

## UNOFFICIAL TRANSLATION

Pursuant to the first paragraph of Article 35 of the Chemicals Act (Official Gazette of the RS, 36/99, 11/01 – ZFfS, 65/03), the Minister of Health hereby issues the

### **RULES on the reporting of data on chemicals**

#### I. GENERAL PROVISIONS

##### Article 1 (content and purpose of the Rules)

(1) These Rules lay down the method of presenting and updating data, as well as exceptions regarding the reporting of data on chemicals. Data shall be reported for the purposes of establishing and maintaining a national list of chemicals produced in the Republic of Slovenia or imported into the Republic of Slovenia.

(2) The list of chemicals shall be established and maintained by the National Chemicals Bureau (hereinafter: the Bureau) and shall be used to protect human health and the environment in the Republic of Slovenia.

##### Article 2 (meaning of terms)

(1) The terms used in the Chemicals Act (Uradni list RS, 36/99, 11/01–ZFfS, 65/03; hereinafter: the Act) shall be used in these Rules.

(2) The EC number is the identification number of a substance from the European Union list of substances.

(3) Import is any act that causes the transfer of a chemical from another country to the territory of the Republic of Slovenia. The transporting of a chemical is not deemed to be import.

(4) A reporting agent according to these Rules is:

1. a legal or natural person that produces a hazardous chemical in the Republic of Slovenia;
2. a legal or natural person that imports a hazardous chemical into the Republic of Slovenia for professional use.

#### II. REPORTING OF DATA

##### Article 3 (scope of chemicals and method of presentation of data)

(1) The reporting agent must report the following data to the Bureau for every hazardous chemical whose hazardous properties place it in one of the groups from point 10 of Article 2 of the Act:

1. general information on the reporting agent;

2. the tradename of the chemical;
3. the safety data sheet;
4. its designation according to the nomenclature of the customs tariff;
5. whether the chemical is a substance or a preparation;
6. whether the chemical is produced by the reporting agent or is imported into the Republic of Slovenia;
7. the fields of use, with an estimate of market shares;
8. chemical composition.

(2) Data from points 1, 2 and 3 of the preceding paragraph must be reported by the reporting agent upon first release of the chemical to a third party or upon first import of the chemical into the Republic of Slovenia at the latest, using the form from Annex 1 of these Rules. Data from points 4 to 8 of the preceding paragraph must be reported by the reporting agent by 31 March of the year after first release of the chemical to a third party or first import of the chemical into the Republic of Slovenia at the latest, using the form from Annex 2 of these Rules.

(3) For all chemicals from the first paragraph of this Article entered in the list of chemicals, the reporting agent must report data to the Bureau on production and placement in circulation, as well as on import of the chemicals into the Republic of Slovenia, by 31 March of the current year for the previous year, using the form from Annex 3 of these Rules.

#### Article 4 (updating data)

(1) The reporting agent must report changes to any data on chemicals from the first paragraph of the preceding Article to the Bureau using the forms from Annexes 1 and 2 of these Rules.

(2) The reporting agent must report data from the preceding paragraph to the Bureau by 31 March of the current year at the latest for data from the previous year.

(3) The reporting agent shall not be required to report changes to general information about the reporting agent from point 1 of the preceding paragraph if these changes have been reported pursuant to regulations governing procedures for obtaining licences for the performance of activities (Article 44 of the Act).

(4) Notwithstanding the second paragraph of this Article, a reporting agent that imports a chemical into the Republic of Slovenia and that does not require a licence for the performance of activities in accordance with the Act must report changes to general information about the reporting agent from point 1 of the first paragraph of the preceding Article to the Bureau within 15 days of the occurrence of the change at the latest.

(5) Notwithstanding the second paragraph of this Article, the reporting agent must report the following to the Bureau immediately upon occurrence of the change:

1. changes to the tradename of the chemical (point 2 of the first paragraph of the preceding Article);
2. changes to the safety document (point 3 of the first paragraph of the preceding Article), if the changes are required on account of an increase in the level of hazard of the chemical to human health.

Article 5  
(reporting in electronic form)

The Bureau may lay down the form and method of reporting data from Articles 3 and 4 of these Rules in electronic form.

Article 6  
(entry in the list of chemicals)

(1) After receiving the data from Article 3 of these Rules, the Bureau shall enter the chemical in the list of chemicals, determine the record and report number for the reported chemical, and report the report number to the reporting agent.

(2) After receiving the data from Article 4 of these Rules, the Bureau shall change the record and report number of the chemical if required, and report the report number to the reporting agent.

Article 7  
(exceptions)

(1) Notwithstanding Article 3 of these Rules, the reporting agent shall not be required to report data for chemicals listed in Annex 4 of these Rules.

(2) The provisions of the first and second paragraphs of Article 3 and the provisions of Article 4 of these Rules shall not apply to biocides for which data is already subject to reporting in accordance with regulations governing the placement of biocides in circulation.

Article 8  
(deletion from the list of chemicals)

A reporting agent that has withdrawn a chemical from circulation in the Republic of Slovenia or that no longer imports a chemical into the Republic of Slovenia must report this to the Bureau upon the occasion of the annual reporting of quantities from the third paragraph of Article 3 of these Rules. The Bureau shall enter the change in the list of chemicals.

Article 9  
(confidentiality of data)

(1) If the reporting agent can reasonably argue that any disclosure of data that constitutes a production or business secret might cause economic damage to another person, with the exception of an authorised body or institution, he may mark it as confidential.

(2) If the reporting agent decides to disclose data marked confidential, he must notify the Bureau of this in writing.

### III. FINAL PROVISIONS

#### Article 10 (annulment of previous Rules)

On the day these Rules enter into force, the Rules on the Reporting of Data on Chemicals (Official Gazette of the RS, 73/99, 45/00) shall cease to be applied.

#### Article 11 (entry into force of the Rules)

These Rules shall enter into force on the 15<sup>th</sup> day after their publication in the Official Gazette of the Republic of Slovenia.

No. 022-5/2003  
Ljubljana, 10 October 2003

Dr. Dušan Keber  
Minister of Health

Annex 1

**Report on chemicals**

**First report on chemicals**                       **Change to data**                      (mark accordingly)

**1. General information on the reporting agent**

**a. Name** \_\_\_\_\_

**b. Registered office** \_\_\_\_\_

**c. Registration no.** \_\_\_\_\_

**d. Tel/fax** \_\_\_\_\_

**e. Email** \_\_\_\_\_

**2. Data on chemicals**

No.	Tradename of chemical	Report no.

(The tradename of the chemical must be the same as the tradename in the safety data sheet. For changes to data, complete the third column of the table with the existing report numbers)

**2.1. Data on chemicals from Annexes 1 and 2 that has changed since the last report was filed**

(Fill in any changes to the data, e.g. changes to the R phrases in safety data sheets, changes of address of the reporting agent in safety data sheets, changes to the field of use of the chemical. If a change to the data merely involves the concentration of a substance, that change should only be stated if the concentration of the substance has changed by over 15% relative to the level stated when the data was first reported.)

\_\_\_\_\_  
\_\_\_\_\_

**Enclosed: safety data sheets for individual chemicals**

**Name of preparator**

**Date**

**Signature**

\_\_\_\_\_

Annex 2

**Supplementary report on chemicals**

**1. General information on reporting agent**

**a. Name** \_\_\_\_\_ **b. Registered office** \_\_\_\_\_ **c. Registration no.** \_\_\_\_\_

**2. Data on chemicals**

Tradename of chemical	NCT code	Substance/preparation (S/P)	Production/import (P/VEU/VDD)	Field of use, with estimate of market shares			Narrower field of use	Methods of use
				Industry and crafts (%)	Agriculture and specialist trade (%)	General use (%)		

((1) NCT code – four-digit tariff code according to the nomenclature of the customs tariff; (2) Production/import: P– production, VEU – admission from EU states, VDD – admission from non-EU states)

**Enclosed: chemical compositions for individual chemicals (point 2.1.)**

**Name of preparator**

**Date**

**Signature**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**2.1. Chemical composition of a chemical with a tradename:** \_\_\_\_\_

Chemical name of substance (IUPAC)	EC No.	CAS No.	INDEX No.	R phrases (xy)	Concentration (% by weight)

(The name of the substance according to the ISO (International Standard Organisation) or the CI (Colour Index) may be given in place of the IUPAC name.)

## **Additional instructions**

a. Under point 2, complete the eighth and ninth columns of the table for all chemicals intended for general use (unspecified buyer):

- narrower area of use of the chemical, e.g. drain cleaner, bathroom cleaner, furniture cleaner, dishwashing agent, wood protection agent, anti-freezing agent, photographic developer, glue for wooden surfaces, stain remover, chemical for use in swimming pools, etc.
- methods of use of the chemical, e.g. spraying, smearing, sprinkling, rinsing, soaking, etc.

b. Under point 2.1., enter data on chemical composition for all chemicals entered under point 2:

b.1. If the substance contains additives for stability or impurities, the following must be stated, in addition to the substance itself: all additives or impurities whose hazardous properties place the substance in any of the groups from point 10 of Article 2 of the Act and which have a bearing on classification of the substance. Concentrations shall be given in intervals of 0 to 3% as precisely as possible; higher concentrations may be rounded up or down to the nearest whole number. In the event of accidental standard fluctuations due to the production procedure, the middle value of the concentration interval should be stated.

b.2. For preparations, all the hazardous substances they contain must be stated. Substances whose hazardous properties place them in any of groups (f) to (o) from point 10 of Article 2 of the Act must be stated when the regulations on the production of safety documents prescribes that such substances must be stated under point 2 of the safety document. All substances whose hazardous properties place them in any of groups (a) to (e) from point 10 of Article 2 of the Act must be stated when they have a bearing on the classification of the preparation. Concentrations shall be given in intervals of 0 to 3% as precisely as possible; higher concentrations may be rounded up or down to the nearest whole number. In the event of accidental standard fluctuations due to the production procedure, the middle value of the concentration interval should be stated.

For preparations in liquid form, the substance that is the main (highest) solvent medium of the preparation must always be stated, regardless of whether it is classified in any of the hazard groups from point 10 of Article 2 of the Act.

b.3. In these instructions, concentration always means percentage by weight.

b.4. If the reporting agent does not receive all the required data on chemical composition from the supplier/producer of the chemical, the reporting agent may agree with the supplier/producer that they submit the missing data direct to the Bureau. In this case, the supplier/producer must state the name of the reporting agent and the tradename of the chemical on the Slovenian market.

b.5. Data on chemical composition does not need to be submitted for those chemicals for which all required data on chemical composition has already been stated in Article 2 of the safety document, in accordance with the requirements of the above points b.1 and b.2.



Annex 3

**Annual report on the production, placement on the market and import of chemicals**

1. Name and registered office of reporting agent		2. Registration no. of reporting agent		3. Year	
4. Tradename of chemical	5. Report No. of chemical	6. Quantity produced (t)	7. Quantity imported into Slovenia (t)	8. Quantity placed on the market (t)	
				Domestic market	Export

(Fill in the tradenames of chemicals in alphabetical order, or in order of report number and annual quantities in tons)

**Name of preparator**

**Date**

**Signature**

\_\_\_\_\_

## Annex 4

### Chemicals for which reports do not need to be filed

1. Chemicals classified according to their hazardous properties as explosive, oxidising, extremely flammable, highly inflammable or flammable which producers/importers produce or import in quantities of less than 100 kg.
2. Chemicals exclusively for laboratory use (laboratory chemicals) which producers/importers produce or import in quantities of less than 100 kg.
3. Chemicals exclusively for the production of medicines (raw materials for medicines).
4. Petroleum and petroleum derivatives and other organic chemicals used for engine or heating fuel.
5. The following chemicals, in accordance with the nomenclature of the customs tariff:
  - Chapter 25 (all) – salt; sulphur; soils and rocks; gypsum, lime and cement
  - Chapter 26 (all) – ores, slag and cinders
  - Tariff codes 2701 – hard coal, including briquettes of various forms
  - 2702 – brown coal (lignite), agglomerated or non-agglomerated, except gagatite
  - 2703 – peat (including peat straw), non-agglomerated or agglomerated
  - 2704 – coke and semi-coke from hard coal, brown coal, lignite or peat, non-agglomerated or agglomerated; charcoal retort
  - 2705 – gas from hard coal, water gas, generator gas and similar gases, except petroleum gases and other hydrocarbon gases
  - 2714 – bitumen and asphalt, natural; bituminous and oil shale, and tar sand; asphalt and asphalt aggregate
  - Tariff codes 3101 – fertilisers of animal or plant origin, unmixed, mixed with each other or chemically treated; fertiliser obtained through the mixing or chemical treatment of products of animal or plant origin
  - Tariff code 3406 – candles of various sizes and similar
  - Chapter 39 (all) – plastic materials and products made therefrom
  - Chapter 47 (all) – cellulose, wood or other materials made from fibre; paper or cardboard waste and residues
  - Chapters 68 to 81 (all)

Notwithstanding the above-mentioned chapters, data on the following chemicals must be reported for entry in the list of chemicals:

- Tariff code 2503 – sulphur of all types except sublimated, sedimentary or colloid sulphur
- Tariff code 2511 – natural barium sulphate (barite), natural barium carbonate (viterite), burnt or unburnt, except barium oxide under tariff code 2816
- Tariff code 2524 – asbestos
- Tariff codes 3901 to 3914 – plastic materials in their primary forms intended for use as raw materials
- Tariff code 6812 10 – processed asbestos fibres; mixtures with an asbestos base or an asbestos and magnesium carbonate base
- Tariff code 7804 20 – lead powder and flakes