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Guidelines for Manufacturers of Common Use Items

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I INTRODUCTION

The purpose of these Guidelines is to provide support to all subjects dealing with common use items that manufacture and sell common use items (widely used products), for adequate and practical implementation of legal requirements set up by the Act on Common Use Items (Official Gazette No 39/13, 47/14) and other sub legal acts.

In accordance with the existing commitments, economic operators dealing with common use items must ensure that the raw materials and products comply with legislation and are safe during all phases of manufacturing (production, processing and distribution phases) which are under their supervision.

The Guidelines apply to requirements regarding health safety/compliance of materials and active substances used in the production of common use items, vessels, utensils, equipment and machines for production of common use items, packaging of common use items and cosmetic products.

The guidelines will be updated in the light of new scientific findings and experience as well as amendments to legal and regulatory requirements.

They were created in 2019 by the Department of Common Use Items, Division for General Environmental Health of the Croatian Institute of Public Health, in cooperation with the Department of Common Use Items and Protection from Noise, Office for Sanitary Inspection of the Ministry of Health. The Guidelines are not legally binding but may serve as a useful tool in addition to the existing obligations arising from the Acts on common use items. They do not represent an official interpretation of regulations.

II INGREDIENTS

In terms of purity, on the condition that they do not pose a health risk and do not have an adverse effect on the health safety/compliance of the finished product, the materials and active substances used in the manufacturing of common use items or necessary during the production process must comply with the pharmacopoeia standards and other recognised regulations and criteria (e. g. essential oils).

III VESSELS, INSTRUMENTS, EQUIPMENT AND DEVICES FOR MANUFACTURING COMMON USE ITEMS

For the purposes of these Guidelines, vessels, utensils, equipment and devices refer to vessels, utensils, equipment and devices used in the preparation and production of cosmetic products.

Vessels, utensils, equipment and devices must not be made from materials that release substances harmful to health or in quantities harmful to health, or negatively affect the organoleptic, physical or chemical properties of common use items with which they come into direct contact, or maintaining them safe for human health.

Vessels, utensils, equipment and machines must be made in a way that enables easy and thorough cleaning, washing and disinfecting when necessary.

Vessels, utensils, equipment, machines, working surfaces and employees' hands must be microbiologically tested. The frequency of the testing is determined by the manufacturer according to the dynamics of production.

Vessels, utensils, equipment and machines must be made from safe materials such as: stainless steel, aluminium alloys, enamel, porcelain, glass or polymeric materials.

IV PACKAGING MATERIALS FOR COMMON USE ITEMS

The requirements related to health safety apply to packaging which comes into contact with cosmetic products as well as objects and substances that come into direct contact with skin or mucous membranes, for which tests are conducted in accordance with the requirements for food contact materials and the pharmacopoeia standards, where applicable.

The packaging must be made from materials that do not have any adverse effect on the organoleptic, chemical, physical and microbiological properties of common use items with which they come into contact.

Regarding the requirements related to waste management, packaging or a packaging component must be made from materials with total concentration of lead, cadmium, mercury, hexavalent chromium or their compounds that does not exceed 100 ppm mass units, except in a special case, in accordance with the relevant legislation.

V COSMETIC PRODUCTS

<u>Microbiological testing:</u>

Microbiological testing is conducted with harmonised standards on all cosmetic products according to categories:
Category 1: products for children under three years of age, products for the area around the eyes, mucous membranes, damaged skin, for the elderly and for people with compromised immunity, where:

- The number of aerobic mesophilic microorganisms (bacteria according to HRN EN ISO 21149 and yeast and mould according to HRN EN ISO 16212) may not exceed 10^2 cfu/g or ml

Category 2: other products

- The number of aerobic mesophilic microorganisms (bacteria according to HRN EN ISO 21149 and yeast and mould according to HRN EN ISO 16212) may not exceed 10^3 cfu/g or ml

In cosmetic products per 1mL or 1g the following microorganisms may not be confirmed:

- *Staphylococcus aureus* (according to HRN EN ISO 22718)
- *Pseudomonas aeruginosa* (according to HRN EN ISO 22717)
- *Echerichia coli* (according to HRN EN ISO 21150)
- *Candida albicans* (according to HRN EN ISO 18416)

The efficacy assessment of the used preservative is conducted in accordance with the standard HRN EN ISO 11930 Cosmetics-Microbiology-Evaluation of the antimicrobial protection of a cosmetic product (Challenge test) and is mandatory for all products except low risk products according to HRN EN ISO 29621 (e. g. for products with pH value >3 and <10 microbiological tests must be conducted).

An example of low risk products: hairsprays, nail polish, aerosols that are not water-based, hair dye, soap- based shaving creams, depilatories, hair styling products, stick deodorants, products for cold permanent hair waving and neutralisers, eau de Cologne and perfumes, oils and oil baths that do not contain water, and generally products with water activity and/or pH and/or alcohol content that prevents growth of microorganisms in the product.

<u>Technical unavoidable substances – metals:</u>
Cosmetic products must not contain metals and their compounds such as lead, cadmium, chromium, nickel, antimony, arsenic and mercury. The limit of mercury concentration does not apply to products for the eye area if they contain thiomersal and phenylmercury salts. In this case, the mass concentration of mercury must not be higher than 0.007%, and the presence of these two ingredients must be clearly declared (Ref. no. 16 and 17, Annex V of Regulation (EU) no. 1223/2009). The unintentional presence of metals in cosmetic products is only allowed if it is technically unavoidable according to good manufacturing practice (GMP) and if the products

are still safe for human health. Safety must be demonstrated for each individual case in the Cosmetic Product Safety Report. There are three categories of MAC (maximum allowable concentration) due to type and purpose of products.

1. Products for dental and oral hygiene and care and toothpastes may not release more than:

Metals	MAC in mg/kg (maximum allowable concentration)
Cadmium	0.1
Mercury	0.1
Arsenic	0.1
Lead	1
Chromium	1
Nickel	1
Antimony	0.5

2. Decorative cosmetics, lip and eye colouring, and other decorative cosmetic products except for hair and nails may not release:

Metals	MAC in mg/kg (maximum allowable concentration)
Cadmium	3
Mercury	3
Arsenic	3
Lead	10
Chromium	50*
Nickel	5
Antimony	5

*Cr (VI+) below detection level

3. Other products which is in prolonged contact with the skin and mucous membranes may not release more than:

Metals	MAC in mg/kg (maximum allowable concentration)
Cadmium	0.1
Mercury	0.1
Arsenic	0.1

Lead	1
Chromium	1
Nickel	1
Antimony	0.5

If the measured metal content in cosmetic products corresponds to the stated values, further risk assessment of metal content is unnecessary.

OTHER TECHNICALLY UNAVOIDABLE SUBSTANCES - the presence of technically unavoidable substances (PAH, nitrosamines etc.), unless otherwise specified, must be in accordance with new scientific knowledge, or other recognized procedures and recommendations.

pH value of the products

Depending on the type and purpose of a cosmetic product, the following pH values are recommended:

1. Products staying in contact exclusively with the mucous membrane may have a pH value 4.0 to 9.0 except eye make-up products, which may have a pH value 3.5 to 9.0 and calcium carbonate based toothpastes and soaps, which may have a pH value up to 10.0;
2. Products staying in prolonged contact with the skin may have a pH value 3.0 to 8.0 except face and body make-up products and body and legs foundation, which may have a pH value up to 9.0 and soap-based deodorants and anti-perspirants, which may have a pH value up to 9.5;
3. Products that are quickly removed from the skin, hair or nails and are used for: face and body cleaning may have a pH value 3.0 to 9.0 except products for professional use, which may have a pH 2.5 and after which neutralising agents are immediately applied;
4. Cleaning and shaving products for face and body may have a pH value 3.0 to 12.0; for depilation up to 12.7; for washing and hair care 3.0 to 7.5 except products for cold permanent waving, which may have a pH value up to 9.5; for nail cuticle removal up to 14.0;
5. Products staying in prolonged contact with the hair and nails may have a pH value from 3. 0 to 8.5;
6. Products staying in prolonged contact with the skin used for neutralising previously used products as specified in point 3 may have a pH value 2.5 to 12.5.

The pH value is not determined for products that do not contain water or contain organic solvents and form a film on the hair or nails after use (hairspray, nail polish etc.), and nail polish removers.

VI OTHER TECHNICAL UNAVOIDABLE SUBSTANCES

Unless otherwise specified, the presence of technical unavoidable substances must comply with new scientific findings and other acknowledged procedures and recommendations.

VII REFERENCES

1. Act on Common Use Items (Official Gazette No 39/13, 47/14, 114/18, 53/22)
2. Ordinance on Special Conditions for the Production and Placing on the Market of Common Use Items (Official Gazette No 80/18)
3. Ordinance on Health and Safety of Common Use Items (Official Gazette No 125/09, 23/13, 90/13, 53/22)
4. Ordinance on Control Frequency and Microbiological Purity Normatives in Facilities under Sanitary Surveillance (Official Gazette No 137/09)
5. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
6. Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
7. The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 11th revision, 30–31 March 2021, SCCS/1628/21
8. Ordinance on Packaging and Packaging waste (Official Gazette No 97/05, 115/05, 81/08, 31/09, 156/09, 38/10, 10/11, 81/11, 126/11, 38/13, 86/13, 88/15, 78/16 i 116/17)
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10. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/guidance-heavy-metal-impurities-cosmetics.html
11. Guide for production of cosmetics https://zdravlje.gov.hr/UserDocsImages/dokumenti/VODI%C4%8C%20ZA%20PROIZVODNJU%20KOZMETI%C4%8CKIH%20PROIZVODA.pd f
12. HRN EN ISO 22716:2008, Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices (ISO 22716:2007, Corrected version 2008-05-15)
13. Course on minimum hygiene request for workers with cosmetics and in beauty salons https://www.hzjz.hr/wp-content/uploads/2021/04/Obrazovni-materijali-ZARAZNE-BOLESTI.pdf