and represents several importers designated by that manufacturer;

h.[20] *scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions and involving quantities of less than 1 tonne per year;

i.[21] *product and process-orientated research and development* means any scientific development connected with product development or the further development of a substance as such, or contained in a preparation or in an object in the course of which pilot plant or production trials are used to define the production process or test the fields of application of the substance.

j.[22] *robust study summary* means a detailed summary of the aims, methods, results and conclusions of a comprehensive study report providing information sufficient for an independent assessment of the test, thus minimising the need to consult the full study report.

19 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
20 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
21 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
22 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[3] Any other terms which are used in various senses in the legislation underlying this Ordinance are used here as defined in the Chemicals Act.

[4] The use of terms mentioned in Articles 56*a,* 56*c* and 56*d* is governed by the Regulation (EC) No. 1272/2008 of the European Parliament and the Council of 16 December 2008[23] on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006 (GHS Regulation).[24]

Art. 3 Hazardous properties

Substances and preparations are deemed to be dangerous if they have one of the properties referred to in Articles 4 to 6 and described in detail in Annex VI to Council Directive 67/548/EEC of 27 June 1967[25] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Directive 67/548/EEC).

Art. 4 Hazardous physico-chemical properties

Substances and preparations which have one of the following properties are deemed to have hazardous physico-chemical properties:

a. *explosive*: if they may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

b. *oxidising*: if they give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

c. *extremely flammable*: if they have an extremely low flash-point and a low boiling point or, as gases, are flammable in contact with air at ambient temperature and pressure;

d. *highly flammable*:[26] if they:

   1. may become hot and finally catch fire in contact with air at ambient temperature without any application of energy,

23 OJ L 353 of 31.12.2008, p. 1. The texts of European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

24 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

25 OJ L. 196 of 16.8.1967, p. 1, last amended by Directive 2006/121/EG of the European Parliament and the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating tot he classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, OJ. L 396 of 30.12.2006, p. 852.*
* Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401)

26 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821). This change has been made throughout the text.

2. in a solid state, may readily catch fire after brief contact with a source of ignition and continue to burn or to be consumed after removal of the source of ignition,
3. have a very low flash-point, or
4. in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

e. *flammable*: if they have a low flash-point.

Art. 5 Properties dangerous to health

Substances and preparations are deemed to have properties that are dangerous to health if they have one of the following properties:

a. *very toxic*: if they cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin in very low quantities;

b. *toxic*: if they cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin in low quantities;

c. *harmful*: if they can cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

d. *corrosive*: if they can, on contact with living tissues, destroy them;

e. *irritant*: if, without being corrosive, they can cause inflammation through immediate, prolonged or repeated contact with the skin or mucous membrane;

f. *sensitising*: if they can elicit a reaction of hypersensitisation following inhalation or skin contact such that on further exposure to the substance or preparation characteristic adverse effects are produced;

g. *carcinogenic*: if they can induce cancer or increase its incidence if they are inhaled or ingested or if they penetrate the skin;

h. *mutagenic*: if they can induce heritable genetic defects or increase their incidence if they are inhaled or ingested or if they penetrate the skin;

i. *toxic for reproduction*: if they can 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 if they are inhaled or ingested or if they penetrate the skin.

Art. 6 Properties dangerous to the environment

Substances and preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment are deemed to have properties dangerous to the environment.

Art. 6*a*[27] Persistence, bioaccumulation and toxicity

[1] Substances are considered *persistent, bioaccumulative and toxic (PBT)* if they fulfil the criteria defined in Chapter 1 of Annex XIII to Regulation (EC) No. 1907/2006 of the European Parliament and the Council of 16. December 2006[28] concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Regulation [EC] No. 1907/2006).

[2] Substances are considered *very persistent and very bioaccumulative (vPvB)* if they fulfil the criteria defined in Chapter 2 of Annex XIII to Regulation (EC) No. 1907/2006.

Title 2: Marketing Requirements

Chapter 1: Self-Regulation

Section 1: Fundamental Obligations

Art. 7

[1] The self-regulation system introduced by Article 5 of the Chemicals Act and Article 26 of the EPA requires manufacturers to assess whether substances or preparations may endanger human life or health or the environment. In accordance with this Ordinance, manufacturers must:

a. classify;

b. package and;

c. label substances and preparations;

d. prepare exposure scenarios and;

e. compile safety data sheets.[29]

[1bis] Manufacturers may classify substances and preparations that are not intended for distribution to the general public in accordance with Articles 8 and 10–15 or in terms of Article 56*a* according to the GHS Regulation requirements.[30]

27 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

28 OJ L 396 of 30.12.2006, p. 1, corrected in OJ L 136 of 29.5.2007, p. 3, last amended by Regulation (EC) No. 1354/2007 of 15 November 2007, OJ L 304 of 22.11.2007, p. 1. The texts of European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

29 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

30 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[1ter] For substances and preparations classified under Article 56*a*, Article 56*d* applies to their labelling and packaging and Article 56*e* to the subsequent obligations related to classification or labelling.[31]

[2] In the case of objects containing dangerous substances (dangerous constituents) or substances rated as PBT or vPvB, self-regulation under Article 26 of the EPA requires manufacturers to assess whether these substances may endanger the environment or indirectly endanger human health when these objects are used as intended, or in a foreseeable manner, or when they are appropriately disposed of. [32]

[3] Manufacturers must collect all available data of relevance to the obligations referred to in paragraphs 1 and 2.

[4] Anyone importing substances, preparations or objects with dangerous constituents in a professional or commercial capacity must comply with the obligations listed under paragraphs 1 and 2 before supplying them to a third party for the first time or, if they are for the importer's own use, before using them for the first time.

Section 2: Classification of Substances

Art. 8 Classification by the manufacturer

[1] Manufacturers must classify substances not covered by official classification on the basis of the criteria laid down in Annex VI to Directive 67/548/EEC.

[2] Classification must be based:

a. in the case of existing substances: on data collected in accordance with Article 7 paragraph 3;

b.[33] in the case of new substances: on data in the technical dossier as specified in Article 18 paragraph 2 letter b.

Art. 9 Official classification

[1] The Federal Department of Home Affairs (FDHA) may prescribe the classification and resultant labelling for certain substances with the agreement of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) and the Federal Department of Economic Affairs (FDEA). It may declare European classifications to be applicable.

[2] The Federal Office of Public Health (FOPH) may, with the agreement of the Federal Office for the Environment (FOEN)[34] and the State Secretariat for Economic Affairs (SECO), update the list of European classifications declared to be applicable.

31 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
32 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
33 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Section 3: Classification of Preparations

Art. 10 Principle

Manufacturers of preparations must classify these on the basis of their:

a. hazardous physical and chemical properties;

b. properties dangerous to health;

c. properties dangerous to the environment.

Art. 11 Classification with regard to hazardous physical and chemical properties

[1] Manufacturers of preparations must classify them with regard to hazardous physico-chemical properties on the basis of the criteria laid down in number 2 of Annex VI to Directive 67/548/EEC.

[2] The flammability and oxidising properties of gaseous preparations must be evaluated in accordance with number 9.1.1 of Annex VI to Directive 67/548/EEC.

[3] If the composition of a preparation is altered, there is no obligation to determine the physico-chemical properties of the altered preparation if it can be assumed, on the basis of the current state of scientific knowledge, that these properties would not lead to any change in the classification.

[4] Manufacturers are not required to classify preparations with regard to hazardous physico-chemical properties if:

a. the preparation is made up exclusively of substances not classified as explosive, oxidising, extremely flammable, highly flammable or flammable; and

b. the preparation itself is highly unlikely to have any of the properties listed in a above.

Art. 12 Classification with regard to properties dangerous to health

[1] Manufacturers of preparations must classify them with regard to properties dangerous to health using the calculation method described in Annex II to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[35] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Directive 1999/45/EC).

[2] Classification may also be based on test results, provided that:

34 The designation of this unit of the Federal Administration was amended in accordance with Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been made throughout the text.

35 OJ L 200 of 30.7.1999, p. 1, last amended by Directive 2006/08/EC (OJ L 19 of 24.01.2006, p. 12).*
* Wording in accordance with Section I of the Ordinance of 28 February 2007, in force since 1 April 2007 (AS **2007** 821).

a. it does not relate to carcinogenic, mutagenic or reproductive toxicity properties;

b. it can be demonstrated that the calculation method referred to in paragraph 1 is not appropriate for classifying the preparation; or

c. available results of animal tests do not permit correct classification.

[3] Classification based on test results must be established in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

[4] If a preparation has been classified both by the calculation method and on the basis of test results, the classification based on test results takes precedence.

[5] Where it can be demonstrated that the dangerous effects of a preparation on human health differ from the effects underlying the classification as specified in paragraphs 1 and 3, this preparation must be classified according to its effects on people. The demonstration must involve:

a. epidemiological studies;

b. scientifically valid case studies as specified in Annex VI to Directive 67/548/EEC; or

c. statistically backed experience from Switzerland or abroad, such as the assessment of data from poison information units or concerning occupational diseases.

[6] If, when a preparation is classified using the calculation method referred to in paragraph 1, it is demonstrated that the properties dangerous to health would be overestimated or underestimated because of interactions between the substances present in the preparation, these interactions must be taken into account in the classification.

Art. 13 Classification with regard to properties dangerous to the environment

[1] Manufacturers of preparations must classify them with regard to their properties dangerous to the environment:

a. using the calculation method described in Annex III to Directive 1999/45/EC; or

b. on the basis of test results as defined in Article 34, using the criteria laid down in Annex VI to Directive 67/548/EEC.

[2] If a preparation has been classified both by the calculation method and on the basis of test results, the classification based on test results takes precedence.

Art. 14 Concentrations requiring substances to be taken into consideration

If a preparation is classified using the calculation method, only those constituents dangerous to health or dangerous to the environment that are present in concentrations above the thresholds laid down in Article 3 paragraph 3 to Directive 1999/45/EC need be taken into consideration.

Art. 15 Re-evaluation with regard to properties dangerous to health or the environment

[1] Manufacturers of preparations must re-evaluate them when they:

a. replace or add a constituent; or

b. alter the composition of a preparation, thereby producing the following changes in initial concentrations:

1. in the case of constituents dangerous to health: as specified in Article 6 number 4 first indent of Directive 1999/45/EC,

2. in the case of constituents dangerous to the environment: as specified in Article 7 number 3 first indent of Directive 1999/45/EC.

[2] Re-evaluation is not required when it can be scientifically demonstrated that it would not result in any change to the initial classification.

Chapter 2: Notification of New Substances and Declaration of New Substances not subject to Notification Requirements

Section 1: Notification of New Substances

Art. 16[36] Obligation to notify

[1] Manufacturers of a new substance or their sole representative must notify the new substance to the Notification Authority before placing it on the market for the first time either alone or within a preparation or object from which it may be released under normal or reasonably foreseeable conditions of use.

[2] The Notification Authority may require the notification of a substance contained in an object if it has reason to believe that the substance may be released when the object is used.

Art. 16*a*[37] Relevant quantity of a substance

The decisive substance quantities mentioned in Articles 17, 18, 18*b*, 22, 59, and 60 and in Annex 3 are determined by the following criteria:

a. if the substance is manufactured within the European Economic Area (EEA): the total quantity manufactured annually in the EEA by a manufacturer, of which a part is supplied to the notifier;

b. if the substance is manufactured in Switzerland, the larger of the following quantities:

1. the annual quantity placed on the market in Switzerland, or

36 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

37 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

2. the largest quantity exported annually to a specific European importer in the EEA;

c. if the substance is manufactured outside Switzerland and the EEA and the notifier imports the substance directly from the country of manufacture: the annual quantity imported into Switzerland;

d. if the substance is manufactured outside Switzerland and the EEA and the notifier imports the substance from an EEA member state: the total quantity imported into the EEA annually by an importer, of which a part is supplier to the notifier.

Art. 17[38] Exemptions from the obligation to notify

[1] Notification is not required for:

a. polymers containing less than two per cent of a new substance in combined form;

b. substances that appear on the No-Longer Polymer-List[39];

c. substances for which the relevant quantity in accordance with Article 16*a* is less than 1 tonne per year;

d. substances placed on the market by a manufacturer:
   1. purely for product and process-orientated research and development purposes,
   2. limited to the quantities required for the said purposes and
   3. for a period not exceeding five years; upon justified request, the Notification Authority may in consultation with the assessment authorities extend this period by an additional five or ten years;

e. substances used exclusively as raw materials, active ingredients or additives in foodstuffs, therapeutic products and animal feedstuffs;

f. substances obtained in Switzerland;

g. intermediates.

[2] If there are reasons to suppose that a given substance that is exempt from notification under paragraph 1 may endanger people or the environment, the Notification Authority shall require the manufacturer to present certain test reports when so requested by an assessment authority. The requirements specified for these test reports must not go beyond those for the technical dossier referred to in Annex 3 number 7 letter a, number 8 letter a and number 9 letter a.

38 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

39 Notification of New Substances in accordance with Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous substances. No-Longer Polymer List Version 3 (EUR 20853 EN/3) 2007. The list can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; it can also be accessed on the Internet at www.cheminfo.

Art. 18[40] Form and content of the notification

[1] The notification must be submitted in quadruplicate. The accompanying letter must be written in an official language and submitted on paper. The information and documents may be written in English instead of in an official language and may be submitted on electronic media instead of on paper.

[2] The notification must contain the following information and documents:

a. the decisive substance quantity in accordance with Article 16*a* together with an indication of which of requirements (Art. 16*a* let. a, b, c or d) applies;

b. a technical dossier with the following information specified in Annex 3:
   1. the identity of the notifier,
   2. the identity of the substance,
   3. information on manufacture and use,
   4. classification and labelling,
   5. guidelines for safe use,
   6. if applicable, an exposure assessment,
   7. robust study summaries with regard to the physical and chemical properties,
   8. robust study summaries with regard to the properties harmful to health,
   9. robust study summaries with regard to the properties harmful to the environment.

c. if the decisive substance quantity in accordance with Article 16*a* amounts to 10 tonnes per year or more: a chemical safety report in accordance with Article 18*a*;

d. a proposed safety data sheet in the case of dangerous substances or PBT or vPvB substances;

e. all available documents and information on exposure and the substance's harmful effects on people and the environment, unless these are already apparent from the technical dossier described under letter b;

[3] Paragraph 2 letter c does not apply to new substances that are placed on the market in the form of preparations if the concentration of the substance is lower than the following levels:

a. the concentration limits described in part B of Annex II or part B of Annex III to Directive 1999/45/EC;

b. the concentration limits established during the official classification (Art. 9);

c. the applicable concentrations established in Article 3 paragraph 3 of Directive 1999/45/EC; or

d. 0.1 % by weight for PBT or vPvB substances.

40 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

4 If in the situations listed in Article 16a letter a or d, certain documents specified in paragraph 2 are not available, or if the notifier cannot reasonably be expected to obtain them, the notifier must provide corresponding proof.

5 The Notification Authority may request that the notifier provide test reports that exceed the scope of the technical dossier and that are relevant to the assessment of the substance, provided they are available and the notifier can reasonably be expected to obtain them.

Art. 18*a*[41] Chemical safety reports

The chemical safety report contains the chemical safety assessment in accordance with Annex I to Regulation (EC) No. 1907/2006. A chemical safety assessment includes the following steps:

a. a human health hazard assessment;

b. a physico-chemical hazard assessment;

c. an environmental hazard assessment;

d. PBT and vPvB assessment;

e. in the event that the substance has dangerous properties or PBT or vPvB properties:

   1. an exposure assessment covering all identified uses (exposure scenario),

   2. a description of the risks associated with all identified uses.

Art. 18*b*[42] Substances for which a notification has been submitted in the EU prior to 1 June 2008

1 For substances notified in the EU prior to 1 June 2008, the documents specified in Article 18 paragraph 2 numbers 2–9 may be replaced by the notification submitted in the EU and any updated information together with the corresponding notification number and the risk assessment, if available.

2 If the decisive substance quantity in accordance with Article 16*a* exceeds the quantity threshold for which the substance has been notified in the EU, the notification must contain the updated information in accordance with Article 18 paragraph 2 that corresponds to the higher quantity threshold.

3 When a new substance is notified for the first time, the Notification Authority may, in consultation with the assessment authorities, accept a summary of the technical dossier if the notifier demonstrates that:

a. the data protection period in the EU has expired; and

41 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

42 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

b. the identity of the substance and the content and identity of the impurities are identical to those for the substance notified in the EU.

Art. 19[43]

Section 2: Use of Data from Previous Notifiers and Data Protection Period

Art. 20 Use of data from previous notifiers

[1] The Notification Authority may refer to data from a previous notifier instead of data produced by the notifier if:

a. the new notifier proves with a letter of access from a previous notifier that the latter agrees to the Notification Authority consulting its data; or

b. the data protection period has expired.

[2] The notifier must not refer to data from previous notifiers regarding:

a. the identity and purity of the substance and the nature of any impurities;

b. action to render the substance harmless.

[3] The rules of competition law and intellectual property are not affected by the provisions of this section.

Art. 21 Data protection period

[1] The data protection period is 10 years.

[2] For data which must be submitted subsequently in accordance with Article 60, the protection period is 5 years. If the data protection period laid down in paragraph 1 has not yet expired, the protection period for data submitted subsequently is extended accordingly.

Art. 22 Mandatory advance enquiries to avoid tests on vertebrates

[1] Anyone planning tests on vertebrates for notification purposes must contact the Notification Authority in writing to enquire whether data from such tests is already available (Art. 12 of the Chemicals Act).

[2] This enquiry must contain information on:

a. the identity of the substance in accordance with Article 18 paragraph 2 letter b number 2;

b. the decisive substance quantity of the substance in accordance with Article 16*a*.[44]

43 Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).

Art. 23 Use of data from previous tests with vertebrates

[1] If the Notification Authority already has adequate data from previous tests with vertebrates, it shall inform the notifier of the extent to which further tests on vertebrates are unnecessary for the purposes of the notification.

[2] If the data is derived from vertebrate tests of previous notifiers and if the protection period for this data has not yet expired, the Notification Authority shall proceed as follows:

a. It shall provide the previous notifiers with information on:
   1. which parts of their data it intends to use for the benefit of the new notifier,
   2. the address of the new notifier;
b. It shall inform the new notifier of the addresses of the previous notifiers.

[3] Within 30 days, the previous notifiers may object to the immediate use of their data and apply for a delay in the use of the data.

[4] If no application for a delay is received, the Notification Authority shall order the use of the data.

[5] If an application for a delay is received, the Notification Authority shall order:

a. which parts of the data of the previous notifiers are to be used,
b. that notification of the substance is to be delayed by the period which would be required by the notifier to supply his own data.

[6] At the request of the new notifier, the Notification Authority shall draw up summaries of the data used; this does not prejudice the provisions on confidential data specified in Article 85.

Art. 24 Previous notifiers' entitlement to remuneration for data from tests on vertebrates

[1] The previous notifiers shall be entitled to fair remuneration from the new notifier for the use of their data from tests on vertebrates protected in accordance with Article 21.

[2] If the notifiers cannot reach agreement on remuneration within 6 months, the Notification Authority, at the request of one notifier, shall decide on the amount of the remuneration, taking the following factors in particular into account:

a. the costs incurred in obtaining the test results;
b. the remaining period of protection for the data concerned;
c. the number of entitled notifiers.

44 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[3] The previous notifiers may request the Notification Authority to prohibit the placing of the substance on the market until the new notifier has paid them the remuneration.

Section 3: Declaration of New Substances for Product and Process-orientated Research and Development[45]

Art. 25[46] Obligation to make a declaration

The manufacturer of a new substance that is exempt from notification under Article 17 paragraph 1 letter d or the manufacturer's sole representative must declare the new substance to the Notification Authority before placing it on the market for the first time either alone or as a constituent in a preparation or object from which the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Art. 26 Form and content of the declaration

[1] The declaration must be submitted in quadruplicate. The accompanying letter must be written in an official language and submitted on paper. The information and documents may be written in English instead of in an official language and may be submitted on electronic media instead of on paper.

[2] The declaration must contain the following information and documents:

a. the name and address of the manufacturer;

b. the name and address of the foreign manufacturer if the manufacturer has imported the substance;

c. essential data relating to the identity of the substance;

d. the intended uses;

e. the amount of the substance that the manufacturer intends to place on the market each year in Switzerland;

f. proposed classification and labelling;

g. the research programme and a list of the people to whom the substance is to be supplied;

h.[47] a proposed safety data sheet in the case of dangerous substances or PBT or vPvB substances.

[3] ...[48]

45 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
46 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
47 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Section 4: Procedure for Notification and Declaration

Art. 27 Confirmation of receipt and forwarding of the documents

[1] The Notification Authority shall confirm to the manufacturer or the sole representative the date on which the notification or declaration was received.

[2] If the documents are not obviously incomplete, the Notification Authority forwards them to the assessment authorities.

Art. 28 Review of the notification or declaration

[1] The assessment authorities, within their area of competence, shall assess whether:

a.[49] the submission is complete or if not, whether the reasons given by the notifier are valid;

a. the data is scientifically plausible;

b. the test reports are based on tests meeting the requirements laid down in Article 34.

[2] The assessment authorities shall report the results of their review to the Notification Authority.

Art. 29 Additions to the documents

[1] If the Notification Authority discovers that the documents are obviously incomplete, it must inform the manufacturer or sole representative accordingly without delay.

[2] If an assessment authority discovers that the documents are incomplete or inaccurate, or that further data or tests are required to assess the dangers associated with the substance in question, it shall inform the Notification Authority accordingly. The Notification Authority shall ask the manufacturer or sole representative to submit additions or corrections.

[2bis] If a robust study summary in accordance with Article 18 paragraph 2 letter b numbers 7–9 does not permit an independent assessment of a specific test, the Notification Authority may request the full study report.[50]

[3] The Notification Authority shall confirm to the manufacturer or the sole representative the date on which the additions and corrections were received.

48 Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
49 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
50 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 30 Acceptance of the notification or declaration

With the agreement of the assessment authorities, the Notification Authority shall order the acceptance of the notification or declaration if the review has shown that the notification or declaration documents are complete and adequate for assessment of the dangers and risks associated with the substance in question.

Section 5: Authorisation to Place Substances on the Market

Art. 31 Placing substances subject to notification requirements on the market

[1] Substances subject to notification requirements may be placed on the market if:

a. the Notification Authority has accepted their notification; or

b. 60 days have elapsed since the confirmed date of receipt of the notification and of any additions or corrections required thereafter, without the Notification Authority having issued any response.

[2] The period referred to in paragraph 1 letter b shall be reduced to 30 days if the notifier has submitted official confirmation that the substance was notified in the EU before 1 June 2008 and that the notification has been accepted.[51]

Art. 32 Placing substances subject to declaration requirements on the market

Substances subject to declaration requirements may be placed on the market if:

a. the Notification Authority has accepted their declaration; or

b. 30 days have elapsed since the confirmed date of receipt of the declaration and of any additions or corrections required thereafter, without the Notification Authority having issued any response.

Chapter 3: Requirements for Tests

Art. 33 Principle

[1] Manufacturers must ensure that the conduct of the tests, test methods and assessment of test results are in accordance with the current state of scientific and technical knowledge.

[2] The FDHA, DETEC and the FDEA may regulate technical details in their respective areas of competence.

[51] Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 34[52] Requirements

[1] Tests designed to determine the properties of substances and preparations must be carried out in accordance with:

a. the test methods defined in Council Regulation (EC) No. 440/2008 of 30 May 2008[53] laying down test methods pursuant to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); or

b. the Guidelines for the Testing of Chemicals drawn up by the Organisation for Economic Cooperation and Development (OECD) of August 2007[54] (OECD Guidelines for the Testing of Chemicals).

[2] Other test methods may be used if:

a. no method is specified in paragraph 1;

b. the manufacturer can show that a specified method for determining a given physico-chemical property is not suitable; or

c. the method is recognised in the EU in accordance with Article 13 paragraph 3 of Regulation (EC) No. 1907/2006.

[3] If other test methods are used, the manufacturer must show that these methods:

a. produce valid results; and

b. take due account of animal protection in the case of tests on animals.

[4] Non-clinical tests designed to determine properties that are dangerous to health or the environment must be carried out in accordance with the principles of Good Laboratory Practice (GLP) specified in the Ordinance of 18 May 2005[55] on Good Laboratory Practice.

[5] If certain tests do not comply with GLP principles or do not comply with them fully, the person submitting the test reports must state the reasons. The Notification Authority shall decide whether to accept these test results after consulting the assessment authorities.

52 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

53 OJ L 142 of 31.5.2008, p. 1. The texts of European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

54 OECD Guidelines for the Testing of Chemicals, August 2007. The texts of the guidelines can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch.

55 SR **813.112.1**

Chapter 4:
Packaging, Labelling, Exposure Scenarios and Safety Data Sheet[56]

Section 1: Packaging

Art. 35 Characteristics of packaging

[1] Packaging must be constructed in such a way that the substances and preparations contained therein do not present any risk to people or the environment during storage or transport.

[2] In particular, packaging must meet the following requirements:

a. it must be so designed and constructed that its contents cannot escape;

b. it must not be damaged by the contents;

c. it must not form harmful or dangerous compounds with the contents;

d. it must safely withstand the normal stresses and strains of handling; in particular, any fastenings must not loosen.

[3] The requirements specified in paragraphs 1 and 2 are deemed to be met if the packaging complies with the regulations concerning transport by post, rail, road, air, water and pipelines.[57]

Art. 36 Design of packaging

Packaging of dangerous substances and preparations sold to the general public must be designed so as not to:

a. attract or arouse the curiosity of children;

b. mislead consumers;

c. lead to confusion with packaging containing foodstuffs, cosmetic products, therapeutic products or animal feedstuffs.

Art. 37 Special provisions

[1] Containers for substances and preparations sold to the general public must be fitted with child-resistant fastenings if: [58]

a. the substances or preparations are labelled as toxic or corrosive;

b. the substances or preparations are labelled as harmful, with the R 65 phrase; this does not apply to aerosols or containers with a sealed spray attachment;

56 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
57 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
58 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).

c. the preparations have a methanol (CAS[59] No. 67-56-1) content equal to or greater than 3 per cent or a dichloromethane (CAS No. 75-09-2) content equal to or greater than 1 per cent.

[2] Containers for substances and preparations sold to the general public and labelled as toxic, harmful, corrosive, extremely flammable or highly flammable must be fitted with a tactile warning of danger. This does not apply to aerosols labelled only as extremely flammable or highly flammable.[60]

[3] The technical properties of the child-resistant fastenings and tactile warnings of danger must comply with Annex IX to Directive 67/548/EEC.

[4] Aerosol dispensers not covered by the Foodstuffs Act of 9 October 1992[61] are subject both to the packaging provisions of this Ordinance and to Articles 1 and 2 of, and numbers 2.1, 3, 4, 5 and 6 of the Annex to Council Directive 75/324/EEC of 20 May 1975[62] on the approximation of the laws of the Member States relating to aerosol dispensers.[63]

Art. 38 Exemptions

Articles 35 to 37 do not apply to explosives or pyrotechnic devices within the meaning of the Explosives Act of 25 March 1977[64], with the exception of pyrotechnic devices designed to produce toxic gases, smoke or dusts.

Section 2: Labelling

Art. 39[65] Labelling of dangerous substances and preparations

[1] Manufacturers supplying dangerous substances or preparations to third parties must ensure that their label states:

a. the name of the substance or preparation;

b. the manufacturer's name, address and telephone number; if the substance or preparation is imported from an EEA Member State and is not intended for distribution to the general public, the manufacturer's name may be replaced by the name of the person responsible for placing it on the market in the EEA defined in Article 10 number 2.2 of the Directive 1999/45/EC.

59 Number assigned by the Chemical Abstracts Service (CAS) to facilitate the identification of substances.
60 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
61 SR **817.0**
62 OJ L 147 of 9.6.1975, p. 40; last amended by Directive 94/1/EC (OJ L 23 of 28.1.1994, p. 28).
63 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
64 SR **941.41**
65 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

c. the fill quantity, if the substances and preparations are made available to the general public;

d. the danger symbols and indications of danger in accordance with Annex1 number 1;

e. the R-phrases in accordance with Annex 1 number 2, indicating special risks;

f. the S-phrases in accordance with Annex 1 number 3, providing safety advice;

g. the chemical name of the dangerous substances in a preparation in accordance with Annex 1 number 4;

h. the EC number[66] for substances.

[2] The chemical name of a dangerous substance must conform to:

a. the official designation in the case of officially classified substances;

b. an internationally recognised nomenclature in the case of substances not officially classified.

Art. 40[67] Labelling preparations posing particular hazards

[1] In addition to the information required by Article 39 paragraph 1 letters a and b, preparations posing particular hazards are subject to the provisions of Annex 1Annex 1 number 5:

Art. 41 and **42**[68]

Art. 43 Protection of the confidentiality of the formulation of a preparation

[1] If the label of a preparation cannot indicate the chemical name of a dangerous substance without putting at risk the confidentiality of the formulation of the preparation, the manufacturer may refer to this substance in accordance with the provisions of Part B of Annex VI to Directive 1999/45/EC either by means of a name that identifies the most important functional groups or by means of an alternative name, if the substance has to be labelled as follows:

a. exclusively as irritant, without R 41 being allocated to it;

b. as irritant and as explosive, oxidising, highly flammable, flammable, extremely flammable or dangerous to the environment, without R 41 being allocated to it;

c. exclusively as harmful; or

66 Number allocated by the European Commission to all registered existing and new substances.

67 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

68 Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).

d. as harmful and as explosive, oxidising, highly flammable, flammable, extremely flammable, irritant or dangerous to the environment.

2 Manufacturers wishing to protect the confidentiality of the formulation of a preparation must make a request in writing to the Notification Authority.

3 Protection of the confidentiality of the formulation may be required for a preparation:

a. in a specific composition;

b. with a specific trade name or a specific designation;

c. containing a substance whose identity must be kept secret in connection with labelling;

d. reserved for certain uses.[69]

4 Personal and non-transferable protection of the confidentiality of the formulation of a preparation shall be granted to a specific manufacturers.[70]

Art. 44 Request to protect the confidentiality of the formulation of a preparation

1 Requests to protect the confidentiality of the formulation of a preparation must contain:

a. the manufacturer's name, address and telephone number;

b. the following information relating to the substances whose identity is to remain confidential on the label:
   1. the chemical name,
   2. the CAS number,
   3. the EC number;

c. the alternative name of the substance;

d. the reasons for the request;

e. the trade name or designation of the preparation;

f. the information on the constituents in accordance with the provisions relating to the safety data sheet;

g. the classification of the preparation;

h. the labelling of the preparation;

i. the intended uses of the preparation;

j. the physical state;

k. if applicable, the safety data sheet.

69 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

70 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[2] The Notification Authority shall decide on the request in agreement with the assessment authorities.

Art. 45 Prohibition on misleading labelling

The labelling and presentation of dangerous substances and preparations must not give the impression that they are not dangerous; in particular, they must not be marked with words such as "non-toxic", "not harmful", "environment-friendly", "non-polluting" or "ecological".

Art. 46 Optional labelling

[1] Manufacturers may provide further indications of dangers for the environment and of protection measures, as shown in Annex 1 number 7, on the packaging of substances, preparations or objects.

[2] If Annex 1 number 7 requires a specific pictogram to be used, manufacturers must not use a different pictogram unless they can demonstrate that it is in common international use.

Art. 47 Implementation of labelling

[1] Labelling information must appear on each package or on a label that is firmly affixed to the packaging. It must be written in at least two official languages and be clearly visible, legible and durable. [71]

[1bis] ... [72]

[2] The details of implementation are based on the provisions of Annex 1 number 6.

[3] With the agreement of individual commercial end users, a substance or a preparation for supply to these end users may be labelled in only one official language or in English. [73]

Art. 48[74] Inner and outer packages

[1] The provisions of Articles 39 to 47 are deemed to have been met if:

a. the outer package is labelled in accordance with the regulations concerning transport by post, rail, road, air, water and pipelines; and

b. the inner package is labelled in accordance with Articles 39 to 47 before the application of or immediately after the removal of the outer package. Responsibility for packaging and labelling rests with the manufacturer.

71 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
72 Inserted by No. I of the Ordinance of 28 Feb. 2007 (AS **2007** 821). Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
73 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
74 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).

[2] In the case of a single package, the danger symbols and indications of danger may be omitted provided that the labelling requirements specified in paragraph 1 letter a are met. This does not apply, in the case of preparations, to the danger symbol N and the indication of danger "dangerous for the environment" if they do not appear in this form on the label.

Art. 48*a*[75] Derogations from the labelling and packaging requirements

[1] The Notification Authority may, after consultation with the assessment authorities, permit derogations from the labelling requirements for certain products or groups of products and allow these not to be labelled or to be labelled in different form:

a. if the packages are too small or otherwise unsuitable for labelling in accordance with Articles 39 to 47; or

b. if the products are distributed in such small quantities that that they pose no risk to humans or the environment.

[2] The Notification Authority shall issue a ruling or a general ruling in response to a reasoned application.

[3] The Notification Authority shall draw up a list of the derogations that have been permitted and make it available to the public.

Art. 49 Labelling of substances and preparations for export

[1] Anyone who exports substances or preparations must label them with at least the following information, taking account of the relevant international standards:

a. the manufacturer's name;

b. the chemical name or trade name;

c. inscriptions concerning the dangers to human health and the environment together with the relevant precautions.

[2] The labelling must be in at least one official language of the importing country, if this can be achieved at reasonable expense. In other cases, the most widely used foreign language in the importing country must be chosen.

Art. 50[76] Exemptions

[1] Articles 39 to 49 do not apply to explosives or pyrotechnic devices (Art. 38), with the exception of pyrotechnic devices designed to produce toxic gases, smoke or dusts.

[2] Articles 40–42[77] do not apply to the following dangerous substances and preparations provided that, in the form in which they are placed on the market, they do not

75 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
76 Amended in accordance with No. I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
77 Now only Art. 39.

represent a danger either to human health as a result of inhalation, ingestion or skin contact, or to water bodies:

a. metals in massive form,

b. alloys,

c. preparations containing polymers or elastomers.

[3] Substances and preparations classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R 65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.

Section 2*a*.:[78] Exposure Scenarios

Art. 50*a*

[1] The manufacturer of an existing dangerous or PBT or vPvB substance that is distributed as such to third parties in a total quantity of 10 tonnes per year or more must prepare an exposure scenario for each identified use of the substance, describing the conditions of use and the relevant risk management measures.

[2] The exposure scenarios must be prepared in accordance with Annex I number 5 to Regulation (EC) No. 1907/2006.

Section 3: Safety Data Sheet

Art. 51 Purpose

Safety data sheets are designed to enable people handling substances or preparations in a professional or commercial capacity to take the measures required for health protection, occupational safety and environmental protection.

Art. 52[79] Obligation to compile a safety data sheet

Where the provision of a safety data sheet is required under Article 54, the manufacturer must compile a safety data sheet for the following substances and preparations:

a. dangerous substances and preparations;

b. PBT or vPvB substances;

c. substances specified in Annex 4;

d. preparations containing at least one substance that is dangerous to health or to the environment in an individual concentration of ≥ 1.0 per cent by weight

78 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

79 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

(non-gaseous preparations) or ≥ 0.2 per cent by volume (gaseous preparations);

e. preparations containing at least one PBT or vPvB substance in an individual concentration of ≥ 0.1 per cent by weight (for non-gaseous preparations);

f. preparations containing at least one substance for which a workplace exposure limit has been laid down in Commission Directive 2000/39/EC of 8 June 2000[80] establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Art. 53 Requirements for safety data sheets and their compilation

[1] Safety data sheets must comply with the requirements laid down in Annex 2.

[1bis] The exposure scenarios specified in the chemical safety report (Art. 18*a*) or prepared in accordance with Article 50*a*, must be attached to the safety data sheet.[81]

[1ter] The safety data sheets relating substances and preparations classified and labelled in accordance with Articles 56*a*–56*d* must include the classification in accordance with the GHS Regulation together with the classification in accordance with Articles 8 and 10–15 for the substance, preparation and their individual constituents.[82]

[2] The FDHA may, in consultation with DETEC and the FDEA, define the technical expertise required for the compilation of safety data sheets.

Art. 54 Obligation to provide safety data sheets

[1] Anyone acting in a commercial capacity who supplies substances or preparations referred to in Article 52 to people who handle these in a professional or commercial capacity must provide them with a safety data sheet.

[2] The safety data sheet must be provided:

a. when supplying a substance or a preparation as defined in Article 52 letters a–c: at the latest at the time it is first supplied, and if requested with other deliveries;

b. when supplying a preparation as defined in Article 52 letters d-f: on request. [83]

80 OJ L 142 of 16.6.2000, p. 47, last amended by Commission Directive 2006/15/EC of 7. Feb. 2006, OJ L 38 of 9.2.2006, p. 36. The texts of European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

81 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

82 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

83 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[3] In the case of substances and preparations supplied via a retail outlet, the obligation to provide safety data sheets exists when a professional or commercial user asks for a safety data sheet.

[4] Safety data sheets must be provided free of charge in the official languages requested by the recipient, but may also be provided in another language by mutual agreement.

[5] Safety data sheets may be provided on paper or, by mutual agreement, in electronic form.

Art. 55 Obligation to provide revised safety data sheets

[1] The supplier must provide safety data sheets which have been revised on account of important new information free of charge to all professional or commercial customers supplied with the substance or preparation concerned within the previous twelve months.

[2] This obligation to provide revised safety data sheets does not apply to safety data sheets provided through retail outlets.

Art. 56 Obligation to retain safety data sheets

Professional or commercial customers are required to retain the safety data sheet for as long as the substance or preparation in question continues to be handled at their workplace.

Chapter 4*a*:[84] Classification, Labelling and Packaging in accordance with the GHS Regulation

Art. 56*a* Principle

The manufacturer who, according to Article 7, paragraphs 1 and 4, is responsible for classifying substances and preparations may, in derogation from Articles 8 and 10-15, classify these according to the GHS Regulation and according to the provisions of Article *56c* if these are not intended for distribution to the general public.

Art. 56*b* Equivalences

[1] Where the GHS Regulation refers to the "supplier", "manufacturer", "importer" or "downstream user", this Ordinance uses the term "manufacturer".

[2] Where the GHS Regulation refers to "mixtures", this Ordinance uses the term "preparations".

[84] Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 56*c* Classification

If classification is based on Article 56*a*, the manufacturer must:

a. classify the substances and preparations in accordance with the requirements of Title II of the GHS Regulation;

b. classify the substances in accordance with Article 4 paragraph 3 of the GHS Regulation, according to Article 9, official classification of the substance has been specified by the FDHA.

2 Existing classifications of substances and preparations in accordance with Articles 8 and 10–15 may be converted in accordance with the requirements of Annex VII to the GHS Regulation.

3 The classification in accordance with the GHS Regulation together with the classification in accordance with Articles 8 and 10–15 must be specified in the safety data sheet cited in Article 53 paragraph 1ter.

Art. 56*d* Labelling and packaging

1 If substances or preparations are classified in accordance with Article 56*a*, they must be labelled and packaged in accordance with Titles III and IV of the GHS Regulation.

2 The labelling must comply with the requirements of Title III of the GHS Regulation as well as the following requirements:

a. the name, address and telephone number must be indicated in accordance with Article 39 paragraph 1 letter b for substances and preparations classified in accordance with Article 56*a*;

b. the text on the label must be written in the languages specified in Article 47 paragraphs 1 and 3.

3 In addition to the requirements of Title III of the GHS Regulation, the information on the label may include further hazard categories provided it complies with the requirements of the Globally Harmonised System of Classification and Labelling of Chemicals[85].

4 Substances and preparations that do not require any labelling in accordance with Articles 39–50 but which are subject to labelling requirement in accordance with the requirements of the GHS Regulation may be placed on the market with labelling satisfying these requirements.

Art. 56*e* Subsequent obligations

As regards subsequent obligations relating to the classification or labelling of substances and preparations which, in accordance with Articles 56*a* and 56*d*, are al-

85 Version of the United Nations, New York & Geneva, 2007 (2nd revised edition). The texts of legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

ready classified and labelled according to the GHS Regulation, the classification according to Articles 8 and 10-15 contained in the safety data sheet and the resulting labelling according to Annex 1, sections 1-3 must be taken into account

Title 3: Obligations after Placing on the Market

Chapter 1: Taking Account of new Information Relevant to Assessment, Classification and Labelling

Art. 57 Reassessment of substances, preparations and objects

Manufacturers must reassess or further assess substances, preparations and objects containing dangerous constituents and reclassify them where necessary if:

a. they are to be supplied for different purposes;

b. they are to be used in a different way;

c. they are to be used in much larger quantities than before;

d. variations arise in the nature and quantity of impurities, which could have adverse effects on human health or the environment;

e. the evaluation of the risks they pose to human health or the environment needs to be modified in the light of practical experience, new data or new information.

Art. 58 Updating and retention of documents

[1] Manufacturers are required to update documents continuously with new information relevant to health and the environment for as long as they continue to supply the substance, preparation or object containing dangerous constituents.

[2] They must retain or ensure the availability of the main documents used in the assessment and classification, together with the results of the assessment and classification, for at least ten years after the products are last placed on the market. They must retain samples and specimens for as long as their condition allows them to be analysed.

Chapter 2: Updated Information and Additional Test Reports on new Substances

Art. 59 Updated information

[1] Notifiers must inform the Notification Authority in writing without delay, if:

a. the details referred to in Article 18 paragraph 2 letter b numbers 1-6 or Article 26 paragraph 2 change;

b. the decisive substance quantity in accordance with Article16*a* is likely to have reached one of the thresholds laid down in Article 60 paragraph 1; in this case, the notifier shall specify which tests it intends to conduct in order to produce the supplementary information mentioned in Article 60 paragraph 1;

c. the decisive substance quantity in accordance with Article16*a* has increased or decreased by a factor of more than two compared with the quantity last notified;

d. new information comes to their attention regarding the effects of the substance on human health or the environment;

e. they place the substance on the market for a new use or become aware that this substance is being used for purposes other than those indicated to the Notification Authority;

f. they compile, or have compiled for them, test reports going beyond the technical dossier referred to in Article 18 paragraph 2 letter b for the substance in question;

g. they are able to obtain other test reports going beyond the technical dossier referred to in Article 18 paragraph 2 letter b.[86]

[2] Sole representatives must ensure that they have access to up-to-date data, particularly as regards the quantities of substances imported annually by the importers they represent.

[3] Importers represented by a sole representative for notification of a new substance must inform that representative annually of the imported quantities of the substance concerned.

Art. 60[87] Information to be submitted based on quantities

[1] Notifiers of a substance must provide the Notification Authority with the following additional information based on the decisive subtance quantity in accordance with Article16*a*:

a. for quantities of 10 tonnes per year or more: the information mentioned in Annex 3 number 8 letter b and number 9 letter b and a chemical safety report in accordance with Article 18*a*;

b. for quantities of 100 tonnes per year or more: the information mentioned in Annex 3 number 7 letter b, number 8 letter c, number 9 letter c and a chemical safety report in accordance with Article 18*a*;

c. for quantities of 1,000 tonnes per year or more: the data mentioned in Annex 3 number 8 letter d, number 9 letter d and a chemical safety report in accordance with Article 18*a*.

86 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

87 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[2] After receiving the information specified in Article 59 paragraph 1 letter b, the Notification Authority shall in accordance with Article 23 inform the notifier of the data that it already holds.

[3] If the risks associated with a given substance cannot be adequately evaluated, the Notification Authority shall, if so requested by an assessment authority, require the notifier to submit additional information or carry out additional tests relating to the substance or its transformation products.

[4] The Notification Authority, after consulting the notifier and with the agreement of the assessment authorities, shall draw up a timetable for carrying out the additional tests.

[5] If the notifier fails to submit the additional test reports by the specified deadline, the Notification Authority may arrange for the required tests to be carried out at the notifier's expense and, if necessary, prohibit the notifier from continuing to place the relevant substance on the market.

Chapter 3: Obligation to Register

Art. 61[88] Obligation to register existing dangerous, PBT or vPvB substances and dangerous preparations

Manufacturers of existing dangerous, PBT or vPvB substances and dangerous preparations must register them with the Notification Authority within 3 months after first placing them on the market if they:

a. are likely to be placed on the market in quantities in excess of 100 kg per year; or

b. are very toxic, toxic, carcinogenic, mutagenic or toxic to reproduction or if they are identified as PBT or vPvB or are listed in Annex 4, which corresponds to Annex XIV to Regulation (EC) No. 1907/2006, and are likely to be placed on the market in quantities in excess of 10 kg per year.

Art. 62[89] Obligation to register certain dangerous new substances

Manufacturers of very toxic, toxic, carcinogenic, mutagenic or toxic-to-reproduction new substances which are exempt from the obligation to notify in accordance with Article 17 must register them with the Notification Authority within 3 months after first placing them on the market:

a. if they are classified as very toxic, toxic, carcinogenic, mutagenic or toxic to reproduction or if they are identified as PBT or vPvB; or

88 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

89 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

b. if they are expected to be placed on the market in quantities exceeding 10 kg per year.

Art. 63[90] Obligation to register non-dangerous preparations

[1] Manufacturers of preparations not classified as dangerous that must be accompanied by a safety data sheet and are sold to the general public must register them with the Notification Authority within 6 months after first placing them on the market if they are likely to be placed on the market in quantities in excess of 100 kg per year and if the preparation:

a. the preparations are sold to the general public; or

b. the preparations contain at least one substance listed in Annex 4.

[2] If the identity of the manufacturer is not mentioned on the label, the preparations must be registered as specified in paragraph 1 before they are sold to a third party for the first time.

Art. 64 Content of the registration application

[1] The registration application must contain the following data:

a. the manufacturer's name and address;

b. name of the person responsible for placing on the market in the EEA in accordance with Article 10 number 2.2 of the Directive 1999/45/EC, if the manufacturer's identity is not mentioned on the label;

c. in the case of substances as defined in Articles 61 and 62:
   1. the chemical name according to Article 40 paragraph 2,
   2. the CAS number,
   3. the EC number,
   4. the classification and labelling;
   5. if applicable, the identification as a PBT or vPvB substance,
   6. the chemical safety report available in the EEA, provided the notifier can reasonably be expected to obtain it;

d. in the case of dangerous preparations as defined in Article 61 and non-dangerous preparations as defined in Article 63:
   1. the trade name,
   2. data relating to the constituents in accordance with the provisions relating to the safety data sheet,
   3. the name and concentration of the substances listed in Annex 4, stating whether the European Commission has granted authorisation for the intended uses,
   4. the classification and labelling,

90 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

5. the intended uses,
6. the physical state. [91]

[2] In the case of preparations already notified or declared in accordance with the provisions of existing law before this Ordinance comes into force, only the labelling and the quantity likely to be placed on the market annually according to the categories defined in Article 65 paragraph 4 need to be registered. [92]

Art. 65 Extended registration application

[1] In the case of dangerous preparations sold to the general public, the Notification Authority must be informed of the full composition. Non-dangerous constituents may be designated in accordance with Part B of Annex VI to Directive 1999/45/EC either by a name that identifies the most important functional groups or by an alternative name.

[2] In the case of new substances subject to registration in accordance with Article 62, the following information must be submitted in addition to the data referred to in Article 64 1 letter c.

a. the molecular and structural formulas;
b. the degree of purity (as a percentage);
c. the nature and the percentage of impurities;
d. the intended uses;
e. the physical state of the substance;
f. all available information on the physico-chemical properties, and properties harmful to health and to the environment;
g. all available information on the exposure assessment.[93]

[3] In the case of carcinogenic, mutagenic or toxic-to-reproduction existing substances, the registration application must include a list and summary of all the data on which the classification is based, in addition to the data referred to in Article 64 paragraph 2. If so requested by an assessment authority, the Notification Authority may subsequently call for the detailed data.

[4] In the case of existing substances dangerous to the environment and preparations dangerous to the environment, the registration application must include, in addition to the data referred to in Article 64 paragraph 1, the quantity likely to be placed on the market annually within one of the following categories: less than 1 tonne, between 1 and 10 tonnes, between 10 and 100 tonnes, more than 100 tonnes. [94]

91 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
92 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2009 (AS **2009** 401).
93 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
94 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

Art. 66 Form of the registration application and the extended registration application

[1] The registration application and extended registration application described in Article 65 paragraph 1 must be submitted:

a. using an electronic form or, where this is justified, on a paper form which can be processed electronically;

b. in an official language or in English.

[2] The additional information and data described in Article 65 paragraphs 2 to 4 must be submitted:

a. on electronic media or on paper;

b. in an official language or in English.

Art. 67 Modifications

[1] Any modifications to the data referred to in Article 64 paragraph 1 and Article 65 paragraphs 1 to 3 must be registered within 3 months.

[2] If the quantity of existing substances dangerous to the environment and preparations dangerous to the environment actually supplied in a year is outside the registered category of quantities placed on the market (Art. 65 paragraph 4), the quantity placed on the market in the previous year must be registered by 31 March of the following year in accordance with the categories specified in Article 65 paragraph 4.[95]

Art. 68[96] Special form of compliance with the obligation to register

The obligations to register in accordance with Articles 61 and 63 are deemed to have been met if a request to protect the confidentiality of the formulation (Art. 44) has been submitted and the Notification Authority possesses to the information that is required by Article 64 and, if applicable, in Article 65.

Art. 69 Exemptions from the obligation to register

The registration requirements specified in this Chapter do not apply to:

a. substances and preparations which are classified only as highly flammable or flammable;

b. intermediates;

c. substances and preparations placed on the market solely for research and development;

95 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

96 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

d. [97] substances and preparations used exclusively for foodstuffs, therapeutic products and animal feedstuffs;

e. fertilisers which require authorisation from the Federal Office for Agriculture (FOAG) or have to be notified to the FOAG under the Fertiliser Ordinance of 10 January 2001[98];

f. [99] explosives and pyrotechnic devices which require authorisation under the Explosives Ordinance of 27 November 2000[100];

g. [101] substances obtained in Switzerland;

h. [102] preparations obtained in Switzerland and supplied in packaging other than that intended by the original manufacturer, provided that:

1. the trade name, composition and intended use are unchanged, and
2. the name of the original manufacturer is also indicated;

i. [103] gas mixtures consisting exclusively of registered gases.

Title 4: Handling of Substances, Preparations and Objects

Chapter 1: General Provisions

Art. 70 Taking account of the information provided by the manufacturer

[1] Substances, preparations and objects may be promoted, offered or supplied professionally or commercially only for the uses and methods of disposal stated by the manufacturer.

[2] The advice and instructions given on the package and in the safety data sheet must be taken into account.

Art. 71 Environmental release

[1] Substances and preparations may be released directly into the environment only to the extent that is necessary for the intended use.

[2] To this end, users must:

a. use equipment allowing correct and accurate application;

97 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
98 SR **916.171**
99 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
100 SR **941.411**
101 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
102 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
103 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

b. take steps to prevent substances and preparations, as far as possible, from entering surrounding areas or water bodies;

c. take steps to ensure that, as far as possible, animals, plants, their biocoenoses and habitats are not threatened.

[3] Preparations may be released directly into the environment only for the uses specified by the manufacturer.

Art. 72 Storage

[1] When substances and preparations are stored, the advice and instructions given on the package and, if applicable, in the safety data sheet must be taken into account.

[2] Dangerous substances and preparations and their containers must be protected against hazardous impacts, especially those of a mechanical nature.

[3] Dangerous substances and preparations must be clearly identifiable and kept separate from other goods. No foodstuffs, animal feedstuffs or therapeutic products may be kept in the immediate vicinity.

[4] Paragraphs 1 to 3 also apply to objects from which substances or preparations are released in quantities that may endanger human health or the environment.

[5] Substances and preparations that may react dangerously with each other must be stored separately.

[6] Dangerous substances and preparations that are not commercially supplied may only be filled and stored in containers meeting the following requirements:

a. the packaging must not be capable of being confused with packaging containing foodstuffs, cosmetics, therapeutic products or feedstuffs;

b. the name of the substance or preparation must be given in the labelling; and

c. the construction of the packaging must comply with the requirements of Article 35.[104]

Art. 73 Specific obligations when supplying substances and preparations

Anyone who supplies a substance or preparation in a commercial capacity and is required to provide a safety data sheet to the purchaser must be familiar with and capable of interpreting the content of the safety data sheet.

Art. 74 Chemicals contact person

[1] Companies and educational establishments must notify the cantonal enforcement authorities of their chemicals contact person, to be appointed under Article 25 paragraph 2 of the Chemicals Act.

[2] The FDHA sets down the rules for mandatory notification in accordance with paragraph 1; it defines the form and content of the notification.

104 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

[3] It defines the requirements that the chemicals contact person must meet, particularly with regard to technical qualifications and operational responsibilities.

Art. 75 Advertising

[1] Advertising for substances, preparations and objects must not give a misleading impression as to the risks posed to human health and the environment or as to their environmental acceptability, and must not encourage inappropriate use or disposal.

[2] Terms such as "degradable", "environmentally harmless", "environment-friendly" and "water-friendly" may be used in advertising only if the properties thus described are at the same time explained in more detail.

[3] Anyone who advertises dangerous substances or preparations that the general public can purchase without seeing the labelling beforehand must indicate their hazardous properties in a comprehensible and clearly legible or audible manner. [105]

Chapter 2: Handling of Particularly Dangerous Substances and Preparations

Art. 76[106] Particularly dangerous substances and preparations

The following are deemed to be particularly dangerous if:

a. substances and preparations that must be labelled:
   1. as very toxic,
   2. as toxic,
   3. as corrosive,
   4. as explosive,
   5. as highly flammable, with the R-phrases R 15 or R 17,
   6. with one of the following R-phrases, which indicate additional physico-chemical hazards: R 1, R 4, R 5, R 6, R 16, R 19 or R 44, or
   7. as dangerous to the environment, with R-phrase R 50/53, in the case of packages containing more than 1 kg; or

b. PBT or vPvB substances and preparations containing at least one such substance in an individual concentration of ≥ 1.0 per cent by weight;

c. substances listed in Annex 4 and preparations containing at least one such substance in an individual concentration of ≥ 1.0 per cent by weight;

d. substances and preparations intended for self-defence.

105 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

106 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 77[107] Storage

[1] For the storage of particularly dangerous substances or preparations, the provisions of Article 72 apply.

[2] Anyone storing such substances or preparations must ensure that they are not accessible to unauthorised persons.

[3] Such substances or preparations that are not commercially supplied may only be filled and stored in containers if these are labelled with the required danger symbols.

Art. 78 Exclusion of self-service

[1] Self-service must not be permitted for:

a. particularly dangerous substances and preparations as defined in Article 76 letter a if they are supplied to the general public;

b. [108]particularly dangerous substances and preparations as defined in Article 76 letters b-d. [109]

[2] Paragraph 1 does not apply to engine fuels.

Art. 79 Supply restrictions

[1] Substances and preparations labelled as very toxic must not be supplied to the general public.

[2] Particularly dangerous substances and preparations may be commercially supplied only to adults. [110]

[3] Paragraph 2 does not apply to legal minors who have to handle these substances, preparations or products in a professional or commercial capacity.

[4] Paragraphs 1 and 2 do not apply to engine fuels.

Art. 80 Special obligations with regard to supply

[1] Anyone supplying a substance or preparation in a commercial capacity must inform the purchaser expressly of the precautions required and the correct method of disposal if the substance or preparation is labelled as follows:

a. the substance or preparation is labelled as follows:
   1. very toxic;
   2. toxic with R-phrases R 45, R 46, R 49, R 60 or R 61; or
   3. explosive.

107 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
108 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
109 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
110 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

b. if the substance or preparation is considered to be particularly dangerous as defined in Article 76 letter b or c.[111]

[2] Anyone supplying a particularly dangerous substance or a particularly dangerous preparation in a commercial capacity to the general public must inform the purchaser in an appropriate manner, at the time of supply, of the precautions required and the correct method of disposal. [112]

[3] When supplying commercially to the general public any substances or preparations labelled as toxic, explosive or corrosive with R-phrase R 35 or any preparations intended for self-defence, the supplier must, in addition to the obligations laid down in paragraph 2: [113]

a. check the purchaser's identity on the basis of a passport or identity card and record the following information:
   1. the purchaser's name and address,
   2. the name and quantity of the substance or preparation,
   3. the intended uses,
   4. the date of supply;

b. require the purchaser to confirm in writing that he or she will use the substances or preparations correctly and observe the manufacturer's safety instructions.

[3bis] The shipment of substances and preparations intended to be used for self-defence is exempt from the obligations laid down in paragraph 3: in this case, the consignment must be dispatched by registered post and marked "delivery to addressee only". [114]

[4] The supplier must retain the records made in accordance with paragraph 3 for 3 years after last supplying the substance or preparation.

[5] Substances and preparations may be supplied in accordance with paragraphs 2 and 3 only to persons who can be assumed by the supplier to be capable of sound judgement and able to comply with the duty of care under Article 8 of the Chemicals Act and the requirements set out in Article 28 of the EPA.

[6] The obligations referred to in paragraphs 1 to 4 do not apply to the supply of engine fuels.

111 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
112 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
113 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
114 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

Art. 81 Knowledge required to supply

[1] Anyone supplying a particularly dangerous substance or a particularly dangerous preparation in a commercial capacity to the general public must have special knowledge. The Federal Department of Home Affairs may provide for exemptions. [115]

[2] The FDHA may regulate:

a. how the knowledge requirements are to be met; in this connection, it takes into account professional training and experience;

b. the content, duration and organisation of courses for people seeking to acquire such knowledge.

3 Article 11 of the Chemical Risk Reduction Ordinance of 18 May 2005[116] (ORRChem) applies by analogy.[117]

Art. 82 Theft, loss, erroneous placing on the market

[1] In the event of the theft, loss or erroneous placing on the market of substances or preparations that are very toxic, toxic, corrosive or explosive, the person suffering the theft or loss or the person who placed the substance or preparation on the market must notify the police without delay.

[2] The police must inform the cantonal authority responsible for enforcing this Ordinance as well as the Federal Office of Police.

[3] The cantonal authority must decide whether the public needs to be warned of any danger.

Art. 83 Samples

Very toxic, toxic or corrosive substances and preparations may be provided for promotional purposes only to professional or commercial users.

Title 5: Data Processing

Art. 84 Register of products

[1] The Notification Authority shall maintain a register of substances and preparations that fall within the scope of the following Ordinances:

a. this Ordinance;

b. the ORRChem [118];

c. the Biocidal Products Ordinance of 18 May 2005[119];

115 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
116 SR **814.81**
117 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
118 SR **814.81**

d. the Plant Protection Products Ordinance of 18 May 2005[120].

[2] The register is compiled on the basis of data:

a. that has been collected or produced by a Swiss authority under one of the ordinances cited in paragraph 1;

b. that is made available by foreign authorities or by international organisations.

Art. 85 Confidential data

[1] The enforcement authorities shall treat data as confidential when an interest in its confidentiality is worthy of protection, unless there is an overriding public interest in its disclosure.

[2] The Notification Authority shall designate the confidential data in consultation with the assessment authorities. It shall designate it before sending it on to the competent cantonal or federal authorities cited in Article 87 paragraph 2.

[3] In particular, the interest in maintaining commercial/manufacturing secrecy, including information on the full composition of a substance or preparation and the quantities placed on the market, shall be deemed worthy of protection.

[4] If the Notification Authority discovers that data deemed to be confidential has subsequently been disclosed by lawful means, this data shall no longer be treated as confidential.

[5] The following are not deemed confidential under any circumstances:

a. the trade name;

b. the name and address of the person subject to notification, declaration or registration requirements;

c. the physico-chemical properties defined in Annexes VII A, VII B, VII C and VII D to Directive 67/548/EEC;

d. procedures for proper disposal, for possible recycling or reuse, and for other ways of rendering materials harmless;

e. the summary of results of toxicological and ecotoxicological tests;

f. the degree of purity of a substance and the identity of the impurities and additives that are relevant for classification;

g. recommendations regarding precautions during use and emergency measures in the event of an accident;

h. information that appears in the safety data sheet;

i. suitable analytical methods for determining the exposure of human beings and presence in the environment.

119 SR **813.12**
120 SR **916.161**

[6] The Notification Authority and assessment authorities may allow public access to data in the register of products, which is in no case deemed to be confidential.

Art. 86 Data to be passed on to the Notification Authority and the assessment authorities

The following data concerning substances, preparations and objects must be passed on to the Notification Authority and the assessment authorities if requested and if necessary for enforcement of this Ordinance:

a. data collected by the FOAG under:
   1. the Fertilisers Ordinance of 10 January 2001[121],
   2. the Animal Feedstuffs Ordinance of 26 May 1999[122],
   3. the Plant Protection Products Ordinance of 18 May 2005[123];

b. data on contaminants and constituents in foodstuffs and on substances in articles of daily use collected by the FOPH and by the Federal Veterinary Office under the Foodstuffs Ordinance of 1 March 1995[124];

c.[125] data collected by the Federal Customs Administration from customs declarations;

d. data collected by SECO, by the Swiss National Accident Insurance Fund (SUVA) or by cantonal employment inspectorates under legislation on the protection of workers;

e. data collected by the Toxicological Information Centre (Art. 91);

f. data collected by testing centres under Article 12 paragraph 3 of the ORRChem[126];

g. data collected by cantons in connection with the enforcement of this Ordinance or of other legislation governing the protection of human health or the environment from substances, preparations or objects.

Art. 87 Exchange of information and data

[1] The Notification Authority and assessment authorities must, insofar as is required for the performance of their duties, make available to each other the data that they have collected or have had collected on their behalf under this Ordinance or any other legislation governing the protection of human health or the environment from

121 SR **916.171**
122 SR **916.307**
123 SR **916.161**
124 [AS **1995** 1491, **1996** 1211, **1997** 292 1145 1198 Art. 24, **1998** 108, **1999** 303 No. I 8 1848, **2002** 573, **2003** 4915 No. II, **2004** 457 3035 3065 No. II 1, **2005** 1057 1063 2695 No. II 15. AS **2005** 5451 Annex 2 No. I 1]. cf: the Foodstuffs and Utility Articles Ordinance of 23 Nov. 2005 (SR **817.02**).
125 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
126 SR **814.81**

substances, preparations or objects. To this end, they may establish automated retrieval procedures.

[2] The Notification Authority and assessment authorities must make available to the cantonal and federal authorities responsible for enforcing legislation governing the protection of human health or the environment from substances, preparations or objects the data necessary for the performance of their duties. To this end, they may establish automated retrieval procedures.

[2bis] The Notification Authority may make data concerning manufacturers and the substances or preparations that they have placed on the market accessible to the authorities listed below, if these authorities require the data in order to perform their duties:

a. the assessment authorities;

b. the customs authorities;

c. the cantonal authorities specified in paragraph 2;

d. the Toxicological Information Centre (Art. 91).[127]

[3] The Notification Authority and assessment authorities may, in special cases, pass on data relating to substances, preparations and objects to bodies other than those cited in paragraph 2, if these bodies require the data in order to perform their duties.

[4] Confidential data relating to the composition of preparations may only be passed on under paragraphs 2, 2[bis] and 3 if this is required by a criminal prosecution authority or if the data serves to answer medical queries, particularly in cases of emergency or to prevent an imminent danger to human life or health or to the environment. [128]

[5] The cantons must inform the Notification Authority of the results of surveys and analyses regarding the quality of indoor air and pass on available data on indoor air to the Notification Authority.

Art. 88 Passing-on of data to other countries and to international organisations

[1] The Notification Authority and assessment authorities may pass on data that is not confidential to foreign authorities and institutions, and to international organisations.

[2] They may pass on confidential data if:

a. this is required by international agreements or decisions of international organisations; or

b. it is necessary to prevent an imminent danger to human life or health or to the environment.

127 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

128 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Title 6: Enforcement
Chapter 1: Confederation
Section 1: Organisation

Art. 89 Notification Authority and steering committee

[1] The Notification Authority is administratively attached to the FOPH.

[2] A steering committee is appointed for the Notification Authority. It is composed of the directors of the following federal offices:

a. FOPH;

b. FOAG;

c. FOEN;

d. SECO.

[3] The steering committee has the following duties and powers:

a. appointing the management of the Notification Authority;

b. defining the strategy of the Notification Authority;

c. inspection and application rights concerning the budget of the Notification Authority.

[4] The steering committee makes decisions by mutual agreement.

Art. 90 Assessment authorities

The assessment authorities are:

a. the FOPH, for matters concerning the protection of human life and health;

b. the FOEN, for matters concerning the protection of the environment and indirect protection of human beings;

c. SECO, for matters concerning the protection of workers.

Art. 91 Toxicological information centre

[1] The toxicological information centre established by Article 30 of ChemA is the Swiss Toxicological Information Centre in Zurich (STIZ).

[2] The FOPH shall enter into an agreement with the STIZ setting the amount of remuneration that it receives for the services it provides under Article 30 paragraph 2 of ChemA. [129]

129 Amended in accordance with No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 92 Expert Committee for Chemicals

[1] The FDHA may, in consultation with DETEC and the FDEA, appoint an Expert Committee for Chemicals.

[2] The Expert Committee for Chemicals shall be composed of specialists from federal and cantonal bodies, from the fields of science, business and consumer protection and from interested groups.

[3] It shall advise the federal departments on fundamental questions of legislation and enforcement concerning substances and preparations and is authorised to put forward proposals. It may call in external experts for consultation.

Art. 93 Expert Committee for Ecotoxicology

[1] DETEC may appoint an Expert Committee for Ecotoxicology.

[2] The Expert Committee for Ecotoxicology shall be composed of specialists from federal and cantonal bodies, from the fields of science, business and environmental protection and from interested groups.

[3] It advises the FOEN on questions of environmental chemistry and ecotoxicology.

Section 2: Review of Existing Substances

Art. 94

[1] The assessment authorities may review any existing substances which:

a. represent a particular risk to human life or health or to the environment, owing to the quantities manufactured or placed on the market or owing to their dangerous nature or the dangerous nature of their secondary products or wastes; or

b. are included in an international existing substances programme.

[2] If an existing substance is to be reviewed, the Notification Authority, at the request of an assessment authority, shall require all the manufacturers concerned to provide the following information:

a. the name and address of the manufacturer, and the name and address of the foreign manufacturer if the manufacturer imports the substance;

b. all documents used in assessing and establishing the hazardous properties of the substance;

c. the known uses;

d. information on the quantities placed on the market by the manufacturers.

e.[130] the registration dossier that was submitted to the European Chemicals Agency, provided it is available and the notifier can reasonably be expected to obtain it.

[3] If requested by an assessment authority, the Notification Authority shall request one of the manufacturers to carry out investigations or studies. The costs incurred by the manufacturer shall be borne jointly by all the manufacturers concerned.

Section 3: Review of Self-Regulation and Monitoring

Art. 95 Review of self-regulation

[1] The assessment authorities must review, in their area of competence, for substances, preparations and objects:

a. the assessment and classification;

b. the information that appears in the safety data sheet.

[2] They may instruct the Notification Authority:

a. to verify the composition and the physico-chemical properties of substances, preparations and objects;

b. to ask cantonal enforcement authorities to take samples.

[3] If there is reason to suppose that the assessment or classification has not been carried out or has not been carried out correctly, the Notification Authority, at the request of an assessment authority, must require the manufacturer concerned to provide:

a. all the documents used in establishing the hazardous properties or in the assessment;

b. the safety data sheet, if appropriate.

[4] At the request of an assessment authority, the Notification Authority must require the manufacturer to perform tests or additional assessments if there are indications that:

a. substances or preparations and their secondary products or wastes may endanger human health or the environment;

b. objects, their secondary products or their wastes may endanger the environment.

[5] Moreover, the enforcement authorities have the powers assigned to them by Article 42 of the Chemicals Act and, in the case of a danger to the environment, also Article 41 of the Chemicals Act.

130 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[6] If a manufacturer does not comply with an official order, the Notification Authority must, if so requested by an assessment authority, prohibit it from continuing to supply the substances, preparations or objects concerned.

[7] As regards cosmetic products, and raw materials and additives intended exclusively for these products, the body responsible for these products must order the necessary measures. The participation of the FOEN is governed by Articles 62*a* and 62*b* of the Federal Act of 21 March 1997[131] on the Organisation of the Government and the Administration.

Art. 96 Monitoring with regard to national defence

In matters concerning national defence, the Notification Authority must examine, in consultation with the assessment authorities, whether the provisions of this Ordinance are being respected.

Art. 97 Monitoring of imports and exports

[1] Customs offices must check, at the request of the Notification Authority, whether substances, preparations or objects comply with the provisions of this Ordinance.[132]

[2] The assessment authorities may call upon the Notification Authority to submit a request as defined in paragraph 1.

[3] In cases of suspected infringement, the customs offices are authorised to detain goods at the border and call in the other enforcement authorities in accordance with this Ordinance. These authorities must carry out further investigations and take the necessary measures.[133]

Section 3*a*:[134] Adaptations to the Annexes of EC legislation

Art. 97*a*

In consultation with the FOEN and SECO, the FOPH shall adapt Annex 4 to the amendments in Annex XIV of Regulation (EC) No. 1907/2006.

131 SR **172.010**
132 Amended in accordance with Annex 4 No. 41 of the Customs Ordinance of 1 Nov. 2006, in force since 1 May 2007 (SR **631.01**).
133 Amended in accordance with Annex 4 No. 41 of the Customs Ordinance of 1 Nov. 2006, in force since 1 May 2007 (SR **631.01**).
134 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Section 4: Delegation of Duties and Powers to Third Parties

Art. 98

[1] The competent federal bodies may delegate to appropriate public corporations or private persons all or some of the duties and powers assigned to them by this Ordinance.

[2] To the extent that enforcement of health protection is concerned, delegation is limited to the following:

a. review of self-regulation;

b. as part of a review, assessment of notification and updated information;

c. provision of information under Article 28 of the Chemicals Act;

d. risk assessment under Article 16 of the Chemicals Act.

Section 5: Charges

Art. 99

The obligation to pay charges and the calculation of charges for administrative actions by the federal enforcement authorities in accordance with this Ordinance is based on the Chemical Charges Ordinance of 18 May 2005[135].

Chapter 2: Cantons

Section 1: Further Inspection

Art. 100 Duties of the cantonal enforcement authorities

[1] By means of random sampling, the cantonal enforcement authorities must inspect substances, preparations and objects placed on the market.

[2] Within the framework of these inspections, the cantonal enforcement authorities must verify:

a. that the notification, declaration and registration requirements (Articles 16, 25, 61 to 63, 65, 67 and 68) and the provisions governing updated information (Art. 59) have been respected;

b. that packaging conforms to the provisions on packaging (Articles 35 to 37);

c. that labelling conforms to the provisions on labelling (Articles 39 to 49 and Annex 1);

135 SR **813.153.1**

d. that the provisions on the provision, revision and retention of the safety data sheet (Articles 54 to 56) are being respected and that the information in the safety data sheet is not obviously incorrect;

e. that the provisions on advertising (Art. 75) and product samples (Art. 83) are being respected.

Art. 101 Cooperation between the cantonal and federal enforcement authorities

[1] The Notification Authority must, on its own initiative or at the request of an assessment authority, instruct the cantonal enforcement authorities to inspect certain substances, preparations or objects, especially in accordance with Article 95 paragraph 1.

[2] The cantonal enforcement authorities must collect samples at the request of the Notification Authority.

[3] If the inspections identify serious concerns, the authority that performed the inspections must inform the Notification Authority and the authorities responsible for orders under Article 102.

[4] If there are grounds for suspecting incorrect classification, the authority that performed the inspections must inform the Notification Authority.

Art. 102[136] Orders of cantonal enforcement authorities

If the inspection reveals infringements of the provisions referred to in Article 100 paragraph 2 and Article 101 paragraph 1, the competent authority of the canton in which the infringing party is domiciled or has its registered office must order the measures which need to be taken.

Section 2: Monitoring of Handling and Promotion of Environmentally Sound Practices

Art. 103

[1] The cantonal enforcement authorities must monitor compliance with the specific provisions relating to handling (Articles 70 to 74 and 76 to 82). Article 25 paragraph 1 second sentence of the Chemicals Act applies accordingly.

[2] The cantons must promote environmentally sound practices.

136 Amended in accordance with No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).

Title 7: Final Provisions
Chapter 1: Transitional Provisions

Art. 104-109[137]

Art. 110 Knowledge required to supply and chemicals contact person

The FDHA, in consultation with DETEC and the FDEA, must issue the transitional provisions on:

a. the requirements concerning knowledge required for the supply of particularly dangerous substances and preparations;

b. the requirements concerning the chemicals contact person.

Art. 110*a*[138] Modification of classification or labelling criteria

If classification or labelling criteria are modified by the amendment of this Ordinance dated 28 February 2007, substances and preparations packaged and labelled in accordance with existing legislation:

a. may be placed on the market by the manufacturer for one more year after the amendment comes into force;

b. may be supplied to end consumers for two more years after the amendment comes into force.

Art. 110*b*[139] Transitional provisions to the amendment of 14 January 2009

1 The manufacturer must comply with the requirements of Article 18 paragraph 2 relating to the content of the notification of new substances and those specified in Article 59 paragraph 1 letter b relating to the additional information within six months at the latest of the entry into force of this Ordinance.

2 The manufacturer must comply with the requirements of Article 52 letters b and e and in Article 54 on the preparation and provision of a safety data sheet for PBT or vPvB substances and preparations containing such substances within six months at the latest of the entry into force of the amendment.

3 The manufacturer must comply with the requirements of Article 50*a* relating to the preparation of exposure scenarios by:

a. 1 December 2010 for substances which:

1. are classified as carcinogenic, mutagenic or toxic-to-reproduction with the R-phrases R 45, R 46, R 49, R 60 or R 61,

137 Repealed by No. I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
138 Inserted by No. I of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821).
139 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

2. are classified as harmful to the environment with phrase R 50/53 and placed on the market annually in quantities of 100 tonnes per year or more, or
3. are placed on the market annually in quantities of 1000 tonnes per year or more;

b. 1 June 2013 for substances that are placed on the market annually in quantities of 100 tonnes per year or more;

c. 1 June 2018 for substances that are placed on the market annually in quantities of 10 tonnes per year or more.

Chapter 2: Commencement

Art. 111

This Ordinance comes into force on 1 August 2005.

Annex 1[140]
(Art. 39 para. 2, [141] Art. 40 para. 1, Art. 46, Art. 47 para. 2, Art. 100 para. 2 letter c)

Labelling of substances and preparations

1 Dangers

1.1 Danger symbols and indications of danger

[1] The following danger symbols and indications of danger must be used for labelling of dangerous substances and preparations:

E

Explosive

O

Oxidising

F+

Extremely flammable

F

Highly flammable

N

Dangerous for the environment

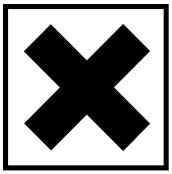
T+

Very toxic

T

Toxic

Xn



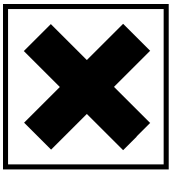
Harmful

C

Corrosive

140 Amended in accordance with No. II para. 1 of the Ordinance of 28 Feb. 2009, in force since 1 April 2007 (AS **2007** 821). Revised in accordance with No. II para. 1 of the Ordinance of 14 Jan. 2009, in force since1 Feb. 2009 (AS **2009** 401).
141 Now Art. 39 para. 1

Xi



Irritant

[2] The symbols must be printed in black on an orange-yellow background.

1.2 Assignment of danger symbols and indications of danger

[1] Dangerous substances and preparations must be labelled with the appropriate danger symbols and indications of danger according to their classification.

[2] Officially classified substances must be labelled with the officially assigned danger symbols and indications of danger.

[3] If the manufacturer's classification requires more than one danger symbol for a substance or a preparation, the following applies:

a. if labelling with the T^+ or T danger symbol is required, the Xn, Xi and C symbols are optional;

b. if labelling with the C danger symbol is required, the Xn and Xi symbols are optional;

c. if labelling with the E danger symbol is required, the F, F^+ and O symbols are optional;

d. if labelling with the Xn danger symbol is required, the Xi symbol is optional.

2 Special Risks

2.1 R-phrases

R 1	Explosive when dry.
R 2	Risk of explosion by shock, friction, fire or other sources of ignition.
R 3	Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R 4	Forms very sensitive explosive metallic compounds.
R 5	Heating may cause an explosion.
R 6	Explosive with or without contact with air.
R 7	May cause fire.
R 8	Contact with combustible material may cause fire.
R 9	Explosive when mixed with combustible material.

R 10	Flammable.
R 11	Highly flammable.
R 12	Extremely flammable.
R 14	Reacts violently with water.
R 15	Contact with water liberates extremely flammable gases.
R 16	Explosive when mixed with oxidising substances.
R 17	Spontaneously flammable in air.
R 18	In use, may form flammable/explosive vapour-air mixture.
R 19	May form explosive peroxides.
R 20	Harmful by inhalation.
R 21	Harmful in contact with skin.
R 22	Harmful if swallowed.
R 23	Toxic by inhalation.
R 24	Toxic in contact with skin.
R 25	Toxic if swallowed.
R 26	Very toxic by inhalation.
R 27	Very toxic in contact with skin.
R 28	Very toxic if swallowed.
R 29	Contact with water liberates toxic gas.
R 30	Can become highly flammable in use.
R 31	Contact with acids liberates toxic gas.
R 32	Contact with acids liberates very toxic gas.
R 33	Danger of cumulative effects.
R 34	Causes burns.
R 35	Causes severe burns.
R 36	Irritating to eyes.
R 37	Irritating to respiratory system.
R 38	Irritating to skin.
R 39	Danger of very serious irreversible effects.
R 40	Limited evidence of a carcinogenic effect.
R 41	Risk of serious damage to eyes.
R 42	May cause sensitisation by inhalation.
R 43	May cause sensitisation by skin contact.
R 44	Risk of explosion if heated under confinement.

R 45	May cause cancer.
R 46	May cause heritable genetic damage.
R 48	Danger of serious damage to health by prolonged exposure.
R 49	May cause cancer by inhalation.
R 50	Very toxic to aquatic organisms.
R 51	Toxic to aquatic organisms.
R 52	Harmful to aquatic organisms.
R 53	May cause long-term adverse effects in the aquatic environment.
R 54	Toxic to flora.
R 55	Toxic to fauna.
R 56	Toxic to soil organisms.
R 57	Toxic to bees.
R 58	May cause long-term adverse effects in the environment.
R 59	Dangerous for the ozone layer.
R 60	May impair fertility.
R 61	May cause harm to the unborn child.
R 62	Possible risk of impaired fertility.
R 63	Possible risk of harm to the unborn child.
R 64	May cause harm to breastfed babies.
R 65	Harmful: may cause lung damage if swallowed.
R 66	Repeated exposure may cause skin dryness or cracking.
R 67	Vapours may cause drowsiness and dizziness.
R 68	Possible risk of irreversible effects.

2.2 Combined R-phrases

R 14/15	Reacts violently with water, liberating extremely flammable gases.
R 15/29	Contact with water liberates toxic, extremely flammable gases.
R 20/21	Harmful by inhalation and in contact with skin.
R 20/22	Harmful by inhalation and if swallowed.
R 20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R 21/22	Harmful in contact with skin and if swallowed.
R 23/24	Toxic by inhalation and in contact with skin.
R 23/25	Toxic by inhalation and if swallowed.

R 23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R 24/25	Toxic in contact with skin and if swallowed.
R 26/27	Very toxic by inhalation and in contact with skin.
R 26/28	Very toxic by inhalation and if swallowed.
R 26/27/28	Very toxic by inhalation, in contact with skin and if swallowed.
R 27/28	Very toxic in contact with skin and if swallowed.
R 36/37	Irritating to eyes and respiratory system.
R 36/38	Irritating to eyes and skin.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 37/38	Irritating to respiratory system and skin.
R 39/23	Toxic: danger of very serious irreversible effects through inhalation.
R 39/24	Toxic: danger of very serious irreversible effects in contact with skin.
R 39/25	Toxic: danger of very serious irreversible effects if swallowed.
R 39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin.
R 39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed.
R 39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed.
R 39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R 39/26	Very toxic: danger of very serious irreversible effects through inhalation.
R 39/27	Very toxic: danger of very serious irreversible effects in contact with skin.
R 39/28	Very toxic: danger of very serious irreversible effects if swallowed.
R 39/26/27	Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin.
R 39/26/28	Very toxic: danger of very serious irreversible effects through inhalation and if swallowed.
R 39/27/28	Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed.
R 39/26/27/28	Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R 42/43	May cause sensitisation by inhalation and skin contact.

R 48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R 48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin.
R 48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R 48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R 48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R 48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed.
R 48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R 48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation.
R 48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin.
R 48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed.
R 48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R 48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R 48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed.
R 48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 68/20	Harmful: possible risk of irreversible effects through inhalation.
R 68/21	Harmful: possible risk of irreversible effects in contact with skin.
R 68/22	Harmful: possible risk of irreversible effects if swallowed.
R 68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin.

R 68/20/22 Harmful: possible risk of irreversible effects through inhalation and if swallowed.

R 68/21/22 Harmful: possible risk of irreversible effects in contact with skin and if swallowed.

R 68/20/21/22 Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.

2.3 Assignment of R-phrases

[1] Dangerous substances and preparations must be labelled with the appropriate R-phrases according to their classification.

[2] Officially classified substances must be labelled with the officially assigned R-phrases.

[3] As a general rule, no more than six R-phrases are to be used. However, each dangerous property of a classified substance or preparation must be indicated by at least one R-phrase drawing attention to the principal hazard. Combined R-phrases are regarded as single R-phrases.

2.4 Choice of R-phrases

[1] For substances, R-phrases must be assigned according to the following criteria and priorities:

a. Dangers to health:
   1. R-phrases corresponding to the category of danger illustrated by a symbol,
   2. R-phrases corresponding to other categories of danger which are not illustrated by a symbol;

b. Dangers arising from physico-chemical properties: R-phrases corresponding to the category of danger illustrated by a symbol;

c. Dangers for the environment: R-phrases corresponding to the category “dangerous for the environment”.

[2] For preparations, R-phrases must be assigned according to the following criteria and priorities:

a. Dangers to health:
   1. R-phrases corresponding to the category of danger illustrated by a symbol. In certain cases the R-phrases must be adopted according to the tables in Part B of Annex II to Directive 1999/45/EC. More specifically, the R-phrases of the constituents which are responsible for the assignment of the preparation to a danger category must appear on the label,
   2. R-phrases corresponding to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol;

b. Dangers arising from physico-chemical properties:
   1. R-phrases corresponding to the category of danger illustrated by a symbol. More specifically, the R-phrases of the constituents which are responsible for the assignment of the preparation to a danger category must appear on the label,
   2. R-phrases corresponding to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol;
   3. The R-phrases R 11 and R 12 need not be indicated where they repeat the wording of the indication of danger used with a symbol;

c. Dangers for the environment:
   1. R-phrases corresponding to the category "dangerous for the environment",
   2. Where the R-phrase R 50 has been assigned in addition to a combined R-phrase R 51/53 or R 52/53 or to the R-phrase R 53 alone, the combined R-phrase R 50/53 must be used.

2.5 Exemptions

[1] It is not necessary to indicate R-phrases for substances that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as irritant, highly flammable, flammable or oxidising; or

b. are classified as harmful and are not sold to the general public.

[2] It is not necessary to indicate corresponding R-phrases for preparations that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as highly flammable, oxidising or irritant, without the R-phrase "Risk of serious damage to eyes" (R 41); or

b. are classified as dangerous for the environment and assigned the N symbol.

[3] When the labelling includes the symbols F or F^+, the R-phrases R 11 or R 12 do not have to be indicated.

3 Safety Advice

3.1 S-phrases

S 1	Keep locked up.
S 2	Keep out of the reach of children.
S 3	Keep in a cool place.
S 4	Keep away from living quarters.
S 5	Keep contents under… (appropriate liquid to be specified by the manufacturer).

S 6	Keep contents under… (inert gas to be specified by the manufacturer).
S 7	Keep container tightly closed.
S 8	Keep container dry.
S 9	Keep container in a well-ventilated place.
S 12	Do not keep the container sealed.
S 13	Keep away from food, drink and animal feedingstuffs.
S 14	Keep away from… (incompatible materials to be indicated by the manufacturer).
S 15	Keep away from heat.
S 16	Keep away from sources of ignition – No smoking.
S 17	Keep away from combustible material.
S 18	Handle and open container with care.
S 20	When using do not eat or drink.
S 21	When using do not smoke.
S 22	Do not breathe dust.
S 23	Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
S 24	Avoid contact with skin.
S 25	Avoid contact with eyes.
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 27	Take off immediately all contaminated clothing.
S 28	After contact with skin, wash immediately with plenty of… (to be specified by the manufacturer).
S 29	Do not empty into drains.
S 30	Never add water to this product.
S 33	Take precautionary measures against static discharges.
S 35	This material and its container must be disposed of in a safe way.
S 36	Wear suitable protective clothing.
S 37	Wear suitable gloves.
S 38	In case of insufficient ventilation, wear suitable respiratory equipment.
S 39	Wear eye/face protection.
S 40	To clean the floor and all objects contaminated by this material, use… (to be specified by the manufacturer).

S 41	In case of fire and/or explosion do not breathe fumes.
S 42	During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer).
S 43	In case of fire, use… (type of fire-fighting equipment to be specified by the manufacturer. If water increases the risk, add: "Never use water").
S 45	In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible).
S 46	If swallowed, seek medical advice immediately and show this container or label.
S 47	Keep at temperature not exceeding… °C (to be specified by the manufacturer).
S 48	Keep wet with… (appropriate material to be specified by the manufacturer).
S 49	Keep only in the original container.
S 50	Do not mix with… (to be specified by the manufacturer).
S 51	Use only in well-ventilated areas.
S 52	Not recommended for interior use on large surface areas.
S 53	Avoid exposure – obtain special instructions before use.
S 56	Dispose of this material and its container at hazardous or special waste collection point.
S 57	Use appropriate containment to avoid environmental contamination.
S 59	Refer to manufacturer/supplier for information on recovery/recycling.
S 60	This material and its container must be disposed of as hazardous waste.
S 61	Avoid release to the environment. Refer to special instructions/safety data sheet.
S 62	If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.
S 63	In case of accident by inhalation: remove casualty to fresh air and keep at rest.
S 64	If swallowed, rinse mouth with water (only if the person is conscious).

3.2 Combined S-phrases

S 1/2	Keep locked up and out of the reach of children.
S 3/7	Keep container tightly closed in a cool place.
S 3/9/14	Keep in a cool, well-ventilated place away from… (incompatible materials to be indicated by the manufacturer).
S 3/9/14/49	Keep only in the original container in a cool, well-ventilated place away from… (incompatible materials to be indicated by the manufacturer).
S 3/9/49	Keep only in the original container in a cool, well-ventilated place.
S 3/14	Keep in a cool place away from… (incompatible materials to be indicated by the manufacturer).
S 7/8	Keep container tightly closed and dry.
S 7/9	Keep container tightly closed and in a well-ventilated place.
S 7/47	Keep container tightly closed and at temperature not exceeding… °C (to be specified by the manufacturer).
S 20/21	When using do not eat, drink or smoke.
S 24/25	Avoid contact with skin and eyes.
S 27/28	After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of… (to be specified by the manufacturer).
S 29/35	Do not empty into drains; waste and containers must be disposed of in a safe way.
S 29/56	Do not empty into drains; dispose of this material and its container at hazardous or special waste collection point.
S 36/37	Wear suitable protective clothing and gloves.
S 36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 36/39	Wear suitable protective clothing and eye/face protection.
S 37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 47/49	Keep only in the original container at temperature not exceeding … °C (to be specified by the manufacturer).

3.3 Assignment of S-phrases

[1] Dangerous substances and preparations must be labelled with the appropriate S-phrases according to their classification. The choice of S-phrases is based on Annex VI to Council Directive 67/548/EEC of 27 June 1967[142] on the approxima-

[142] OJ L 196 of 16.8.1967, p. 1; last amended by Directive 2004/73/EC (OJ L 152 of 30.4.2004, p. 1, corrected in OJ L 216 of 16.6.2004, p. 3 and OJ 236 of 7.7.2004, p. 18).

tion of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Directive 67/548/EEC).

[2] Officially classified substances must be labelled with the officially assigned S-phrases.

[3] As a general rule, no more than six S-phrases are to be used. Combined S-phrases are regarded as single phrases.

[4] An S-phrase concerning disposal of the substance or preparation must be used, unless it is clear that disposal of the substance or preparation or its container does not present a danger for human health or the environment.

[5] With regard to dangerous substances and preparations that are sold to the general public, the following applies:

a. if they are assigned the danger symbols T, T^+ or C during classification, they must be labelled with the S-phrases S 1, S 2 and S 45;

b. if they are assigned a danger symbol other than those referred to under letter a during classification, they must be labelled with S-phrases S 2 and S 46, unless they are only assigned the danger symbol N.

[6] The choice of S-phrases must take account of the intended use and the foreseeable conditions of use.

[7] S-phrases must be chosen in such a way as to avoid any redundancy or ambiguity.

[8] If, for technical reasons, the S-phrases cannot appear on the label or on the packaging, they may be supplied separately as written information.

3.4 Exemptions

[1] It is not necessary to indicate S-phrases for substances that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as irritant, highly flammable, flammable or oxidising; or

b. are classified as harmful and are not sold to the general public.

[2] It is not necessary to indicate S-phrases for preparations that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as highly flammable, flammable, oxidising or irritant, without the R-phrase “Risk of serious damage to eyes” (R 41); or

b. are classified as dangerous to the environment.

The texts of the European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch.

4 Declaration of Dangerous Substances in Preparations

[1] As a general rule, no more than four dangerous substances responsible for the main dangerous properties of a preparation need to be indicated.

[2] In all cases, it is necessary to indicate dangerous substances that have led to the preparation being classified as follows:

a. carcinogenic;

b. mutagenic;

c. toxic to reproduction;

d. very toxic, toxic or harmful, when the effects of a single exposure are not lethal;

e. toxic or harmful, when the effects of repeated or prolonged exposure are severe;

f. sensitising.

[3] Subject to paragraph 2, it is not necessary to indicate dangerous substances that have led to the preparation being classified as follows:

a. explosive;

b. oxidising;

c. extremely flammable;

d. highly flammable;

e. flammable;

f. irritant;

g. dangerous to the environment.

[4] As regards preparations assigned the danger symbol T^+, T or Xn, only those substances with the symbol T^+, T or Xn need to be taken into account, subject to paragraph 3, whose concentration is equal to or in excess of the following lowest limit (Xn limit):

a. the Xn limit established during official classification;

b. if no limit has been established as defined in paragraph a: the Xn limit according to Part B of Annex II to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[143] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Directive 1999/45/EC).

[5] As regards preparations assigned the danger symbol C, only those substances with the symbol C need to be taken into account, subject to paragraph 3, whose concentration is equal to or in excess of the following lowest limit (Xi limit):

143 OJ L 200 of 30.7.1999, p. 1, last amended by Directive 2006/8/EC (OJ L 19 of 24.1.2006, p. 12).

a. the limit established during official classification;

b. the Xi limit according to Part B of Annex II to Directive 1999/45/EC.

5 Provisions relating to Preparations with Special Risks

5.1 Cyanoacrylate-based adhesives

[1] Cyanoacrylate-based adhesives must be labelled as follows: "Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children."

[2] Appropriate advice on safety must accompany the package.

5.2 Preparations containing isocyanates

Preparations containing isocyanates (as monomers, oligomers, prepolymers, etc. or as mixtures thereof) must be labelled as follows: "Contains isocyanates. See information supplied by the manufacturer."

5.3 Preparations containing epoxy constituents with an average molecular weight ≤ 700

Preparations containing epoxy constituents with an average molecular weight ≤ 700 must be labelled as follows: "Contains epoxy constituents. See information supplied by the manufacturer."

5.4 Preparations which contain active chlorine

Preparations containing more than 1% of active chlorine which are sold to the general public must be labelled as follows: "Warning! Do not use together with other products. May release dangerous gases (chlorine)."

5.5 Preparations containing cadmium (alloys) and intended to be used for brazing or soldering

Preparations containing cadmium (alloys) and intended to be used for brazing or soldering must be labelled as follows: "Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions."

5.6 Preparations available as aerosols

Aerosol dispensers not covered by the Foodstuffs Act of 9 October 1992[144] are subject both to the provisions of this Ordinance and to Articles 1, 2 and 9a and numbers 2.2 and 2.3 of the Annex to Council Directive 75/324/EEC of 20 May 1975[145] on the approximation of the laws of the Member States relating to aerosol dispensers.

5.7 Preparations not classified as sensitising but containing at least one substance classified as sensitising

Preparations not classified as sensitising but containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0.1% or in a concentration equal to or greater than that specified for the substance in the official classification (Art. 9) must be labelled as follows: "Contains (name of sensitising substance). May produce an allergic reaction."

5.8 Liquid preparations containing halogenated hydrocarbons

Preparations which show no flashpoint or a flashpoint higher than 55°C and contain a halogenated hydrocarbon and more than 5% flammable or highly flammable substances must be labelled as follows, as appropriate: "Can become flammable in use" or "Can become highly flammable in use".

5.9 Preparations not classified as dangerous but containing at least one dangerous substance and not sold to the general public

Preparations not classified as dangerous but containing at least one dangerous substance and which are not sold to the general public must be labelled as follows: "Safety data sheet available for professional users on request".

5.10 Preparations containing a substance assigned R-phrase R 67

[1] Preparations containing a substance assigned R-phrase R 67 in a total concentration equal to or greater than 15% must be labelled with R-phrase R 67.

[2] The labelling specified in paragraph 1 is not required if:

a. R-phrase R 20, R 23, R 26, R 68/20, R 39/23 or R 39/26 is assigned to the preparation; or

b. the package does not contain more than 125 ml.

144 SR **817.0**

145 OJ L 147 of 9.6.1975, p. 40; last amended by Directive 94/1/EC (OJ L 23 of 28.1.1994, p. 28).

5.11 Dangerous preparations available to the general public

[1] Dangerous preparations sold to the general public must be labelled with S-phrases in accordance with number 3.3.

[2] Where it is physically impossible to give instructions on the package itself, preparations classified as toxic (T) or corrosive (C) must be accompanied by precise and easily understandable instructions for use including, if applicable, instructions for the destruction of the empty package. The instructions must be written in at least two official languages.

5.12 Dangerous preparations intended for use by spraying

Dangerous preparations intended for use by spraying must be labelled with S-phrase S 23, accompanied by S-phrases S 38 or S 51.

5.13 Preparations containing a substance assigned R-phrase R 33

When a preparation contains a substance assigned R-phrase R 33, it must be labelled with R-phrase R 33 if this substance is present in a concentration equal to or higher than 1%, unless different concentration limits are set in the official classification (Art. 9).

5.14 Preparations containing a substance assigned R-phrase R 64

When a preparation contains a substance assigned R-phrase R 64, it must be labelled with R-phrase R 64 if this substance is present in a concentration equal to or higher than 1%, unless different concentration limits are set in the official classification (Art. 9).

6 Label

[1] The label must be affixed to the packaging in such a way that the information can be read horizontally when the package is set down normally.

[2] The dimensions of the label must be as follows:

Capacity of the package	Dimensions (in mm)
not exceeding 3 litres	if possible 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

Capacity of the package	Dimensions (in mm)
greater than 500 litres	at least 148×210

[3] The label must contain only the information stipulated in this Ordinance for labelling, as well as any additional information regarding hygiene and safety which may be applicable.

[4] Each symbol must cover at least one-tenth of the surface area of the label but must not be less than 1 cm^2.

[5] A label is not required if the information specified in Articles 39 to 46 is clearly shown on each package.

[6] The colour and presentation of the label or, in the case of paragraph 5, of the package must be such that the danger symbol and its background stand out clearly from it.

[7] In the case of mobile gas cylinders, the requirements relating to labelling are deemed to have been met if these cylinders comply with the relevant stipulations in Annex VI to Directive 67/548/EEC.

7 Optional Labelling

7.1 Indications of dangers for the environment

Number	Pictogram	Examples of wording
7.1.1	 Toxic to bees	Do not spray before or during flowering. Do not treat plants affected by greenfly. Take care when plants nearby are in full bloom or are interspersed with flowering weeds. Do not use in wind.
7.1.2	 Dangerous for groundwater	Use prohibited in groundwater protection zones S (S 1, S 2 and S 3) of drinking water wells. Do not spread on fallow or temporarily fallow land. Do not use in karstic regions, or on porous soils. Do not use on railways. Storage prohibited in groundwater protection zones S (S 1, S 2 and S 3) of drinking water wells.

7.2 Indications of protection measures

Number	Pictogram	Examples of wording
7.2.1	 Domestic waste	May be disposed of with domestic waste.
7.2.2	 Hazardous waste	Hand in to …(company) as hazardous waste. Return to point of sale as hazardous waste. Return to toxic waste collection point as hazardous waste. Hand in to used oil collection point as hazardous waste. *Note: the label must clearly indicate the recommended method of disposal.*
7.2.3	 Not to be disposed of via drains	Do not empty into the sink or the toilet, but dispose of with domestic waste. Do not empty into the sink or the toilet, but return to point of sale or waste collection point. *Note: the label must clearly indicate the recommended method of disposal.*

Annex 2[146]
(Art. 53)

Requirements for safety data sheets

General provisions

[1] The information in the safety data sheet must be clear, concise and easy to understand for professional or commercial users.

[2] In justified cases, certain data may be omitted or replaced by other equivalent or more appropriate data. Additional information may be necessary in some cases in view of the wide range of properties of substances and preparations.

[3] The date of issue of the safety data sheet must appear on the first page. New versions must be accompanied by the indication "Revision … (date)".

[4] If a safety data sheet has been revised, the information added, deleted or amended must be clearly identifiable.

1 Identification of the Substance or Preparation and of the Company

[1] The following must appear:

a. Identification of the substance or preparation. The term used for identification must be identical to that which appears on the label, packaging or container. Other means of identification available may also be indicated.

b. Use of the substance or preparation. The intended or recommended uses of the substance or preparation must be indicated insofar as they are known. Where there are many possible uses, only the most important or common uses need to be listed. A brief description of what it actually does (e.g. flame retardant, antioxidant) should also be given.

c. Identification of the company. The manufacturer of the substance or preparation must be indicated, including the full address, telephone number and the e-mail address of the person responsible for the safety data sheet.

d. Emergency telephone number. The emergency telephone number of the manufacturer must be indicated. If this phone number is reachable only during office hours, this must be specified. The emergency number of the Toxicological Information Centre (Art. 91) may be given for any medical information.

146 Amended in accordance with No. II para. 2 of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

2 If the exposure scenarios are attached to the safety data sheet, all of the identified uses that are relevant to the recipient of the safety data sheet and which correspond to these exposure scenarios must be specified.

2 Hazards Identification

1 The classification of the substance or preparation must be indicated. The hazards presented by the substance or preparation to human health and the environment must be described.

2 Also to be indicated are hazards (e.g. dustiness, suffocation, freezing or effects on the environment such as hazards to soil-dwelling organisms) which do not result in classification but which contribute to the overall hazards of the substance or preparation.

3 The most important adverse physico-chemical, human health and environmental effects and symptoms relating to the uses and foreseeable misuses of the substance or preparation must be described.

4 The information appearing on the label must be given under number 15.

3 Composition/Information on Ingredients

1 The information in the safety data sheet should enable professional users to identify the hazards of the preparation ingredients without any difficulty.

2 The following ingredients of a dangerous preparation must be indicated, together with their concentration or concentration range:

a. substances dangerous to health or the environment, if their concentration in the preparation is equal to or higher than the limits set in Article 3 paragraph 3 of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[147] concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Directive 1999/45/EC), unless lower limits are set in the official classification (Art. 9) or in Annexes II, III or V to Directive 1999/45/EC;

147 OJ L 200 of 30.7.1999, p. 1, last amended by Commission Directive 2006/8/EC of 23 Jan. 2006, OJ L 19 of 24.1.2006, p. 12. The texts of the European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

b. substances for which an occupational exposure limit has been laid down in Commission Directive 2000/39/EC of 8 June 2000[148] establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Directive 2000/39/EC).

c. PBT or vPvB-substances, if the concentration of a particular substance exceeds 0.1 per cent.

[3] In the case of preparations not classified as dangerous, the following ingredients must be indicated, together with their concentration or concentration range:

a. substances dangerous to health or the environment, if they are present in an individual concentration of ≥ 1.0% by weight for non-gaseous preparations or ≥ 0.2% by volume for gaseous preparations;

b. substances for which an occupational exposure limit has been laid down by Directive 2000/39/EC, if they are present in an individual concentration of ≥ 1.0% by weight for non-gaseous preparations or ≥ 0.2% by volume for gaseous preparations;

c. PBT and vPvB-substances, if they are present in an individual concentration of ≥ 1.0% by weight.

[4] In the case of substances which must appear in the safety data sheet in accordance with paragraphs 2 and 3, the following must be indicated:

a. indications of danger and R-phrases corresponding to dangers to health and the environment, as set out in Annex 1;

b. the hazardous physico-chemical properties;

c. where applicable, the CAS[149], EINECS[150] or ELINCS[151] number and the IUPAC[152] name.

[5] If the indication of the chemical name of the substances that must appear in the safety data sheet in accordance with paragraphs 2 and 3 puts at risk the confidentiality of the formulation of the preparation, the manufacturer may assign these substances an alternative name provided that the conditions specified in Article 43 are

148 OJ L 142 of 16.6.2000, p. 47, last amended by Commission Directive 2006/15/EC of 7 Feb. 2006, OJ L 38 of 9.2.2006, S. 36. Die The texts of the European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

149 Number assigned by the Chemical Abstracts Service (CAS) to facilitate the identification of substances.

150 European inventory of existing commercial chemical substances. OJ C 146 A of 15.6.1990, amended by Corrigendum 2002/C 54/08 (OJ C 54 of 1.3.2002). The text of EINECS can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; it can also be accessed on the Internet at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ein.

151 European List of Notified Chemical Substances.Memorandum from the Commission to the European Parliament – Sixth publication of Elincs (in accordance with Art. 21 of Directive 67/548/EEC), COM (2003) 642 final.

152 International Union of Pure and Applied Chemistry.

met. The assignment of an alternative name is governed by Part B of Annex VI to Directive 1999/45/EC.

4 First Aid Measures

[1] The first aid to be given must be indicated. In particular, the cases in which medical assistance is required are to be specified.

[2] The first aid instructions must be brief, clear and easy to understand for the victim, bystanders and first-aiders. Symptoms and effects must be briefly described. The instructions must indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

[3]The information must be subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion.

[4] If a special product is required to provide specific and immediate treatment, it must be indicated that this is to be available in the workplace.

5 Fire-Fighting Measures

An indication must be given of the measures required for fighting a fire caused by a substance or preparation or which could affect a substance or preparation, especially:

a. suitable extinguishing media;

b. extinguishing media which are not suitable for safety reasons;

c. special hazards arising from the substance or preparation itself, combustion products or resulting gases;

d. special protective equipment for fire-fighters.

6 Accidental Release Measures

[1] Depending on the substance or preparation, an indication must be given of the measures to be taken in the event of accidental release, namely:

a. personal precautions such as removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact;

b. environmental precautions such as keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood;

c. methods for cleaning up such as use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust), reduction of gases or fumes with water, dilution; it may also be necessary to draw attention to ma-

terials which must never be used or to suitable neutralising agents, e.g. "never use" or "neutralise with".

[2] If appropriate, reference must be made to exposure controls and personal protection (No. 8) and to disposal considerations (No. 13).

7 Handling and Storage

7.1 Handling

[1] Precautions must be specified for safe handling, including advice on technical measures such as containment, local and general ventilation, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bunded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or preparation (e.g. procedures or equipment which are prohibited or recommended).

[2] If possible, the measures should be briefly described.

7.2 Storage

[1] Conditions must be specified for safe storage, such as specific design for storage rooms or vessels (including retention walls and ventilation), incompatible materials, conditions of storage (temperature and humidity limit/range, light, inert gas, etc.) special electrical equipment and prevention of static electricity.

[2] If relevant, quantity limits under storage conditions must be indicated.

[3] The type of material used in the packaging or containers of the substance or preparation must be indicated.

7.3 Specific uses

In the case of substances or preparations placed on the market for specific uses, recommendations must be given on safe use for these purposes.

8 Exposure Controls and Personal Protection

8.1 Exposure limit values

[1] An indication must be given of specific control parameters such as occupational exposure limit values and/or biological limit values. The limit values for substances dangerous to health included in the list of exposure limit values published by the

SUVA[153] must be indicated. Information must also be provided on the current monitoring procedures and observation methods. In the case of preparations, values must be provided for those constituent substances that are to be indicated in the safety data sheet in accordance with number 3.

2 If exposure scenarios are attached to the safety data sheet, the relevant Derived No-Effect Level (DNEL) and Predicted No-Effect Concentration (PNEC) must be specified for these exposure scenarios.

8.2 Exposure controls and personal protection

1 Information on exposure control measures must include all precautions to be taken during use of the substance or preparation in order to minimise worker and environmental exposure. If the exposure scenarios are attached to the safety data sheet, a summary of the risk management measures must be provided for all the uses identified in number 1.

2 Appropriate information must be provided so that the employer can carry out the risk assessment required under legislation on the protection of workers and take the necessary action. This information should complement the measures recommended under number 7.1.

3 If personal protection equipment is necessary, the equipment required to ensure adequate protection must be specified in detail. In this regard, account must be taken of the Ordinance of 12 July 1995[154] on the Safety of Technical Installations and Equipment and reference made to the relevant CEN[155] standards:

a. Respiratory protection: in the case of dangerous gases, vapours or dust, the appropriate type of protective equipment must be specified, such as self-contained breathing apparatus, adequate masks and filters.

b. Hand protection: the type of gloves to be worn when handling the substance or preparation must be specified, including the type of glove material and the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure. If necessary, any additional hand and skin protection measures must be indicated.

c. Eye protection: the type of eye protection equipment required must be specified, such as safety glass, safety glasses/goggles, and face shield.

d. Skin protection: if it is necessary to protect parts of the body other than the hands, the required type and quality of protection equipment must be specified, such as full protective suit, apron, and boots. If necessary, specific hygiene measures must be indicated.

153 The booklet «Grenzwerte am Arbeitsplatz» can be obtained against payment from Suva, Postfach, 6002 Lucerne; it can also be accessed on the Internet at www.suva.ch.
154 SR **819.11**
155 European Committee for Standardization

4 If the exposure scenarios are attached to the safety data sheet, a summary of the risk management measures for monitoring the environmental exposure for these exposure scenarios must be provided.

9 Physical and Chemical Properties

1 All relevant information on the substance or preparation must be provided so that proper control measures can be taken, in particular:

a. appearance: the physical state (solid, liquid, gas) and colour of the substance or preparation as supplied;

b. odour: if odour is perceptible, give a brief description;

c. pH: indicate the pH of the substance or preparation as supplied or of an aqueous solution; in the latter case, indicate the concentration;

d. boiling point or boiling range;

e. flash point;

f. flammability (solid, gas);

g. explosive properties;

h. oxidising properties;

i. vapour pressure;

j. relative density;

k. solubility: water solubility, fat solubility (specify solvent);

l. partition coefficient: n-octanol/water;

m. viscosity;

n. vapour density;

o. evaporation rate;

p. other information: indicate important safety parameters, such as miscibility, conductivity, melting point/range, gas group, auto-ignition temperature.

2 If for the properties cited in paragraph 1 letters f to h it is stated that a particular hazard does not apply, it must be indicated whether no information is available or negative test results are available. For preparations, information is normally to be given on the properties of the preparation itself. If it is considered necessary to give information about the properties of individual components, a precise indication must be given of what the data refers to.

10 Stability and Reactivity

An indication must be given of the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions or in the event of release into the environment.

10.1 Conditions to avoid

An indication must be given of conditions such as temperature, pressure, light, shock, etc. which may cause a dangerous reaction. If possible, the reaction is to be briefly described.

10.2 Materials to avoid

An indication must be given of materials such as water, air, acids, bases, oxidising agents or any other specific substance which may cause a dangerous reaction. If possible, the reactions are to be briefly described.

10.3 Hazardous decomposition products

An indication must be given of hazardous materials produced in dangerous amounts upon decomposition. In particular, the following must be addressed:

a. the need for and the presence of stabilisers;

b. the possibility of a hazardous exothermic reaction;

c. safety significance of a change in physical appearance of the substance or preparation;

d. hazardous decomposition products, if any, formed upon contact with water;

e. possibility of degradation to unstable products.

11 Toxicological Information

[1] A concise, but complete and comprehensible description must be given of the various toxicological (health) effects that may occur when professional users come into contact with the substance or preparation.

[2] An indication must be given of dangerous-to-health effects resulting from exposure to the substance or preparation, based on experience or test data. The symptoms must be described in relation to the physical, chemical and toxicological characteristics, with information on the different routes of exposure (inhalation, ingestion, skin and eye contact).

[3] The immediate and delayed effects and chronic effects resulting from short- or long-term exposure must be taken into account, such as sensitisation, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility).

[4] Taking into account the information provided under number 2, it may be necessary to make reference to specific effects of certain substances in a preparation.

[5] If a chemical safety report is required, it must provide information on the following groups of potential effects:

a. toxicokinetics, metabolism and distribution;

b. acute effects (acute toxicity, irritation and corrosivity);

c. sensitisation;

d. repeated dose toxicity; and

e. carcinogenicity, mutagenicity and toxicity for reproduction.

12 Ecological Information

[1] A description must be given of the possible effects, behaviour and environmental fate of the substance or preparation in air, water and/or soil. Where available, the relevant test data (e.g. LC50 fish ≤ 1 mg/l) must be given.

[2] A description must be given of the most important characteristics likely to have an effect on the environment owing to the nature of the substance or preparation and likely methods of use. Information of the same kind must be supplied for dangerous products arising from the degradation of substances and preparations. The following properties must be taken into account:

a. *ecotoxicity:* available data on acute and chronic aquatic toxicity for fish, daphnia, algae and other aquatic plants must be indicated. In addition, toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, must be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants must be mentioned.

b. *mobility:* the potential of the substance or the appropriate constituents of a preparation, if released to the environment, to transport to groundwater or far from the site of release. The following data may be relevant:

   1. known or predicted distribution to environmental compartments,
   2. surface tension,
   3. adsorption or desorption.

c. *persistence and degradability:* the potential of a substance or the appropriate constituents of a preparation to degrade in relevant environmental media, either through biological degradation or other processes such as oxidation or hydrolysis. Degradation half-lives must be indicated where available. The potential of a substance or appropriate constituents of a preparation to degrade in sewage treatment plants should also be mentioned.

d. *bioaccumulative potential:* the potential of a substance or the appropriate constituents of a preparation to accumulate in biota and to pass through the food chain, with reference to the octanol-water partition coefficient (K_{ow}) and the bioconcentration factor (BCF), if available.

e. *PBT assessment:* where a chemical safety report is required, the results of the PBT assessment as mentioned in the chemical safety report must be indicated.

f. *other harmful effects:* if available, information on any other adverse effects on the environment must be indicated, e.g. ozone depletion potential, photochemical ozone creation potential and/or global warming potential.

[3] It must be ensured that information relevant to the environment is provided under other sections of the safety data sheet, especially advice for controlled release, accidental release measures, transport and disposal considerations under numbers 6, 7, 13, 14 and 15.

13 Disposal considerations

[1] If the disposal of a substance or preparation (surplus or waste from the intended use, including packaging) involves the risk that harmful or troublesome effects may arise from improper handling, a description of these residues and information on their safe handling must be provided.

[2] An indication must be given of the appropriate methods of disposal for both the substance or preparation and any contaminated packaging (recycling, incineration, landfilling etc.), giving due consideration to the provisions of legislation on the protection of the environment, particularly the Technical Ordinance of 10 December 1990[156] on Waste and the Ordinance of 22 June 2005[157] on Movements of Wastes.

14 Transport Information

[1] An indication must be given of any special precautions that professional users need to be aware of and to comply with in connection with transport and conveyance within and outside their premises.

[2] Where relevant, information must be provided according to the UN Recommendations and other international agreements on the transport and packing of dangerous goods.

15 Regulatory Information

[1] An indication must be given of the health, safety and environmental information that must appear on the label in accordance with this Ordinance.

[2] An indication must be given of any specific provisions on the protection of health and the environment that apply to substances and preparations which must appear in the safety data sheet (e.g. restrictions on use and placing on the market, occupational exposure limits or emission limits).

156 SR **814.600**
157 SR **814.610**

16 Other Information

Any other information which may be of importance with regard to safety and the protection of health and the environment must be indicated, especially:

a. list of the relevant R-phrases, reproducing the full text of any R-phrases which need to be quoted in accordance with numbers 2 and 3;

b. training advice;

c. restrictions on use recommended by the manufacturer;

d. further information (written references or technical contact point);

e. sources of key data used to compile the safety data sheet.

Annex 3[158]
(Art. 16*a*, 17 para. 2, 18 para. 2 let. b, 60 para. 1)

Technical Dossier

General Provisions

[1] The information in the technical dossier may be submitted in a form approved by the European Chemicals Agency. In this case, certain expressions may differ from those mentioned in this Annex.

[2] The information required under numbers 6–9 depends on the decisive substance quantity in accordance with Article 16*a*.

1 General Notifier Information

[1] The notifier's identity must be provided, specifically:

a. name, address, telephone number and e-mail address;

b. a contact person;

c. if applicable, the location of the notifier's production sites;

[2] In addition, if the notifier is the sole representative, the following information is required:

a. foreign manufacturer's name and address;

b. location of the production sites;

c. authorisation from the foreign manufacturer stating that it appointed the notifier as its sole representative;

d. names and addresses of the importers represented;

e. the quantities that each importer intends to import annually.

2 Identification of the Substance

Information on the substance must be provided in accordance with number 2 of Annex VI to Regulation (EC) No. 1907/2006[159].

158 Inserted by No. II para. 3 of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

159 OJ L 396 of 30.12.2006, p. 1, revised in OJ L 136 of 29.5.2007, p. 3, last amended by Council Regulation (EC) No. 1354/2007 of 15 November 2007, OJ L 304 of 22.11.2007, p. 1. The texts of the European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.

3 Information on Manufacture and Use

The following information must be provided:

a. the estimated overall quantity to be placed on the market by the notifier in the calendar year of the notification;

b. the quantities for the notifier's own use;

c. the form or physical state in which the substance is made available;

d. a brief description of the identified use(s).

4 Classification and Labelling

The classification of the substance according to Article 8 and the hazard label for the substance according to Article 39 must be provided.

5 Guidance on Safe Use

The following information, which must be consistent with that in the safety data sheet, where such a safety data sheet is required in accordance with Article 52, must be stated:

a. first-aid measures (safety data sheet, No. 4);

b. fire-fighting measures (safety data sheet, No. 5);

c. accidental release measures (safety data sheet, No. 6);

d. handling and storage (safety data sheet, No. 7);

e. transport information (safety data sheet, No. 14);

f. exposure controls/personal protection (safety data sheet, No. 8);

g. stability and reactivity (safety data sheet, No. 10);

h. disposal considerations. Information on recycling and methods of disposal for industry and for the public (safety data sheet, No. 13).

6 Exposure-related Information (1–10 tonnes per year)

For substances with a decisive quantity according to Article 16*a* of between 1 and 10 tonnes per year, the following exposure-related information must be provided:

a. main use categories:
   1. industrial use,
   2. professional use,
   3. use by consumers;

b. specification for industrial and professional use:
   1. use in a closed system,
   2. use resulting in inclusion into or onto matrix,
   3. non-dispersive use,
   4 dispersive use;

c. significant routes of exposure:
   1. human exposure: oral, dermal and inhalatory,
   2. environmental exposure: water, air, solid waste and soil,
   3. pattern of exposure: accidental/infrequent, occasional or continuous/ frequent.

7 Information on the Physico-Chemical Properties

Robust study summaries must be provided for the following information:

a. for quantities of 1 tonne per year or more: the information mentioned in number 7 of Annex VII to Regulation (EC) No. 1907/2006;

b. for quantities of 100 tonnes per year or more: in addition to the information required by letter a, information mentioned in number 7 of Annex IX to Regulation (EC) No. 1907/2006.

8 Toxicological Information

Robust study summaries must be provided for the following information:

a. for quantities of 1 tonne per year or more: the information mentioned in number 8 of Annex VII to Regulation (EC) No. 1907/2006;

b. for quantities of 10 tonnes per year or more: in addition to the information mentioned in letter a, the information mentioned in number 8 of Annex VIII to Regulation (EC) No. 1907/2006;

c. for quantities of 100 tonnes per year or more: in addition to the information required by letter b, the information mentioned in number 8 of Annex IX to Regulation (EC) No. 1907/2006;

d for quantities of 1000 tonnes per year or more: in addition to the data specified under letters a-c, relating to the data referred to in number 8 of Annex X to Regulation (EC) No. 1907/2006.

9 Exotoxicological Information

Robust study summaries must be provided for the following information:

a. for quantities of 1 tonne per year or more: the information mentioned in No. 9 of Annex VII to Regulation (EC) No. 1907/2006;

b. for quantities of 10 tonnes per year or more: in addition to the information required by letter a, the information mentioned in No. 9 of Annex VIII to Regulation (EC) No. 1907/2006;

c. for quantities of 100 tonnes per year or more: in addition to the information required by letter b, the information mentioned in No. 9 of Annex IX to Regulation (EC) No. 1907/2006;

d for quantities of 1000 tonnes per year or more: in addition to the information required by letters a-c, the information mentioned in No. 9 of Annex X to Regulation (EC) No. 1907/2006.

10 Omission of certain Tests

Some of the tests specified in Nos. 7–9 may be omitted, if according to the criteria in Annex XI to Regulation (EC) No. 1907/2006:

a. the tests do not appear to be necessary from the scientific standpoint;

b. the tests are not technically feasible;

c. the exposure assessment allows certain tests to be omitted.

Annex 4[160]
(Art. 52 let. c, 63 para. 1 let. b, 64 para. 1 let. d No. 3 and 76 let. c)

List of substances subject to authorisation, derived from Annex XIV to Regulation (EC) No. 1907/2006[161]

This list corresponds to Annex XIV to Regulation (EC) No. 1907/2006.

160 Inserted by No. II para. 3 of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

161 OJ L 396 of 30.12.2006, p. 1, revised in OJ L 136 of 29.5.2007, p. 3, last amended by Council Regulation (EC) No. 1354/2007 of 15 November 2007, OJ L 304 of 22.11.2007, p. 1. The texts of the European Union legal documents mentioned in this Ordinance can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; they can also be accessed on the Internet at www.cheminfo.ch or http://eur-lex.europa.eu/.