

Pursuant to Article 153 of the Rules of procedure of the National Assembly, at its session on 2 October 2003 the National Assembly of the Republic of Slovenia adopted the official consolidated text of the Cosmetic Products Act comprising:

- Cosmetic Products Act (Zakon o kozmetičnih proizvodih – ZKozP, Ur. l. RS, št. 66/2000) of 26 July 2000) and
- Act Amending Cosmetic Products Act (Zakon o spremembah in dopolnitvah zakona o zakon o kozmetičnih proizvodih – ZKozP-A, Ur. l. RS, št. 65/2003) of 4 July 2003.

No. 520-01/00-2/3
Ljubljana, 2 October 2003

COSMETIC PRODUCTS ACT

official consolidated text

(ZKozP-UPB1)

I. GENERAL PROVISIONS

Article 1
(contents)

This act lays down the conditions that must be met by cosmetic products placed on the market in Republic of Slovenia in order to ensure their suitability and undisturbed trade, and governs the control of cosmetic products.

Article 2
(cosmetic products)

A cosmetic product within the meaning of this Act shall be any substance or preparation in its final form intended for appliance on the external parts of the human body (epidermis, scalp, nails, lips or external genitalia organs), or on the teeth and mucous membrane in the oral cavity, with the sole or main intention of cleaning them, scenting or protecting them, keeping them in good condition, changing their appearance or removing unpleasant body odours shall be considered to be a cosmetic product.

Article 3
(definitions)

For the purpose of this act the following definitions shall apply:

1. A supplier is any legal person or sole proprietor with its registered offices in the Republic of Slovenia who:

- manufactures cosmetic products
- declares itself to be the manufacturer of the product by using the name of the company, its trademark or other distinctive mark on the product,
- in any way changes the composition of cosmetic products or the content of labelling laid down in this act.
- is the manufacturers representative or importer (with registered offices in the Republic of Slovenia -this provision has been deleted by Official Gazette of the Republic of Slovenia, No. 47/04-ZdZPZ) if the manufacturer's main office is not in the Republic of Slovenia or in the European Union

2. Trade means sale or any kind of making available of a cosmetic product to the end-user for the purposes laid down in this act. The provisions of this act applying to trade shall apply mutatis mutandis to professional use of cosmetic products.

3. Good Laboratory Practice is a quality system concerned with the organisational process and the conditions under which non-clinical health and environment safety studies are planned, performed, monitored, recorded, archived and reported.

4. Good Manufacturing Practice is a quality assurance system ensuring consistent manufacturing and control of products according to the criteria of quality and suitability for the purpose of use in accordance with product specification.

5. A preservative is any substance added to a cosmetic product with the primary intention of inhibiting the development of micro-organisms in the product.

6. A UV filter is a substance added to cosmetic products with the primary intention of filtering certain ultraviolet sunrays in order to protect the skin from their damaging effects.

7. An authorised laboratory is a laboratory appointed by the minister responsible for health (hereinafter: the Minister) from among accredited laboratories or laboratories assessed as being able to carry out the tests required by law.

8. A cosmetic ingredient is any chemical substance or preparation of synthetic or natural origin used in the composition of a cosmetic product including perfumes and aromatic substances.

9. Import is the customs procedure of release of goods for free circulation.

II. SUITABILITY OF COSMETIC PRODUCTS

Article 4

(suitability of cosmetic products)

Cosmetic products placed on the market shall meet the requirements laid down in this act and must not be harmful to human health under normal, and foreseeable conditions of use and by taking into account of the product`s presentation, labelling, instructions for use and disposal, as well as any other statements or information provided by the supplier.

A supplier that places a cosmetic product on the market shall be responsible for its suitability. Responsibility for taking into account the supplier's instructions on proper use which are indicated on the cosmetic product shall also be borne by any other legal or natural person placing the cosmetic product on the market.

Article 5

(deleted)

Article 6

(assessment of suitability of cosmetic products)

Before placing a cosmetic product on the market the supplier must ensure assessment of suitability for human health. The assessment of suitability must be carried out on the basis of test results and studies, by taking into account the general toxicological profile of the ingredients used, their chemical structure and the level of exposure of the user.

Assessment of suitability may be carried out by experts holding at the minimum professional higher education degree in the field of chemistry or pharmacy or a university degree in the field of medicine or toxicology.

Article 7

(animal testing of cosmetic products)

Cosmetic products which:

– have been tested on laboratory animals for the purpose of ensuring suitability of and compliance with the provisions of this act, or

– contain ingredients or combinations of ingredients that have been tested on laboratory animals for the purpose of ensuring suitability of and compliance with the provisions of this act,

may be placed on the market only if the tests on animals have been performed according to the prescribed methods and in compliance with the principles of Good Laboratory Practice, laid down pursuant to the act governing chemicals.

In the Republic of Slovenia testing of cosmetic products or their prototypes on animals is not allowed.

Suppliers of cosmetic products shall, by 31st January of the current year, inform the competent authority for chemicals on the types and number of tests that they have conducted on animals in connection with cosmetic products in the preceding year with the purpose of ensuring their suitability of and compliance with the provisions of this act.

The Minister shall determine the conditions under which cosmetic products may be labelled with statements on animal testing.

With a prior consent of the European Commission, the competent authority for chemicals and the competent authority for animal health and welfare may exceptionally allow derogation from the provisions of the first paragraph and determine the testing conditions if there is no other way to prevent harmful consequences and doubts regarding the safety of a cosmetic product to the users health.

Article 8

(competent authority for cosmetic products)

Expert and development administrative tasks in accordance with this act are performed by the competent authority for chemicals.

At the international level the competent authority for chemicals shall conduct international data exchange on cosmetic products with other competent authorities, in keeping with international treaties or international notification systems.

On the basis of information acquired by data exchange through international notification systems indicating that there are reasonable grounds for suspecting that a certain cosmetic product may be dangerous to human health, the competent authority for chemicals may issue a decision temporarily banning placement of such product on the market in the Republic of Slovenia or determining special conditions under which it may be placed on the market.

The competent authority for chemicals may also issue a decision temporarily banning or restricting placement of such product on the market in the Republic of Slovenia pursuant to an opinion from the Commission from Article 16 of this act.

III. MANUFACTURE OF COSMETIC PRODUCTS

Article 9

(performance of activity)

A supplier of cosmetic products shall notify its activity in advance to the competent authority for chemicals, on a form laid down by the Minister. The competent authority for chemicals shall keep a register of suppliers including the firm, registered offices, contact person and contact numbers and addresses and shall be available only to authorised persons, bodies and institutions.

A person responsible for manufacture and/or quality assurance of cosmetic products must have completed at least a two year higher education programme in chemistry, pharmacy, medicine or a similar discipline which will assure the implementation of the requirements of suitability of cosmetic products laid down in this act.

The manufacture of cosmetic products must be conducted in keeping with the principles of Good Manufacturing Practice.

The principles of Good Manufacturing Practice shall be laid down by the Minister.

Article 10 (banned substances)

Cosmetic products shall contain no substances and micro-organisms laid down by the Minister pursuant to the EU's unified list of banned substances, or pursuant to a substantiated proposal by the Commission from Article 16 of this act.

Substances from the preceding paragraph may only be present in cosmetic products in traces if technologically unavoidable despite good manufacturing practice and on the condition that their presence does not affect suitability of the product in compliance with Article 4 of this act.

The conditions for microbiological suitability of cosmetic products shall be laid down by the Minister.

Article 11 (substances subject to restrictions)

Cosmetic products containing substances subject to restrictions may be placed on the market only if they meet the conditions and limitations regarding their concentrations, the field and manner of their application, labelling and other limitations that will ensure their suitability in accordance with this act.

Substances subject to restrictions as well as the conditions and limitations for cosmetic products in which they are present shall be laid down by the Minister pursuant to the EU's unified list.

IV. TRADE IN COSMETIC PRODUCTS

Article 12

(information on a cosmetic product)

The supplier of cosmetic product shall, for inspection control purposes, keep at the address stated in the Republic of Slovenia or in the European Union a dossier with information on the cosmetic product in the Slovene, English or another language which the health inspector is familiar with. The content and detailed requirements with regard to the dossier on cosmetic product shall be laid down by the Minister.

For the purposes of appropriate medical treatment, the competent authority for chemicals may forward information on the composition and the ingredients of a cosmetic product to institutes which are, on the basis of the act on chemicals, authorised for gathering, organisation, and continuous forwarding of information on acute poisonings and other effects of chemicals, or request from the supplier to forward the information to the institute. The authorised institutes may use this information exclusively for the purposes for which the information was forwarded to them.

The Minister may determine that certain information or groups of information from a dossier on a cosmetic product are of particular relevance for the awareness of the users of cosmetic products. The supplier of the product shall ensure unrestricted access to this information to all users and interested general public.

Article 13

(notification on a cosmetic product)

Prior to the first placing of a cosmetic product on the market the supplier shall notify the competent authority for chemicals of the production site(s) and/or, in case of importation into the Republic of Slovenia, of the exporting country and country of origin.

The form of notification shall be laid down by the Minister.

Article 14

(packaging and labelling)

Cosmetic products may only be placed on the market if packaged in packaging that enables their correct use and ensures their suitability under foreseeable conditions of use.

Cosmetic products must be properly labelled and must bear information on the supplier and the product. All markings, instructions or lettering must be in indelible, easily

legible and visible lettering. All markings and information which are of particular importance for protection of the users' health must be stated on the packaging in the Slovene language. Details on the content, and the manner of labelling as well as on the markings and the information that are to be stated in the Slovene language, shall be laid down by the Minister.

Article 14a

(confidentiality of data on the composition)

If a supplier considers that indicating one or more ingredients of a cosmetic product, which is/are considered industrial or commercial secret, might harm him commercially, he may submit to the competent authority for chemicals an application requesting that this information is to be treated as confidential.

If the competent authority for chemicals considers that that concealing this information does not reduce the safety of the user, it shall, within four, or exceptionally within six months communicate to the supplier alternative codes for the ingredients in question or else reject the application with a justification.

Confidentiality of data may be maintained no longer than five years. After the expiry of this time period the supplier may request an extension, which may not exceed 3 years.

The procedure and the content of an application for data confidentiality on ingredients of cosmetic products shall be laid down by the Minister.

Data confidentiality obtained on the basis of this Article shall have no bearing on the provisions of Article 12 of this act.

V. ADVERTISING

Article 15

(advertising of cosmetic products)

The advertising of cosmetic products in a manner which might be misleading to the consumer shall be prohibited.

Words or expressions, names, trade marks, pictures or other signs used in labelling, marketing and presentation of cosmetic products shall not claim healing effects and indicate other effects or properties which cosmetic products do not have.

VI. DEALING WITH EXPERT QUESTIONS CONCERNING COSMETIC PRODUCTS

Article 16
(dealing with expert questions)

Following a proposal of the competent authority for chemicals, the Minister shall appoint a committee on cosmetics composed of experts in medicine, pharmacy, cosmetics, toxicology, chemistry and other fields for dealing with expert questions in connection with this act and for the preparation of expert opinions.

For solving expert questions at the international level the Minister shall appoint representatives to relevant international bodies from among the experts from the preceding paragraph.

The work of the Cosmetics Commission shall be harmonised by the competent authority for chemicals.

Chapter VII
(deleted)

Article 17
(deleted)

Article 18
(deleted)

VIII. SURVEILLANCE

Article 19
(inspection surveillance)

Inspection surveillance of the implementation of this act and regulations issued on the basis thereof shall be carried out (performed) by health inspectors.

For inspection surveillance purposes, samples of cosmetic products shall be taken without payment against their value.

Article 20
(analytical methods)

The analyses of samples of cosmetic products taken for the purposes of inspection surveillance shall be carried out by authorised laboratories, in keeping with the methods laid down by the Minister.

Article 21

(the powers of health inspectors)

In addition to the powers granted to them in accordance with the general regulations, health inspectors shall during inspection also have the following powers:

– to take samples of cosmetic products or series of cosmetic products and submit them for analysis to authorised laboratories in order to establish their compliance with the provisions regarding their composition;

– to order that any deficiencies identified be remediated within a specified time limit;

– to request access to and check the information on a cosmetic product;

– to request that a cosmetic product must bear appropriate warnings;

– to ban unauthorised advertising of cosmetic products;

– to order that materials used for unauthorised advertising be removed or destroyed at the expense of the supplier or person placing the product on the market.

– to ban placing on the market or order withdrawal from the market of all cosmetic products that have not undergone a assessment of suitability, are incorrectly labelled, are past their use-by date or have been proven dangerous to human health;

– to order that cosmetic products be destroyed at the expense of the supplier or person placing the product on the market if this is necessary in order to protect the health of consumers;

– to order on-the-spot fines.

IX. PENAL PROVISIONS

Article 22

(fines)

A fine between SIT 200,000 and 10,000,000 shall be levied on a legal person or sole proprietor if they:

1. place on the market a product which does not comply with Article 4 of this act;

2. fail to assure the assessment of suitability or the assessment of suitability of a cosmetic product has not been performed in compliance with the provisions (Article 6), or

they have used tests in assessment of suitability that are not in keeping with the principles of Good Laboratory Practice (Article 7);

3. fail to fulfil the prescribed conditions for performing safety assessment (Article 6);

4. place on the market cosmetic products in contravention of the first paragraph of Article 7 or carry out tests of cosmetic products or their prototypes on animals in breach of the second or fifth paragraph of Article 7 or, fail to communicate information on the performed animal tests contrary to the third paragraph of Article 7;

5. fail to ensure manufacture in keeping with the principles of Good Manufacturing Practice (Article 9);

6. manufacture or import cosmetic products in breach of the provisions of Article 9 of this act;

7. place on the market cosmetic products which are not in compliance with Articles 10 and 11 of this act.

8. fail to submit to a health inspector, the competent authority for chemicals or to an authorised health institute the prescribed information within the prescribed time-limits or fail to ensure access to the information which is of particular relevance to the awareness of the users (Article 12);

9. fail to forward the prescribed information to the competent authority for chemicals, or sending incomplete information (Article 13);

10. place on the market a cosmetic product that is not:

– properly packaged; bearing appropriate information (Articles 12 and 14);

11. Advertise cosmetic products in a manner that could be misleading for the consumer (Article 15).

A fine between SIT 50,000 and 500,000 shall be levied on the responsible person of the legal person or the responsible person of a sole proprietor if they commit an offence from the preceding paragraph.

Cosmetic Products Act – ZkozP (O.J. RS, No. 66/2000) contains the following transitional and final provisions:

X. TRANSITIONAL AND FINAL PROVISIONS

Article 23

(time limits for issuing regulations for the implementation of this act)

Regulations from the third paragraph of Article 4, the first paragraph of Article 10, Article 11, the third paragraph of Article 14 and Article 20 of this act shall be issued by the Minister within six months of entry into force of this act.

The regulation from the sixth paragraph of Article 9 of this act shall be issued by the Minister within two years of the entry into force of this act.

The regulation from the sixth paragraph of Article 25 of this act shall be issued by the Minister within one year of the entry into force of this act.

Article 24

(appointing the committee)

The Commission from the first paragraph of Article 16 of this act shall be appointed by the Minister within one year of the entry into force of this act.

Article 25

(transitional period for entry into force of this act)

Legal and natural persons engaging in the manufacture of or trade in cosmetic products must harmonise their operations with this act within one year of its entry into force.

Cosmetic products already on the market on the day this act enters into force and cosmetic products placed on the market within one year of the entry into force of this act may remain on the market for 30 months after the entry into force of this act.

The Minister may, within one year of the entry into force of this act, authorise laboratories which qualify under the rules of accreditation or equal rules.

Until the authorisation of laboratories from the preceding paragraph, the tasks from this act shall be performed in accordance with this act by laboratories engaged in performing sample analyses of cosmetic products at the time of entering into force of this act.

Good Manufacturing Practice shall be enforced within six years of the entry into force of this act.

Notwithstanding the provision of the preceding paragraph, manufacture must, until the principles of Good Manufacturing Practice are enforced under this act, run in keeping with the instructions for manufacture of cosmetic products issued by the Minister and applying to staff, premises, equipment, documentation, manufacture and quality control.

Article 26

(regulations ceasing to apply)

Until the regulations from the first paragraph of Article 23 of this act have been issued the Regulation on the conditions for the safety for human consumption of items of general use that may be placed on the market (Pravilnik o pogojih glede zdravstvene neoporečnosti predmetov spolšne uporabe, ki smejo v promet, Ur. l. SFRY, 26/83, 61/84, 56/86, 50/89, 18/91), where it applies to items for personal hygiene, body and facial care and beauty products (Chapter V, Article 101-114 inclusive), shall apply, unless contrary to this act.

Article 27
(entry into force)

This Act shall enter in force on the 15th day following its publication in the Official Gazette of the Republic of Slovenia.

The Act Amending the Cosmetic Products Act (Zakon o spremembah in dopolnitvah zakona o kozmetičnih proizvodih – ZkozP-A, Ur. l. RS, št. 65/2003) contains the following transitional and final provisions:

TRANSITORY AND FINAL PROVISIONS

Article 22

The regulation from Article 10 of this act (first paragraph of Article 9 of the Act) shall be issued by the Minister no later than within three months of entering into force of this act.

Notwithstanding the provision of the second paragraph of Article 23 of the Act, the Minister shall issue the regulation from the fourth paragraph of Article 9 of the Act by 31.12.2005.

The regulation from Article 16 of this act (fourth paragraph of Article 14a of the Act) shall be issued by the Minister by 31.12.2003.

Article 23

Suppliers engaging in manufacturing and trade of cosmetic products on the day of entering into force of this act must notify the activity within six months of entering into force of this act.

Article 24

Until the accession of the Republic of Slovenia to the European Union import from any country shall be considered as import into the Republic of Slovenia. After this date import from all states which are not members of the European Union shall be considered import

Article 25

Until the establishment of the competent authority for chemicals, its tasks shall be performed by the National Chemicals Bureau of the Republic of Slovenia.

Article 26

Until 1st January 2005 a natural or legal person that has committed an offence in accordance with Article 21 of this act (article 22 of the Act) concerning independent manufacture and trade, shall be liable to a fine between SIT 500,000 and 3,000,000. A responsible person at the legal person that has committed an offence from Article 21 of this act (Article 22 of the Act) shall be liable to an on-the-spot fine of SIT 50,000.

Article 27

This Act shall enter into force on the fifteenth day of its publication in the Official Journal of the Republic of Slovenia.

President of the
National Assembly
of the Republic of Slovenia
Borut Pahor