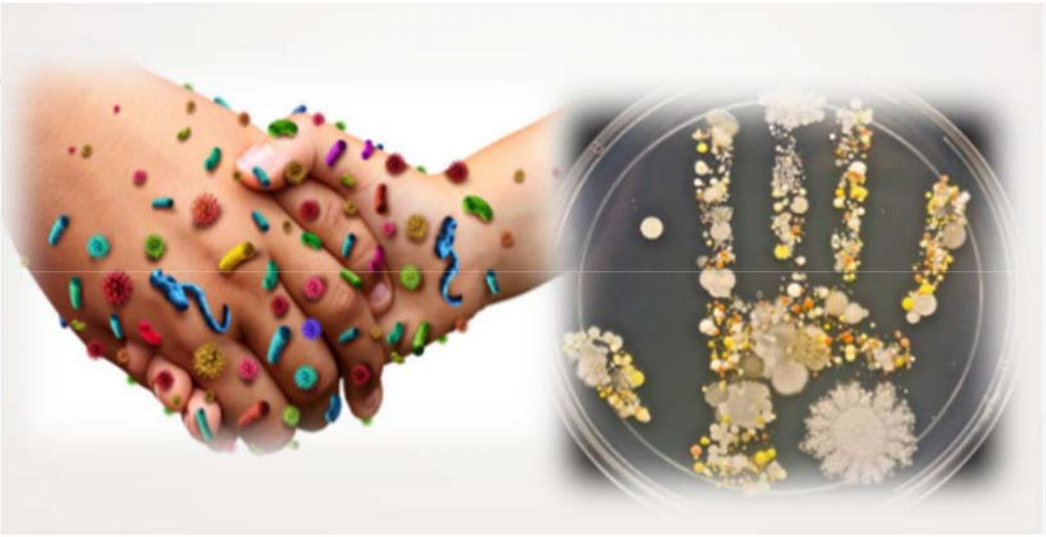
LEARNING MATERIAL FOR THE COURSE ON PREVENTION OF INFECTIOUS DISEASES



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FOREWORD

This educational material contains basic information on personal hygiene, hygiene of space, equipment and utensils, on hazards related to products during manufacturing and/or application, on labelling of cosmetics, and epidemiology of infectious diseases. The material is intended for participants at the course on infectious diseases prevention in accordance with the Rules on the form and programme for mandatory education on infectious disease prevention („Official Gazette“ No. 116/18).

The training course is divided into two parts:

I. FUNDAMENTALS – applies to all activity groups

II. SPECIAL PART – emphasis on the requirements for specific businesses

Training involves all persons who come into direct contact with cosmetics at their workplace and natural persons who independently provide services of face and body care and beautification, as well as persons in professions involving application of dyes and foreign objects into the skin and the mucous membranes.

Pursuant to Article 5, Paragraph 3 of the above mentioned Rules, educational materials will be published on websites of all institutes of public health and the Ministry of Health, and thus be available to everyone.

This educational material is published with the approval from the Ministry of Health with the purpose of educating persons who are required to complete the health education course.

FOR PERSONS WHO ARE TAKING THE COURSE FOR THE FIRST TIME, TRAINING IS BASED ON THEORETICAL LECTURES. FOR PERSONS WHO ARE BRUSHING UP THEIR KNOWLEDGE, EDUCATION IS BASED EXCLUSIVELY ON THIS APPROVED DOCUMENT.

I. FUNDAMENTALS

1. INTRODUCTION / LEGAL FRAMEWORK

Course on the prevention of infectious diseases is a part of health education; it provides basic knowledge on personal hygiene, and hygiene of space, equipment and utensils, to be applied in everyday practice. The course is organised and carried out by public health institutes. Persons who completed the course in accordance with the Rules on the form and programme for mandatory education on infectious disease prevention („Official Gazette“, No. 116/18) are considered to have acquired the necessary knowledge and fulfilled their obligations pursuant to the Act on population protection against infectious diseases („Official Gazette“, No. 79/07, 113/08, 43/09, 130/17 and 114/18).

Five years after completing the course, participants need to retake the course in order to top up their knowledge.

1.1 Legal framework

- Act on population protection against infectious diseases („Official Gazette“, No. 79/07, 113/08, 43/09, 130/17 and 114/18);
- Act on the State Inspectorate („Official Gazette“, No. 115/18)
- Act on General Use Items („Official Gazette“, No. 39/13, 47/14 i 115/18)
- Act on Water for Human Consumption („Official Gazette“, No. 56/13, 64/15, 104/17 i 115/18)
- Rules on control frequency and standards for microbiological safety in facilities under sanitary surveillance („Official Gazette“, No. 137/09)
- Rules on special conditions for manufacturing general use items and their placing on the market („Official Gazette“, No. 80/18)
- Rules on health safety of general use items („Official Gazette“, No. 125/09, 23/13 i 90/13)
- Rules on o medical waste management („Official Gazette“, No. 50/15 i 56/19)
- Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

Guidelines issued by the Ministry of Health:

- https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/sanitarna-inspekcija/predmeti-opce-uporabe-i-zastita-od-buke/kozmeticki-proizvodi-1832/1832
- Guidelines of manufacture of cosmetic products

After the accession of Croatia to the European Union, EU legislation has become a part of Croatian legislation, i.e. EU regulations have become binding in the Republic of Croatia.

The Regulations come into force in Croatia on the same day as in the other Member States.

In addition, the Croatian Institute of Public Health published on its website the Guidelines for manufacturers of general use items: https://www.hzjz.hr/sluzba-zdravstvena-ekologija/smjernice-za-proizvodace-predmeta-siroke-potrosnje/.

The governing body that creates laws and ensures their implementation is the Ministry of Health, with inspections carried out by the State Inspectorate sanitary inspection.

➢ BASIC PROVISIONS FROM RELEVANT LAWS

The Act on population protection against infectious diseases

The above Act defines infectious diseases of which prevention and combating are of governmental interest, as well as measures for protecting the population from infectious diseases.

The above Act is **linked with** other regulations from the domain of general use items because the following obligations are a part of general measures for combating infectious diseases:

1. Ensuring health safety of general use items and sanitary-technical and hygiene conditions for their manufacture and distribution;
2. Ensuring health safety of drinking water with sanitary protection of areas and facilities at the source, as well as devices used for public distribution of drinking water;
3. Ensuring sanitary-technical and hygiene conditions on surfaces, in rooms or facilities under sanitary surveillance;
4. Ensuring sanitary-technical and hygiene conditions for effluence of wastewater, ballast water, and disposal of waste matter;
5. Ensuring the implementation of disinfection, disinsection and deratisation as a general measure on surfaces, in areas, rooms or facilities under sanitary surveillance.

The above Act stipulates:

- Employees that come into contact with cosmetic products at their workplace, independent provders of services of face and body care and beautification, and persons whose job involves applying dyes and foreign objects into the skin and the mucous membranes, are required to complete health check-ups once a year and to have a valid sanitary certificate.
- Employees that come into contact with cosmetic products at their workplace, independent providers of services for face and body care and beautification, and persons whose job involves applying dyes and foreign objects to the skin and mucous membranes, are required to complete training on prevention of inectious diseases.

The Act on General Use Items

The Act on General Use Items establishes the supervisory body and its tasks, obligations of subjects dealing with general use items, official controls, administrative measures and sanctions. The above Act, as well as the Act regulating procedures of the Sanitary Inspection, and the Act on the State Inspectorate, regulate the competence and authority of the Sanitary Inspection and stipulate measures to be taken in case of violations.

The following provisions of the Act should be remembered:

Each inspector works and decides independently on measures to be taken based on facts established during surveillance.

The determined measures can be lenient, such as issuing an ordinance on the elimination of faults within a specified time period, or more severe, such as a work ban or prohibition of placing a certain general use item on the market if continuation of work under established conditions poses a threat.

In addition to the above measures, sanctioning may involve an immediate (mandatory) fine or submitting a formal claim before the Magistrates' Court.

General use items include: dishes, utensils, equipment and devices for manufacturing general use items, packaging for general use items, children's toys, products for infants and children under the age of three for easier feeding, nursing, calming and sleeping, cosmetic products described in Regulation (EC) No. 1223/2009 on cosmetic products, detergents described in Regulation (EC) No. 648/2004 on detergents, tobacco, tobacco products and smoking accessories (accessories which during smoking come into contact with the mouth and oral cavity: pipe and cigarette case – mouthpieces), certain items and agents that during use come into contact with the skin and/or the mucous membranes, including items for adult entertainment and items for decorating face and body parts (e.g. tattoo, piercing, permanent make-up), and imitation jewellery.

Only safe and compliant general use items may be placed on the market. Items must be compliant in regards to organoleptic properties, type and content of harmful substances, product labelling, composition and microbiological safety where necessary, and must not be harmful to human health or the environment.

It is prohibited to advertise general use items in a manner that misleads consumers regarding their actual composition, properties, and purpose.

It is prohibited to attribute and advertise healing properties of a general use item such as, for example, the cosmetic product called Gavez ointment.

INCORRECT **CORRECT**

Note: In addition to intended use, concentrations of gavez in the product and substance purity are also important. When labelled as cosmetics, this type of product should not state the above health claims. Otherwise, it would be considered as medicine.

Surveillance of general use items manufacturing includes internal and external inspections, while surveillance of placing on the market falls within the scope of the Inspectorate.

Internal surveillance refers to the manufacturer's obligation to:

- Keep records on the procurement and compliance of materials and packaging,
- Implement systematic control of manufacturing conditions as regards facilities, equipment, utensils, workers and transport in the manufacturing process, and
- Implement systematic control of the finished product.

For dealing in manufacture and placing general use items on the market, business facilities must meet the sanitary-technical and hygienic requirements.

- Businesses must employ sufficient number of workers with completed required graduate study or specialist graduate study, who will supervise production.
- They must have separate facilities for storage to ensure the health and safety conditions.

- Cosmetic products manufacturing and placing on the market must follow the principles of good manufacturing practice for this product type.
- Persons working in the production of cosmetic products who come into contact with the above mentioned products must don special workwear and, where necessary, also footwear, in order to ensure safe manufacturing conditions.
- Working clothes and footwear should not be used outside of the working area.

Subjects that manufacture or import general use items must conduct laboratory analyses of products and keep records on the conducted analyses.

Business subjects manufacturing cosmetic products are required to conduct microbiological analyses for testing cleanliness of equipment, utensils and hands of persons involved in the production process.

If subjects dealing with, or placing on the market general use items, discover or have a valid cause to believe that a general use item they manufactured or placed on the market is not compliant with health and safety requirements and rules stipulated in the Act on General Use Items, or rules arising from the above Act, they must immediately stop manufacturing general use items, recall them from the market, and ensure their withdrawal from consumers. Also, the Ministry of Health must be notified when there is a change of owner.

All manufacturers of general use items are required to report their business to the Ministry of Health.

The Act on general use items **cites Regulation (EC) No. 1223/2009 of the European Parliament and the Council of November 30th 2009 on cosmetic products,** which stipulates basic principles of which **all subjects dealing with cosmetic products need to be aware of and comply with.**

Cosmetic products in the EU territory are regulated with Regulation (EC) No. 1223/2009 of the European Parliament and the Council of November 30th 2009 on cosmetic products.

The above Regulation represents a legal framework which all cosmetic products placed on the market must follow in order to comply with the rules of the common market while ensuring a high level of human health protection.

Base definitions from the Regulation:

1. ‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

2. ‘end user’ means either a consumer or professional using the cosmetic product;

3. manufacturer’ means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

4. ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market;

5. ‘importer’ means any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market;

5. ‘placing on the market’ means the first making available of a cosmetic product on the Community market;

6. ‘undesirable effect’ means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;

7. ‘serious undesirable effect’ means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death;

8. ‘withdrawal’ means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;

9. ‘recall’ means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;

10. „responsible person“ means a legal or natural person that has all the information on the product, that is responsible for reporting undesirable effects; and it shall be stated on product labelling. If several addresses are declared on the product label, only the address of the responsible person shall be highlighted.

Regulation (EC) No. 1223/2009 on cosmetic products includes 7 annexes:

- Annex I : COSMETIC PRODUCT SAFETY REPORT
- Annex II: LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS
- Annex III: LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN
- Annex IV: LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS
- Annex V: LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS
- Annex VII: SYMBOLS USED ON PACKAGING/CONTAINER
- Annex VIII: LIST OF VALIDATED ALTERNATIVE METHODS TO ANIMAL TESTING

Cosmetic products on the market must be submitted to the European Cosmetic products notification portal (CPNP) and have a notification number.

Each cosmetic product placed on the market must have the appropriate documentation which shall be kept ten years from the date when the last series of the cosmetic product was placed on the market.

Documentation with cosmetic product information must include:

(a) description of the cosmetic product that enables the product information file to be clearly linked with the cosmetic product;

(b) cosmetic product safety report;

(c) description of the manufacturing method with statement on compliance with good manufacturing practice referred to in Article 8 of Regulation;

(d) where justified by the nature or the effect of the cosmetic product, proof of its claimed effect;

(e) information on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including animal testing performed to meet the legislation or regulations of third countries.

The responsible person shall make the product information file readily available to the competent authority (e.g. inspection carried out by the State Inspectorate) of the Member State in which the file is kept in electronic or other format at the address indicated on the label.

Labelling of cosmetic products

Cosmetic products shall be made available on the market only if product container and packaging contain the following information in indelible, visible and easy to read letters:

- **Name or registered name and address of the responsible person**; this information may be abbreviated as long as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the address where the responsible person makes the product file readily available will be highlighted. Imported cosmetic products must have specified the country of origin;

- **Nominal content at the time of packaging**, by weight or volume, except for packaging containing less than five grams or five millilitres, free samples and single-application packs. For pre-packaged products sold together as one unit, for which information on weight or volume are not relevant, it is not necessary to state the content if the number of items is indicated on the packaging. This information is not necessary if the number of items is visible from the outside, or if the product is only sold individually;

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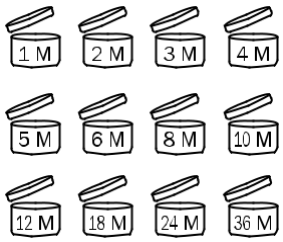
- **The date** until which the cosmetic product, when stored under appropriate conditions, will retain its original function and in particular, will remain compliant with Article 3 (**'date of minimum durability'**).

- The date, or information on where it is declared on the packaging, must be preceded by a symbol or the words: 'best before".
- Date of minimum durability must be clearly indicated and contain the month and year, or day, month and year, in that order.
- If necessary, the above information is supplemented with conditions that must be fulfilled to guarantee the declared durability.
- Indicating the minimum durability date is not mandatory for cosmetic products with minimum durability longer than 30 months. For such products, the period after opening is indicated, during which the product is safe for use without risk. This information is stated, except in cases where durability after opening is not relevant, by a symbol followed by the durability period (in months and/or years).



PAO (*period-after-opening*) symbol

- **Special precautions** that need to be considered during use, with any special precautionary information on cosmetics for professional use.
- **Manufacture batch or reference number** for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information may appear only on the packaging.
- **Function of the cosmetic product,** unless it is evident from its presentation.

- The **list of ingredients** must be stated in descending order according to weight of the ingredients at their time of adding to the cosmetic product.
- Ingredients in concentrations less than 1 % may be listed in any order after the ingredients in concentrations higher than 1 %.

- All ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word ‘nano’ in brackets.
- Colorants other than colorants for hair may be listed in any order after the other cosmetic ingredients.
- For decorative cosmetic products marketed in several colour shades, all colorants other than hair colorants from the range may be listed, provided that the words ‘may contain’ or symbol ‘+/-’ are added. The CI (Colour Index) nomenclature must be used, where applicable).

Labelling of cosmetic products

Where to access relevant legislation?

- In Croatia, all acts and regulations are published in the Official Gazette and can be searched by year and number via website: **https://www.nn.hr/**
- European legislation, which can also be accessed by year and number, is published on the website: **https://eur-lex.europa.eu/homepage.html?locale=hr**

1.2. The role of course participants in health protection and disease prevention

Each person involved in the manufacture of cosmetic products plays a key role by ensuring safe practices for adequate storage, manufacture, placing on the market and use of cosmetic products, as well as safe use of tools and instruments when providing services to their clients in terms of personal hygiene.

All persons involved in the manufacture of cosmetic products must know how to protect themselves and others from infectious diseases by maintaining appropriate personal hygiene and correct handling of cosmetic products, and use of tools and instruments in providing services. This way, they also protect their jobs and the reputation of their establishment.

2. PERSONAL HYGIENE

Personal hygiene refers to general and practical procedures for ensuring a person's health and cleanliness. The above procedures, aimed at disease prevention and improved health, vary from culture to culture. Therefore, something that is acceptable in one culture will not necessarily be acceptable in another. Medically speaking, the term "hygiene" refers to maintaining health and a healthy lifestyle. It is a branch of medicine dealing with rules, general and practical procedures for maintaining and improving health. The above term is also referred to as personal hygiene, home hygiene, dental hygiene whereas occupational hygiene is often used in relation to public health.

2.1. The importance of personal hygiene

Personal hygiene

Personal hygiene refers to hygienic procedures through which persons take care of their physical health and wellbeing. Its purpose is reducing diseases, need for treatment, optimal health and sense of wellbeing, social acceptance and prevention of disease spreading to others.

Personal hygiene procedures include: medical visits, visits to the dentist, regular body washing (baths or showers), regular hand washing, tooth brushing and care, basic manicure and pedicure, etc. Personal care is a broader term than personal hygiene and refers to maintaining good personal and public appearance that does not necessarily mean hygienic.

Personal hygiene is achieved by using personal hygiene products including: soap, shampoo, hair products, toothbrush, toothpaste, q-tips, deodorant, lip balm, creams, lotions, face wipes, hair trimmer, nail clipper, mouthwash, nail file, peels, razor, shaving cream or foam, skin cream and toilet paper. Additional personal hygiene and care products can be used for improving health and wellbeing.

There is a difference between personal hygiene in daily routine and hygiene in professional establishments and services.

Professional hygiene

Professional hygiene refers to procedures involving care and use of instruments in providing personal hygiene/beautification services for clients:

Professional hygiene procedures include:

- Disinfection and/or sterilisation of instruments used by hairdressers, beauticians, nail technicians etc.
- Sterilisation (with an autoclave) of instruments used for body piercing, tattoos and hand hygiene.

Personal hygiene of employees is important for maintaining and improving health. It is a well-known fact that microorganisms are usually transmitted due to a lack of, or inadequate implementation of personal hygiene procedures through:

- Unclean hands,
- Sneezing or coughing,
- Blowing the nose,
- Body secretions (pus etc.), or
- Contaminated objects.

Rings, watches, and bracelets should be removed before direct contact with a client. False nails or nail polish on natural nails are not recommended. Regular maintenance of hygiene habits (practices), especially hand washing, is a prerequisite for preventing the spread of infectious diseases; it also reflects social and cultural habits of individuals and our environment. Hygiene

habits (practices) refer to the procedures carried out for maintaining personal hygiene; they should be carried out daily and in a correct manner.

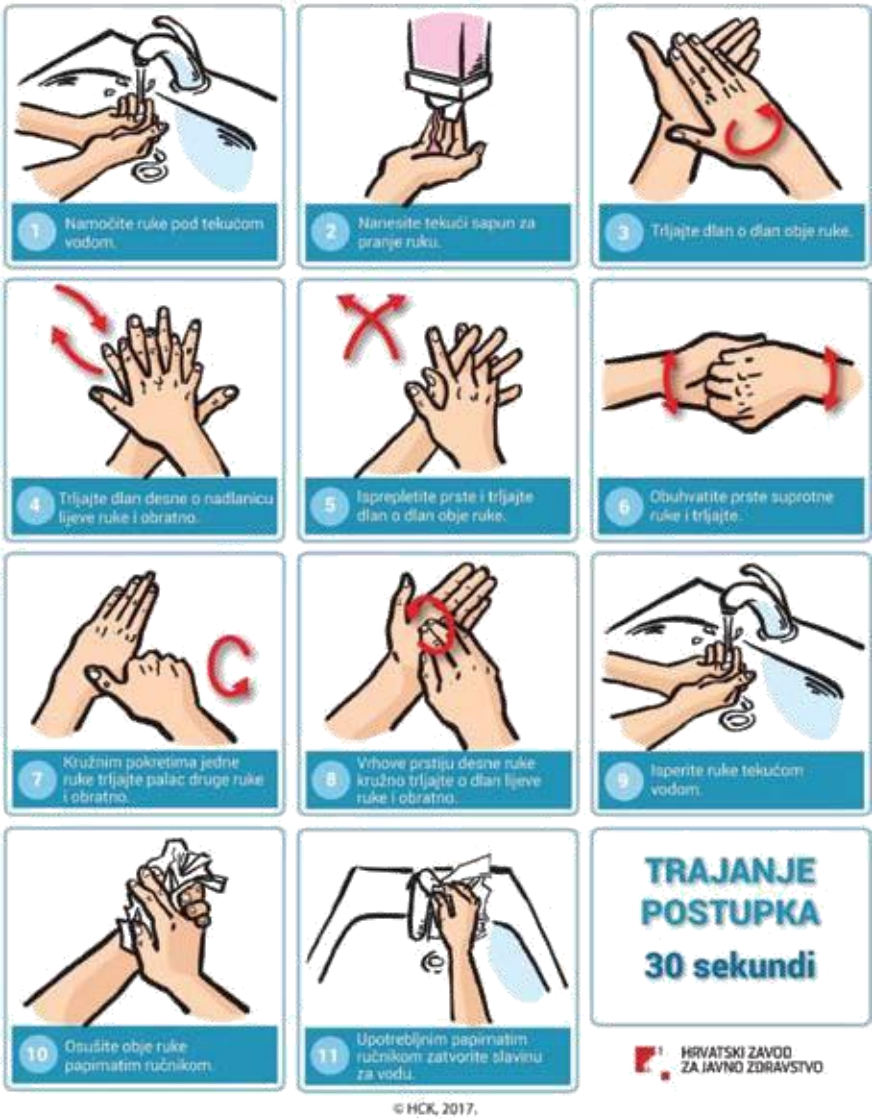
2.2. The importance of hygienic safety of products

Raw materials and packaging materials must comply with regulations regarding health safety. Every material and product must be adequately labelled in order to avoid confusion, and adquately stored according to manufacturer's instructions. It is important to check the following information on the product:

- All ingredients in the product,
- Purpose of the product,
- Expiration date,
- Warnings,
- Frequency of use,
- Age group for which the product is intended,
- Way of application (the surface on which the product is applied, skin condition, the amount and time).

2.3. How to wash hands

Many infectious diseases are spread via soiled hands or hands contaminated from contact with contaminated material or objects. Therefore, hand washing is the principal procedure and a prerequisite for personal and professional hygiene. Soiled hands are the most common route of transmission of agents causing infectious diseases. Correct hand washing and disinfection should be carried out in a designated sink equipped with items for hygienic hand washing and drying.



How to wash hands

- Hand washing includes soaking hands with water, applying liquid soap, rubbing in the foam (for at least 15 seconds on all hand surfaces). If necessary, use a brush to remove dirt from pores, underneath and around fingernails. Afterwards, hands are thoroughly washed with warm water until all traces of soap are removed. Soap containing disinfectant is recommended. Hands are dried with paper towels or a hand drier.
- After hand washing and in everyday work, when hands are not visibly soiled, use of hand sanitizers is recommended to minimize the presence of microorganisms on the hands. Disinfectants are rubbed into the skin according to manufacturer's instructions for 15-30 seconds, until the hands become dry. Disinfectants should be carefully selected taking into consideration their active ingredients and characteristics.

2.4. The importance and hygiene of protective clothing and footwear

- ✓ Work clothes must always be clean and appropriate for the type of work
- ✓ Clothing should be made of cotton material that is easy to boil wash and iron

Work clothes should be clean and kept in separate lockers (a locker needs to have two separate compartments, for work clothes and civilian clothes). It is not allowed to keep clothes and footwear in storage rooms, toilets, or working areas!
If disposable gloves are used, they should be changed with every change of the working process. After use, disposable gloves are placed in a designated waste container. Re-use of used gloves is prohibited. Depending on the job, workers should wear comfortable professional footwear made from suitable materials.

Protective clothes and footwear

3. ENVIRONMENTAL HYGIENE

3.1. Water safety

Other than for living and hygiene, water used in treatments and care needs to be safe and regularly tested. In addition, water supply must be adequately and regularly maintained and cleaned to avoid contamination of indoor water supply (e.g. if tap water is insufficiently rinsed, or the faucet filter is not regularly cleaned, the bacterium *pseudomonas aeruginosa* or aerobic mesophilic bacteria can develop.

Water is considered safe if:

- It does not contain microorganisms, parasites or their developmental forms in numbers that pose a threat to human health,
- It does not contain harmful substances in concentrations that, alone or combined with other substances, pose a threat to human health,
- It does not exceed values of microbiological and chemical water safety parameters prescribed in the Rules.

Public water suppliers (municipal water supply) are regularly controlled by in-house or external laboratories, through monitoring or official controls. Therefore, business subjects are "less" required to monitor this safety aspect if they are connected to public water supply. However, various contaminants can be present in water as a consequence of inadequate "internal" network (*legionella spp, pseudomonas aeruginosa*).

→ All public suppliers are required to publish all water analysis results on their website and results are available to all subjects.

→ Subjects connected to **individual systems** (e.g. wells, cisterns, small water tanks etc.) who, as a rule, cannot efficiently monitor the water being used, are required to test water safety 4 times a year (quarterly) for basic parameters (A parameters of analysis) and implement measures for ensuring safety if water analysis detects deviations from the set parameters.

→ Conversely, if subjects are connected to the so-called **local water supply** (which is not managed by public suppliers), they should control more frequently the water in their facilities.

3.2. Waste management

- ✓ Regulated by the Act on sustainable waste management („Official Gazette“, No. 94/13, 73/17 and 14/19)

Waste refers to matter or items which their owner needs to discard, and collection, transport and processing of which are necessary for protecting the public interest.

One of the principles of waste management is »polluter pays« – producer of waste, previous owner of waste, and owner of waste covers the expenses of waste management and is financially responsible for the implementation of reparation measures for damage that was caused or might be caused by waste.

The Rules on medical waste management („Official Gazette“, No. 50/15 and 56/19) stipulate that medical waste refers to waste created while providing care, protection and maintaining human and/or animal health; waste created during research, and waste created during various services which include contact with human and/or animal blood and/or excrements.

According to properties, medical waste can be:

- ➢ Hazardous medical waste, and
- ➢ Non-hazardous medical waste.

Medical waste management refers to activities for collecting, transporting, and processing of medical waste.

The producer of medical waste is required to ensure its management at the point of generation, especially in terms of separate collection, keeping records, disposal into adequate containers and temporary storage in a separate area until processing or handover to an authorised person.

Hazardous medical waste must be collected separately at the point of generation, the containers need to be resistant to hazardous contents, breakage and puncture, they must contain a label with basic information on the generator of the waste, reference number and type of waste in accordance with special regulations.

3.3. Cleaning, washing and disinfection of utensils, equipment and surfaces

Utensils, devices and rooms in facilities where care and treatment are provided must be regularly cleaned and disinfected. All utensils and devices must be kept in good condition to minimise the risk of contamination. Various products are available on the market for maintaining hygiene of premises and equipment. These products must be appropriate for cleaning utensils, devices and surfaces.
Cleaning tools, equipment, and chemicals are used for washing and disinfection.

All visible traces of dirt (grease, bodily fluids etc) on objects and surfaces must be removed before disinfection. Tools and equipment must be fit for purpose (cloths, sponges, brooms etc.) and regularly changed when they become worn out.

Disinfection

Disinfection destroys a series of vegetative microorganisms or reduces them to a level that does not pose a threat to human health and eliminates infection, making objects safe for handling. Workers and users are protected with disinfection and use of disposable materials (e.g. disposable gloves that are changed after each client).

→ Disinfection is very important in pedicure because it involves many instruments that are not single-use. Instruments that are not disposable must be disinfected after each use and/or submerged in disinfectant volume at least double of the instruments' volume (in accordance with manufacturer's instructions).

→ Tools are washed and disinfected after each use. Scissors and combs should be washed and disinfected after cutting hair and before re-use. Hair brushes must be regularly washed and cleaned.

→ Products that come into contact with the skin or the mucous membranes, such as lip or eye brushes and liners, also need to be disinfected after each use. When applying make-up, single-use applicators are recommended (e.g. mascara applicator). When applying lipstick, for example, it should be transferred with a single-use stick on a clean and disinfected surface and applied with a brush from this surface instead of directly from the original lipstick tube.

→ Floors and surfaces need to be washed every day and disinfected with a low-level disinfectant.

Sterilisation

After using certain tools and instruments, sterilisation is also necessary after washing and disinfection. Sterilisation is a procedure which destroys all types and forms of microorganisms on objects. Most common sterilisation methods today include hot pressurised steam for utensils that are heat resistant, or formaldehyde, ethylene oxide, plasma peroxide and ionising radiation for materials that are not heat resistant.

Keep in mind:

- After washing and assembling, instruments and tools are adequately labelled and packed into sterilisation pods, special paper, non-woven wrapping, textile, bags or foils intended for sterilisation.
- After sterilisation, the sterilised material needs to be cooled down to room temperature.
- Sterile material must be stored under controlled conditions (protected from damage, dust, humidity etc.).
- Sterilisation devices and procedures must be regularly controlled.
- Devices are routinely checked with vacuum test and „Bowie&Dick“ test every day before beginning sterilisation.
- Devices are validated in given time intervals in accordance with standards set by accredited institutions.
- The sterilisation procedure is verified with physical, chemical and biological methods.

3.4. Pest control

Controlling the presence of pests is extremely important because pests are carriers of infectious diseases that can also cause physical damage to equipment and working facilities. There are different ways for noticing their presence.

The facilities must be built in a way that prevents the entry of pests by:

- Placing nets on ventilation and other openings,
- Closing the drains and other openings through which pests might enter the facilities with nets and siphon bells,
- Maintaining floors, walls, roofs, doors, and windows that open in good condition without damage and holes.

COMMON PESTS	THEIR TRACES INDOORS
Rats and mice	Small traces in dust, feces, holes in walls and doors, nests
Flies and flying insects	Insect bodies, live insects, nests, buzzing, larvae
Cockroaches	Eggs, insects (cockroaches), feces
Ants	Small heaps of sand or soil, insects, flying ants during hot days
Birds	Feathers, feces, nests, noise, birds
Other insects	Moving insects, small worms

- ✓ If employees notice the above traces of pests, they should inform their supervisor or contact an authorised legal person.

Each business subject providing care and treatment services must have a Pest Control Plan. The Plan is implemented through preventive DDD measures, for which the business subject has to sign a contract with an authorised legal person.

- **Business subjects are not allowed to implement chemical measures for disinsection and deratisation on their own!**
- **Disinsection** refers to different measures/ways (mechanical, chemical) for reducing the population or complete extermination of harmful arthropods. Disinsection also includes ways of preventing the entry and lingering of harmful arthropods on surfaces, within the premises, or in the facility.
- **Deratisation** refers to different measures (mechanical, chemical) for reducing the population or complete extermination of harmful rodents. Deratisation also includes all measures taken for preventing the entry, lingering, and proliferation of harmful rodents on surfaces, in the premises, or in the facility.

4. EPIDEMIOLOGY

Epidemiology studies disease factors and spread in the population; it is widely applied in medicine when establishing risk factors for certain diseases and determining best health practices in everyday work.

Communicable or infectious diseases refer to diseases caused by microorganisms, with the possibility of transmission from a diseased person to a healthy individual.

4.1. Relationship between microorganisms and macroorganism as host

Every day humans come into contact with microorganisms which are all-pervasive in the environment. Biologically, microorganisms are divided into several groups of which the most relevant for development of infectious diseases are bacteria, viruses, fungi and parasites. Although they are pervasive, microorganisms rarely penetrate, proliferate and cause diseases in humans. Some diseases are very mild and without symptoms. In contact between microorganisms and humans, the main prerequisite for disease development is adherence. Adherence is the specific process between a human cell and the microorganism after which the microorganism can remain at the point of entry or spread to other sites. Certain microorganisms have the ability to produce toxins which act on target human cells and cause disease.

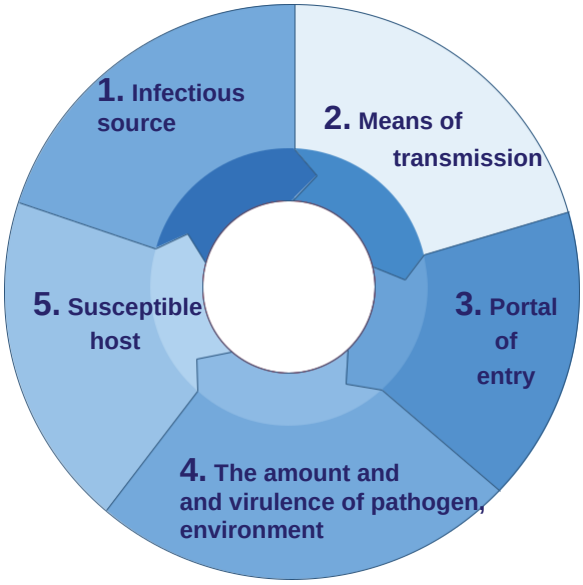
There are three types of relationship between microorganisms and a human host:

- Simbiotic, where both the microorganism and the host have benefits,
- Commensal, where the microorganism has benefits without causing harm to humans,
- Parasitic, where the microorganism benefits by causing harm to the host.

4.2. Conditions for infectious disease outbreaks and spread

Three groups of factors influence an individual's health: internal (biological characteristics such as age, sex, and immunity), external (living environment, lifestyle and socioeconomic factors), and the available healthcare system. Infectious diseases are characterised by their potential for spreading from a diseased person, germ carrier or animal to a healthy person. For outbreaks and spread of infectious diseases, the following needs to be present (the so-called epidemiological or Vogralik's chain):

- Infectious agent (human, carrier, or animal);
- Transmission routes from source to host such as touching, via objects, blood, air, water, or food;
- Portal of infection entry, usually the respiratory system, digestive system, skin and visible mucous membranes;
- Infectious agent, or microorganism, in sufficient amount and sufficiently virulent (a group of factors contributing the ability of microorganisms to cause a disease);
- Vulnerable host (human), i.e. susceptibility to disease.



Epidemiological (Vogralik's) chain

If one of the above conditions hasn't been met, the epidemiological chain will be broken and there will be no infection.

4.3. General measures for preventing and combating infectious diseases

General measures implemented in everyday practice for preventing and combating infectious diseases are focused on interrupting the factors necessary for the spread of infectious diseases; they include:

- Ensuring sanitary-technical and hygienic conditions on surfaces, within the premises or facilities;
- Ensuring health safety of water for human consumption;
- Ensuring the implementation of disinfection, disinsection and deratisation as a general measure on surfaces, within the premises or facilities.

- **Measures at the level of infection source:** If the infection source is a diseased person or germ carrier, medicines, isolation or vaccination can be applied. In animal carriers, measures include disinsection (destroying insects) and deratisation (destroying rodents).
- **Measures at the level of transmission route:** Disinfection of objects in the environment, personal hygiene, safe water supply.
- **Measures at the portal of entry:** To prevent the entry of microorganisms into an organism, the host's portal of entry must be protected (facemasks and gloves, goggles and clothes), wounds must be covered with sterile bandages and risks such as using non-sterile equipment must be avoided.

- **Measures at the level of cause:** Agents are destroyed with disinfection (reducing the number of microorganisms) and sterilisation (complete elimination of all microorganisms) measures.
- **Measures at the level of host:** Host resistance can be achieved with healthy lifestyle habits or medications for preventing infections in at-risk persons, and vaccination.

Particularities of face and body care and beautification, and jobs involving insertion of colorants and foreign objects into skin and mucous membranes

There are four potential infectious agents in the above professions: bacteria, viruses, fungi and parasites.

- Bacteria are single cell microorganisms that can be successfully removed with adequate chemicals (disinfectants on objects and surfaces, or antiseptics on live tissues) or sterilisation procedures. Typical example is hand disinfection with a poly-alcohol based antiseptic after hand washing.

- Viruses are the smallest existing microorganisms bordering between living and inanimate nature, which can pose a threat to human health. Special risk is related to viruses that spread via infected blood. They include hepatitis B and C viruses, and the HIV virus. In case of injuries caused by needles or objects contaminated with another person's blood, there is a risk of transmission of the above infectious diseases.

- Fungal infections occur in many forms, usually on the skin, although they can also occur on mucous membranes. Onychomycosis is a common infection caused by fungi – fungal infection of fingernails which can occur due to inadequate procedure during pedicure.

- Parasitic skin infections cause severe itching and can be alarming. Lice infestation is a contagious disease of the scalp, body, pubic area and eyelashes caused by lice. Lice are wingless insects that live on the scalp and feast on blood.

Professional rules must be followed in everyday work; single-use tools should be disposed in designated waste areas while equipment intended for multiple use needs to be regularly disinfected or sterilised. Pedicure tools and equipment need to be regularly maintained according to professional rules and manufacturer's instructions. All hairdressing equipment needs to be washed in warm water and detergent after each use. Special emphasis needs to be placed at waste separation, especially of sharp objects and materials that were in contact with tissue and blood.

4.4. Vaccination as a specific protective measure against infectious diseases

Today, vaccination represents the most effective and cheapest method for preventing infectios diseases. Based on the Act on population protection against infectious diseases („Official Gazette“, no. 79/07, 113/08, 43/09, and 130/17) and Rules on immunisation, seroprophylaxis and chemoprophylaxis against communicable diseases („Official Gazette”, No. 103/13), children, travellers, seamen, healthcare workers and other at-risk persons are being vaccinated as well as persons who are under increased risk from infection at their workplace where they come into contact with infected persons and materials (blood, excretions, secretions).

Each year, the Croatian Ministry of Health prescribes mandatory vaccines according to the vaccination calendar. In addition, there are also non-mandatory vaccines such as the flu vaccine.

Although in most cases there is no reaction, every vaccine can cause an adverse reaction. Most reactions are mild, such as pain, redness, mild swelling at the injection site and slightly increased temperature. The decision on contraindication (in cases of hypersensitivity to vaccine ingredients or severe previous adverse reactions) or delaying vaccination (e.g. due to an acute illness) is made by a physician based on the examination pre-vaccination. The vaccination card serves as a certificate on an individual’s protection. It may be required in case of injury, travel, enrolment at educational institutions or placement into certain collectives, or in the case of epidemic outbreaks of infectious diseases.

4.5. Germ carriers and their role in the spread of infectious diseases

Germ carriers carry a certain microorganism without presenting any symptoms or signs of disease. Germs can persist after recovery from an infectious disease such as hepatitis B. The infected person might not be aware of it, and pose a threat to their environment if they do not follow hygiene and protection measures at the workplace. In terms of duration, the carrier state can be acute or chronic. Health surveillance of individual disease carriers is regulated by law.

II. SPECIAL PART

1. MANUFACTURING AND TRADE OF COSMETICS

1.1. Principles of good manufacturing practice

Each manufacturer of cosmetic products in the Republic of Croatia is required to register their business before the Ministry of Health in accordance with the Rules on special requirements for general use items manufacturing and their placing on the market („Official Gazette“, No. 80/18).

Each manufacturer of cosmetic products in the Republic of Croatia is required to have a place of business that meets the sanitary-technical and hygienic requirements in order to ensure the health safety of manufactured products. ALL manufacturers of cosmetic products in the Republic of Croatia must comply with the law, regardless of the type of registered business (company/manufacture/family business), and the manufactured amount. Manufacture of cosmetic products refers to preparing, processing, finishing, packing and storage of cosmetic products.

HRN EN ISO 22716 – Cosmetics – Good manufacturing practices (GMP) - Guidelines

Within the European Union, all cosmetic products placed on the market must be manufactured in accordance with good manufacturing practices described in the ISO 22716 Standard. The above Standard prescribes guidelines for good manufacturing practices in the production, control, storage and distribution of cosmetic products.

The Standard stipulates requirements for quality system management, requirements for maintaining premises and equipment, product realisation, managing complaints, and continuous system improvement. Special importance is placed on trained personnel and communication among them, adequate maintenance of facilities and adequate use of equipment. The Standard stipulates handling of equipment in accordance with good manufacturing practice. All businesses must have a procedure in case of non-compliant operating or product. Internal audits and continuous improvements are important.

Good manufacturing practices represent general instructions – principles for ensuring quality of the manufacturing process, they serve as basis for manufacturers to elaborate good manufacturing practices adjusted to their manufacturing conditions. They are implemented throughout the manufacturing process, from entry of raw material into the shop to the dispatch of the finished product.

For the manufacturing process, premises need to be designated for:

- Manufacture;
- Storage of materials;
- Storage of packaging;
- Storage of finished products;
- Area for employees;
- Area for preparing, finishing touches and packaging of products.

Premises need to be defined, designed, built and used in a way that:

- Ensures product protection;
- Enables efficient cleaning with sanitary processing and maintenance, when necessary;
- Minimises the risk of product, materials and packaging mix-ups (cross contamination).

Building specifications of premises are important because adequate room positioning prevents or minimises cross contamination.
Cross contamination refers to the unwanted transfer of microorganisms and other contaminants from employees' hands/surfaces/objects/equipment to other employees/ surfaces/objects/equipment, or crossing pathways between materials/finished products/employees/ equipment etc.

→ In the manufacture of small batches of cosmetic products and products manufactured with simple technologies, a single area is allowed to have a shared purpose.

→ If the manufacture area is also used for manufacturing other types of products other than cosmetics, cross contamination needs to be prevented by limiting the manufacturing time of different product types.

Manufacture of cosmetic products **may not be carried out in home environment, or in an area of living quarters.** The exception is artisan manufacture or manufacture in family-agricultural businesses, but only if manufacture is functionally and technically separated from other areas.

The facility where cosmetics are manufactured must ensure sufficient amount of safe water for human consumption, as well as sufficient running water for cleaning and washing the premises, the industrial unit, the assembly lines, equipment, utensils and packaging, and maintaining personal hygiene of workers.

Building materials for the premises where cosmetics are manufactured must enable easy cleaning, washing and disinfection, as well as maintaining microclimate conditions (temperature, humidity, air flow) necessary for preserving health safety of materials and finished products.

All **floors** need to be made from materials that are sturdy, easy to clean and wash, non slippery and resistant to hazardous chemicals used in the manufacturing process. Selection of floors depends on the manufacturing characteristics. When selecting a floor for a smaller, simple manufacture, it is sufficient to ensure a high level of cleanliness. The floor drains must have installed siphons with safety nets that prevent the entry of insects and rodents.

Wall surfaces in all premises must be made from materials resistant to cleaning, washing and disinfection, with levelled and smooth surfaces that prevent the accumulation of dirt. In addition to coverings, walls can be coated with colours that are resistant to washing, cleaning, and disinfection, with straight and smooth surfaces that prevent dirt adherence.

Lighting in the manufacturing facilities may be natural or artificial. When installing artificial lighting, it must be fitted in a way that prevents the spread of debris in case of breakage and that the light source is adequately protected in the case of breakage.

Ventilation in the manufacturing area may be natural or artificial. The selected ventilation has to be adjusted to the size of the manufacturing area, purpose of the manufacturing space and the technological manufacturing process. If the area is naturally ventilated, windows and shafts that can be opened must be fitted with protective nets to prevent the entry of insects and rodents. Nets should be fitted in a way that is easy to remove for maintenance.

Equipment used in the manufacturing process needs to be fit for purpose and made from sturdy material that is non-porous, non-absorbent and resistant to mechanical and chemical damage. Surfaces of the industrial unit, furniture, devices and tools that come into contact with materials and finished products must be smooth and made from a material that does not release harmful substances.

- Selection of materials for equipment and working surfaces depends on the technological process;
- The equipment used in manufacturing must be regularly maintained;
- Procedures for maintaining equipment and working surfaces must not affect product quality.

→ Keeping and storage of materials also affect durability. Exposure to light and air can significantly reduce the best before period, in terms of visible changes in color and texture, or development of stale odor.

→ For storage and transportation of certain cosmetic products, adequate devices are necessary for maintaining health safety by avoiding contamination of individual products, and protecting them from heat, cold, light, humidity and other adverse conditions.

Correct and incorrect cosmetics manufacturing

Cleaning and sanitary measures

Premises for manufacturing or storage need to be kept clean and suitable. Cleaning must be carried out daily, in accordance with the dynamics of cosmetics manufacturing. All equipment used in manufacture and storage needs to be adequately cleaned.

Working surfaces need to be maintained clean in accordance with production dynamics. Cleaning programs should be documented and available at the manufacture site.

Cleaning products need to be efficient and stated in the cleaning program. If cleaning products are classified as hazardous chemicals, their safety-technical sheets must be kept. If cleaning products are obtained from retail and are classified as typical household cleaning products, the safety-technical sheet is not necessary. When possible, cleaning products should be adequately stored separately from materials for manufacture.

The list of biocidal formulations (type 1 and 2, biocides for personal hygiene and surface disinfection) which have been approved for placing on the market in the Republic of Croatia, is published on the Ministry of Health website in the Register of Biocidal Formulations.

1.2. The role of raw materials in cosmetics manufacturing

Raw materials and packaging materials in cosmetics manufacturing must be of adequate purity as required by the pharmacopoeia (publication stipulating requirements and criteria for materials and medicines prescribed and approved by highest professional authorities), and safe. Each material needs to have the appropriate analytical report indicating compliance with certain requirements. Each material needs to be adequately labelled to avoid mix-ups, and stored according to instructions of the material manufacturer (room temperature, +4°C, etc.).

Water – crucial material affecting the microbiological purity of products

Other than for hygiene, water used as raw material needs to be safe and periodically tested.

In addition, the water distribution system in the technological process of manufacture needs to be maintained with regular cleaning to avoid product contamination (e.g. with *pseudomonas aeruginosa* and aerobic mesophilic bacteria).

The water processing equipment needs to be fitted in a way that avoids stagnation or contamination, and used materials need to be safe and not affect water quality.

Manufacturing processes

All phases of manufacture need to be detailly described and available to workers. The type of equipment and materials used must be clearly indicated (adequately labelled with series number and the required quantity in the formulation), as well as sequence of adding materials, temperature, speed, mixing duration, process control with critical points affecting the finished product, packaging, packaging control, storage, cleaning and when the equipment needs to be disinfected. Tasks and responsibilities of workers in the manufacturing process need to be clearly defined.

1.3. Storage conditions for cosmetic products

Before shipment, the finished products need to be stored for a limited period in a designated area. The storage area needs to ensure clear entry/exit and record keeping. Storage conditions are related to stability tests created during product development.

Quality control

The manufacturer needs to assure the quality of finished products by contracting an accredited laboratory, with clearly defined criteria for acceptability of organoleptic product properties, microbiological purity, pH value and metal content in the product, taking into consideration Regulation (EC) No. 1223/2009 on cosmetic products regarding safety of the finished product and use of materials.

Acceptability criteria need to be established for defining the requirements that materials, packaging material, loose products, and finished products must comply with. If products that are non-compliant with the established specifications are discovered, the cause of non-compliance must be determined with risk elimination measures and adequate disposal of the product in question. Also, it is recommended that several samples from each batch are adequately stored, so that additional analyses can be carried out in case of adverse health effects or complaints before eventual product withdrawal.

1.4. Contamination of cosmetic products

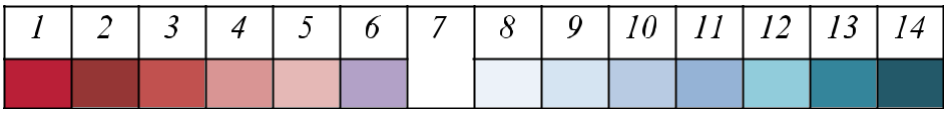
Contamination of cosmetic products can be microbiological and physical-chemical. Only microbiologically and chemically safe materials can be used in the manufacture of cosmetic products. Additionally, technological manufacturing process, temperature, and pH value affect the development of microorganisms.

1) Microbiological contamination

Microbiological purity of products is affected by:

- Presence of water in the product,
- Temperature affects the development of microorganisms (e.g. if temperature higher than 65°C is reached for a minimum of 10 min during the production process, the microbiological risk decreases)
- pH value, etc. (e.g. due to their extreme pH value (around 12), products for permament hair curling prevent the growth of most microorganisms).

pH is the measure for acidity or alkalinity of aqueous solutions
pH scale:



Acidic----------Neutral----------Alkaline

Microbiological analysis is required for all products with pH value > 3.0 or < 10.

Assessment of microbiological purity refers to all products, especially products used around the eyes, on the mucous membranes, damaged skin, on children under three years of age, the elderly and persons with compromised immune system.

Low risk products include: solid soaps, hair spray, nail polish, aerosols that don't contain water, hair dyes, soap-based shaving creams, depilatory creams, hair styling products, solid deodorants, formulations for cold permanent curling and neutralisers, cologne and perfumes (containing alcohol!), oils and oily baths that don't contain water, and antiperspirants containing 25% aluminium chlorohydrate.

2) Physical-chemical contamination

Causes of physical-chemical contamination include: natural content of an individual material (e.g. metals in inorganic pigments), contamination during the technological manufacturing process or during manufacture of the finished product (e.g. presence of nickel from stainless steel containers where the ingredients are mixed).

In addition, physical-chemical reactions can occur due to product aging. Causes can be external, such as temperature (high and low temperatures during manufacturing process, storage or transport), humidity (soap, eye shadow, bath salts can become soft and sticky), oxygen permeability of packaging, vibrations during transport (formulation can be affected because vibrations lead to phase separation, hardening or changes in viscosity).

Internal causes of contamination include: inadequate material selection (incompatibility: changes in physical condition of the product such as sedimentation and opacity), pH value, organoleptic and physical changes (e.g. a cream containing vitamin C can turn brown), and interactions between materials and packaging (packaging loses shape with stagnation).

In addition to health safety of the material and packaging input, product stability tests are also conducted (e.g. testing microbiological stability of a product with a *challenge test* – efficiency test for preservatives in a product) as well as physical-chemical tests (organoleptic properties, testing homogeneity, color, odor, pH value, active ingredients content, allergens, etc.).

All procedures need to be documented as part of product technical documentation, which serves for determining the product expiration date, and as foundation for creating the Safety Asessment Report for a cosmetic product, which is required for all cosmetics placed on the market.

For risk control at the manufacturing process level, it is necessary to consider the limitations related to procurement of materials, as cosmetic products may not contain:

(a) prohibited substances;

(b) restricted substances;

(c) colorants, except the ones specified in Regulation (EC) No. 1223/2009;

(d) preservatives, except the ones specified in Regulation (EC) No. 1223/2009;

(e) UV-filters, except the ones specified in Regulation (EC) No. 1223/2009.

Unless specified otherwise, unintentional presence of small quantities of a prohibited substance resulting from impurities in natural or synthetic ingredients, manufacturing process, storage and substance migration from packaging, which is technically inevitable in adequate manufacturing practices, is allowed if the cosmetic product is safe for use.

2. FACE AND BODY CARE OR BEAUTIFICATION, AND APPLYING COLORS AND FOREIGN OBJECTS INTO THE SKIN AND THE MUCOUS MEMBRANES

2.1. Good hygiene practices (examples according to participants' line of work)

HAIR SALONS

Hair salons are required to comply with the standards related to hygiene of premises, equipment, and staff, in order to provide treatment that is maximally safe in terms of health for their clients.

Special importance should be placed on appropriate and regular maintenance of hairdressing equipment.

Hair salons need to be equipped with products and devices for disinfection, sterilisation and maintenance of hairdressing tools. Adequate use of these products ensures hygiene and, consequently, the safety of salon visitors.

All hairdressers are required to keep their equipment, tools and stocks clean and hygienically safe as follows:

- All products, brushes and other tool components need to be cleaned after each visitor in order to remove hair and other physical dirt, carefully washed afterwards with water and detergent, and disinfected.
- At the end of the working day, all hairdressing equipment should be cleaned and hygienically treated in an approved manner.
- The above procedure is also applied after clients with skin irritations or conditions.
- Each product, instrument or tool that was dropped or otherwise compromised needs to be disinfected.

- Electrical appliances, shavers and instruments that are not assembled must be carefully cleaned with a clean brush to remove all hairs and physical debris, and blades must be wiped with a cotton ball soaked in disinfectant.
- When not in use, all hairdressing equipment must be stored in designated lockers or special lidded containers. Their interior needs to be clean and wiped with disinfectant at least once every working day.
- Separate clean towels and paper towels are used for each client. After use, they are disposed in a special container intended for that purpose only.
- All the equipment that will be cleaned and disinfected is also kept in a special separate clean and closed container.

According to national classification, cosmetic treatments include:

- Hair salons;
- Pedicure salons;
- Cosmetic salons;
- Body massage.

Premises and equipment for cosmetic treatments

The premises need to be:

- Situated in a way that enables thorough cleaning and disinfection;
- Adequately ventilated, naturally or artificially;
- Adequately lighted;
- Equipped with surfaces where dyes or care products are prepared;
- Equipped with chemically resistant surfaces.

Hygiene conditions:

- Cross contamination between individual procedures must be avoided.
- Beauticians must ensure that the used equipment, tools, agents and products meet the regulatory requirements.
- The equipment needs to be technically flawless, regularly maintained and serviced according to manufacturer's instructions.
- The equipment needs to be serviced annually or as required by the manufacturer.
- Beauticians are required to ensure the minimum health requirements and use technologies that are acceptable in terms of health and the environment. They need to ensure the highest possible level of health protection for their clients.
- Premises must be equipped with a sink for hand washing and personal hygiene of staff. Sanitary facilities need to be fitted with a sink featuring hot and cold water, with liquid soap and paper towels.

- For treatments where clients need to undress, changing cubicles and lockers need to be installed.
- In the premises were services are provided, it is recommended to display a visible sign containing information on health risks and service limitations for persons with skin or nail conditions, or persons affected by skin or scalp parasites, written in big letters that are easy to read.

Protection of workers and clients:

- A beautician with symptoms of infectious diseases or visible skin, scalp or mucous membrane infection, or parasitic infection, is not allowed to work with clients.
- A client with signs of scalp, skin, nail or parasitic infection needs to report this to the beautician before starting treatment.

✓ **Special considerations:**

- The first aid kit needs to be located in working or auxilliary premises.
  NOTE: Be aware of the expiration date!
- If cosmetic chairs or beds come into contat with clients' skin, use disposable protective coverings.
- Beauticians are required to provide clean towels for their clients.
  NOTE: A lidded, easy-to-clean, basket is required for dirty towels.
- Depilatory wax must be for single use.
- Foot soaking basin needs to be made from materials that are easy to clean and disinfect, which must be done after each use.
- During manicure and pedicure, single-use nail buffer blocks must be used.
- Today, UV lights are often used for maintaining hairdressing equipment.
  NOTE: Each client needs to have their own nail buffer block that should be handed to them after treatment. This prevents fungal and other infections.

Disinfection and sterilisation:

Regular cleaning and disinfection is required. Providers of services where equipment and tools come into contact with bodily fluids must disinfect and sterilise their equipment and tools. The plan for sterilisation of equipment and tools must be established.

The plan for sterilisation of equipment and tools must contain the following information:

- Items that are sterilised;
- Time of sterilisation;
- The person conducting sterilisation;
- Sterilisation method: dry steriliser (180°C), 90 minutes in sterilisation bags or aluminium foil;
- Controls of steriliser functioning.

Control of steriliser functioning

Physical method is used for physical parameters (temperature, time, pressure, concentration of gasses, ionizing radiation dose), chemical method with integrator test strips is used for controlling each set or the entire sterilisator load, while biological indicators must be used after each maintenance or repair of the sterilisation device, or after longer periods of inactivity, i.e. at least once a year with the help of *bacillus atrophaeus* dry air sterilisation spores or *geobacillus stearothermophilus* for autoclaves.

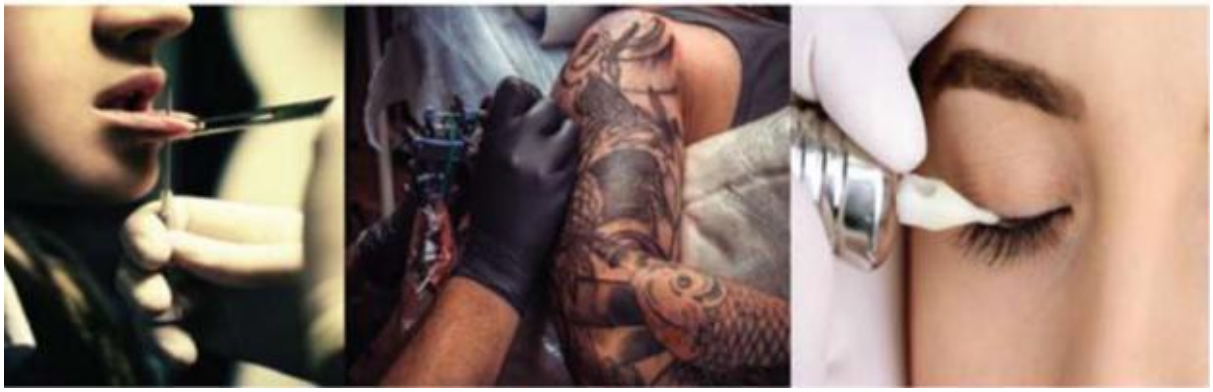
The above sterilisation control is documented in a logbook (usually notebook) with appropriate fields for entering information after each sterilisation procedure on the type and amount of sterilised material, start and finish time for each sterilisation cycle, the responsible person, and sterilisation control findings.

Before use, the sterile material needs to be stored under controlled conditions (protected from damage, dust, humidity, and sudden changes in temperature).

Professional pedicure equipment needs to be of high quality. Professional instruments made of stainless steel are considered to be of highest quality available on the market because:

- Surface damage will not cause corrosion,
- Longevity of instruments is guaranteed with adequate maintenance,
- They usually don’t cause allergies to metals.

TATTOO, PIERCING, MICROBLADING, PERMANENT AND SEMI-PERMANENT MAKEUP



Tattoos are permanent; they are created by applying (injecting) pigment into the dermal layer of the skin. On the other hand, piercing is not permanent, however it carries greater health risks because it involves mechanical piercing of skin or tissue in an area were decoration is wanted. Subsequently, the functioning of certain organs can become damaged, e.g. a damaged tongue nerve from tongue piercing.

Risks associated with breaking of the skin barrier

The art of tattooing and piercing carries certain risks because it involves breaking one of the most significant body defense barriers – the skin. This increases the risk from infection if not performed correctly.

→ The most frequent complications are inflammations, swelling, and anomalies.

→ **Hepatitis C** can be transmitted by using the same needle for different clients, inadequate needle sterilisation, and reckless behavior– e.g., when the tattoo artist tests needle sharpness immediately before the procedure and thus contaminates the needle. Most carriers of the hepatitis C virus are asymptomatic. Symptoms usually appear after several years and manifest as cirrhosis, or liver cancer.

→ Among other risks, there is also a small chance of contracting **tetanus** if the person is not vaccinated against tetanus, or **hepatitis B** and **HIV** virus if procedures are not carried out professionally.

✓ During tattooing procedures, sterile needles in sterile packaging need to be used and opened in front of clients. After single use, they must be discarded into special containers for infectious waste.

The most important thing in tattooing and piercing, even more important than artistry, is following measures for personal and professional hygiene:

→ Hand hygiene (washing and disinfection), cleaning of workspace, working surfaces and instruments, and disinfection and sterilisation of utensils.

→ Smoking is prohibited in the working area and the air needs to be purified with an ioniser or ozoniser, or ventilation and use of ambiental disinfection sprays. The floor in the working area also needs to be regularly cleaned and disinfected. Working surfaces (tables etc.) need to be smooth, without coarse materials because only smooth materials can be thoroughly cleaned and disinfected (from microorganisms and microscopic particles).

→ Tools and instruments for which it is required, need to be sterilised in order to destroy all microorganisms on their surfaces.

→ Single-use materials must be used in everyday work: disposable needles, disposable gloves, pigment containers etc.

→ Disinfection includes working areas, surfaces, and instruments that do not come into contact with clients, as well as disinfection and maintaining hygiene of working premises.

→ As regards the sterilisation procedure, AUCTOCLAVE high pressure steriliser is used at a temperature of 131°C for a minimum of 30 minutes. Needles, tubes, tweezers, medical containers and similar tools that come into contact with clients' blood, sweat, lymph, mucous membranes, and skin must be sterilised in the above described manner. The above sterilisation is the only realiable and acceptable method, except sterilisation in a dry air steriliser [for 180 minutes at 180°C], which is impractical for tattoo artists because in this type of sterilisation the needles unsolder and lose their sturdiness. Needles and tubes must be cleaned in an ultrasound device (cleaner) before sterilisation. This is the only way to extract all pigments and dirt from tiniest pores in the material of tubes and needles.

→ If tattoos are made professionally, with original tattoo inks, the risks of infection or allergy are minimised.

Regulations on the ingredients/dyes injected into the skin

At the EU level, legislation is intensively being harmonised as regards tattooing and permanent make-up. This is done in order to regulate the EU market with respect to hazardous chemicals (REACH framework). Some Member States have adopted the *Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up)*, which stipulates basic requirements related to safety of these products.

Tattoo inks are often reported in the RAPEX (rapid exchange of information system for unsafe consumer products) system as non-compliant products in terms of the presence of metal content, carcinogenic azo dyes, and polycyclic aromatic hydrocarbons (PAHs).

Note:

→ After tattooing, the healing process is relatively simple and lasts between one and three weeks. Healing of piercings is a more complex process which vastly depends on the body part were piercing was made.

→ During tattooing, it is important to keep in mind that tattoos are permanent and their complete removal is almost impossible.

→ Many people don't see the difference between tattooing in a professional studio or a friend's house (who "has a tattoo machine and does great work free of charge!"). People who choose to get tattoos "at a friend's home" (so-called scratchers) have a higher risk of infections and infectious diseases.

PIERCING

Body piercers, like tattoo artists, must be adequately trained. Mandatory measures, similar to those before tattooing, must be applied before piercing.

Most common piercing spots include:

- Ears,
- Nostrils,
- Belly button,
- Tongue.

It is also recommended to consider the material of jewelry that will be inserted, and determine if there is a possibility of an allergic reaction to said material. Jewelry needs to be made from inert materials that do not cause allergic reactions (e.g. steel, gold, titanium, platinum and niobium). Persons sensitive to nickel may develop contact dermatitis.

Note

→ Piercing is not recommended in certain allergies, diabetes, skin conditions, immune conditions, and pregnancy. For this reason, it is recommended to consult with a physician on potential existence of medical reasons against piercing.

→ Healing time for puncture wounds depends on the piercing site. Facial piercings usually heal within two months while covered areas heal within six months. However, even after the piercing site has healed, it needs to be observed for at least a year until skin epithelialization is completed.

Potential health risks associated with lip or tongue piercings:

- Infection – the most common occurrence as the oral cavity is full of bacteria;
- Hemorrhage – a cluster of vessels becomes damaged, especially in tongue, lips or chin piercings;
- Pain and swelling – when the injured tongue starts to swell, this can cause difficulty breathing;
- Injured palate – on rare occasions, tongue piercing causes damage to the mucous membrane of the palate, which leads to inflammations;
- Injured gums – usually from lip or tongue piercings as metal jewelry is in constant contact with the gums, causing friction which leads to injury;
- Chipped or broken tooth – common in persons with piercings;
- Gapped teeth – people with tongue piercings often “play” with balls attached to tongue jewelry and bash them against front upper teeth, which causes gapped teeth;

- Increased susceptibility to cavities – cracks and dents in tooth enamel encourage food build up and formation of plaque, which can lead to cavities;
- Allergies – jewelry containing nickel often causes allergic reactions; it is advisable to be informed on the material used and jewelry made of non-toxic materials is recommended;
- Infectious diseases (hepatitis, AIDS) – non-sterile needles used for piercing promote the occurrence of diseases;
- Endocarditis (heart disease) – occurs from infection in the oral cavity caused by piercing.

Hygienic working conditions

Tattoos and piercings must be made exclusively in licensed salons by trained staff.

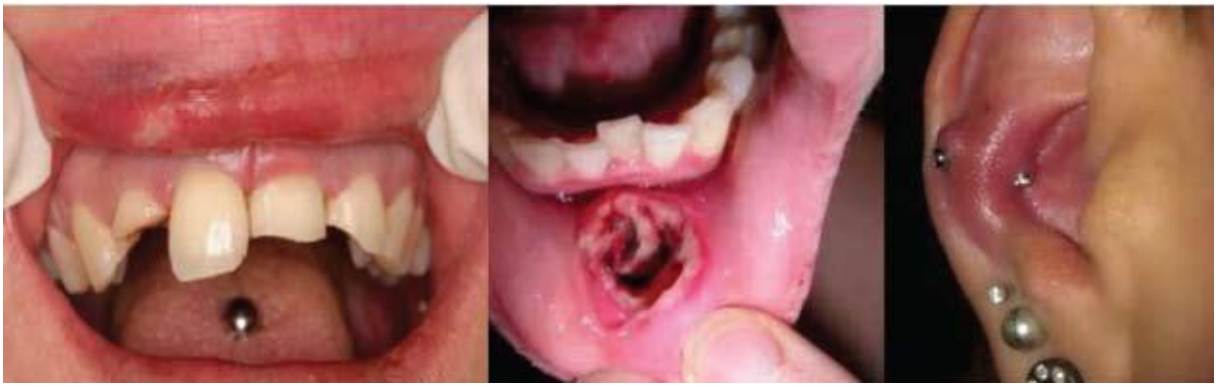
- The room where tattoos and piercings are made must be clean and tidy, and the person doing the procedure needs to disinfect their hands and don protective gloves.
- Employees must have appropriate work clothes that can be boil washed, and work footwear.
- Employees must wear single-use gloves for each new procedure, use sterile and disposable needles, have a device for instrument sterilisation (sterilisator/autoclav), disinfectants for working surfaces, floors, and workspace, inks with the associated documentation, and certificates of analysis.

Correct and incorrect ear piercing

In case of complications

- If complications occur after piercing, the client needs to be referred to a doctor (approx. two thirds of clients with problems seek medical assistance).
- In mouth piercings, ice chips or cold fluids can bring relief and reduce swelling in the initial stage of healing. Eventually, tongue piercings can damage teeth while tongue, cheek and lip piercings can affect gums. Infections are more frequent in mouth and nose piercings.

- Bacterial infections are the most common complication after piercing. They are usually caused by staphylococcus, streptococcus, and pseudomonas bacteria. In such cases, a targeted pharmacological intervention is recommended after establishing the pathogen that caused the infection. However, because processing of bacterial cultures requires a certain time, postponing treatment is not always advisable because infection may worsen. If the pierced area becomes infected, initially it is recommended to keep the jewelry inserted because this encourages drainage and healing of the epidermis, whereas its removal promotes abscess formation.
- Areas where jewelry is inserted are also exposed to secondary trauma – injuries from impact, scratching or tears. They usually occur in the pierced belly button area (40 percent), ear (35 percent), nose (12 percent), tongue, skin below the chin, eyebrows, outer genitals, and nipples. The usual complications involve hemorrhage, torn tissue, infections, nerve damage, scarring, and allergies.



Complications after piercing

FIRST AID BASICS

The employer is responsible for ensuring a safe working environment for employees. This includes prevention of physical injuries from:

- Prolonged standing or staying in an uncomfortable position,

- Carrying objects that are too heavy,

- Falls or slips that cause injuries.

Damage caused by chemicals present in many products used at the workplace and in the beauty industry must also be taken into consideration. While all products must be safe for use on clients, this does not necessarily make them safe for employees working with them because they are exposed for much longer than their clients.

Employees must follow health and safety instructions and use personal protective equipment according to manufacturer's instructions, e.g. don gloves, eye protection etc.

- **Dermatitis**

There are three types of dermatitis:

1. Frequent hand washing can cause skin dryness. Regular use of protective hand creams or gloves is recommended for creating a physical barrier. Solvents such as ethanol or acetone also cause skin dryness.

2. The second type is contact dermatitis, an inflammatory reaction to substances that come into contact with the skin. This is why gloves need to be donned during certain procedures, like working with peroxide for hair bleaching.

3. Third type refers to allergic reaction or hypersensitivity to a certain substance. It is a reaction by the immune system that leads to tissue damage. In case of an allergic reaction, a product with different composition should be used.

- **Hypersensitivity reactions**

Various chemicals can provoke an allergic response with time, so that even in small quantities they can cause an allergic reaction.

For the past few years, p-Phenylenediamine (PPD) has been added to hair colors, and it is responsible for many cases of sensibilisation in staff as well as clients. Once a person becomes sensitised, subsequent contact may cause a severe reaction that requires hospitalisation. Such products should be avoided if possible and using substitutes is recommended. It is important to determine the cause of reaction and re-exposure can be avoided by reading the product label. It is best to use another product that does not cause reactions, or don gloves in accordance with manufacturer's instructions.

- **Injuries**

A wound refers to a physical injury of live tissue involving the skin or mucous membranes that can penetrate deeper tissue layers and is usually caused by a mechanical force (e.g., a razor during shaving).

Nursing a wound requires covering it with a sterile gauze and bandage, and avoiding touching. Larger wounds should not be rinsed with clean water, and powders, ointments or creams should be avoided. Only minor superficial wounds that do not bleed profusely are rinsed with clean water.

- **Hemorrhage**

Hemorrhage refers to bleeding from a damaged blood vessel. It can be external (outward, when skin is damaged) or internal (inside the body, into the body cavities or organs). For external hemorrhage, the primary way of stopping blood loss is by applying pressure to the wound. This constraints the damaged blood vessels and prevents further blood loss.

- **Burns**

Burns refer to injuries to the skin or subcutaneous tissue caused by heat (hot liquids, steam, fire), electric current, chemicals, friction, or radiation. The severity of burns depends on the affected body surface and how deep they penetrated into the skin.

Burns are divided into superficial burns (skin redness, swelling and pain when touched)
– 1st degree: partially deep burns where damage penetrates into lower skin layers and destroys the superficial layer of the skin, they are characterised by formation of blisters on the skin,

– 2nd degree: burns involving all skin layers, and

– 3rd degree: full thickness burns.

In superficial burns, it is important to cool the burn site with clean cold water as soon as possible. The affected body part needs to be submerged in cold water as soon as possible, or placed under a stream of cold running water; cooling should last for at least 10 minutes (until the pain subsides). The burn should not be touched, and the injured area needs to be covered with a sterile gauze or bandage to protect it from infection.

Burnes caused by electric current can cause muscle tension, and even stop the heartbeat.

- **Puncture incidents**

Needle punctures and injuries from sharp objects are the most common risks for healthcare workers. However, all persons using needles and sharp objects in their line of work are at risk.

After disinfection of the injured area, cases of punctures or contact with potentially infectious material with mucous membranes and wounds, need to be reported to a doctor.

Punctures with contaminated needles and sharp objects pose a risk from blood borne diseases such as hepatitis B, C, and HIV.

USEFUL INFORMATION

Cosmetovigilance

Adverse reactions may develop when using a cosmetic product. They are categorised as:

- Irritative contact dermatitis (itching, rash or blotchy skin; the most sensitive parts are the eyelids and the areas with dry and cracked skin).
- Allergic contact dermatitis (in persons who are allergic to some of the ingredients): Symptoms usually include redness, swelling, and itching.

They usually appear on the face, eyes, lips, ears, and neck, although they can appear anywhere on the body.

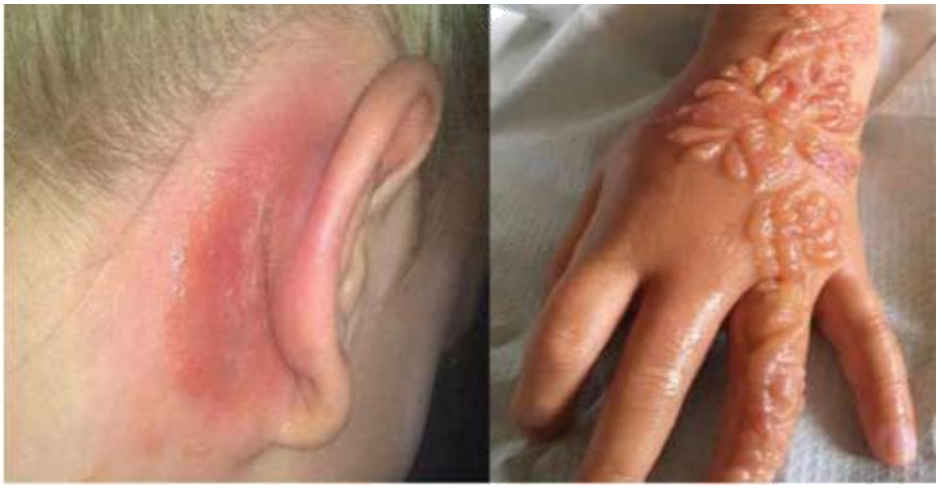
If the above symptoms occur, a doctor should be contacted to establish the cause and treat the symptoms if necessary. It is important to keep the product and its packaging in order to idenitify the cause by serial or batch number (the product might be unsafe).

Reporting such cases provides useful information for healthcare workers to take further actions, and for health and safety inspectors of the State Inspectorate if the product needs to be revoked from the market. This is also useful for product manufacturers that create product labelling.

Therefore, all undesirable effects should be REPORTED to the manufacturer/distributor whose information are declared on the product label.

Unlike the above side effects, SERIOUS UNDESIRABLE EFFECTS caused by a cosmetic product present a great concern. They include:

- Hospital treatment (hospitalisation);
- Temporary or permanent functional disability (los of taste, smell, etc.);
- Disability;
- Congenital anomalies;
- Immediate vital risk, or
- Death.

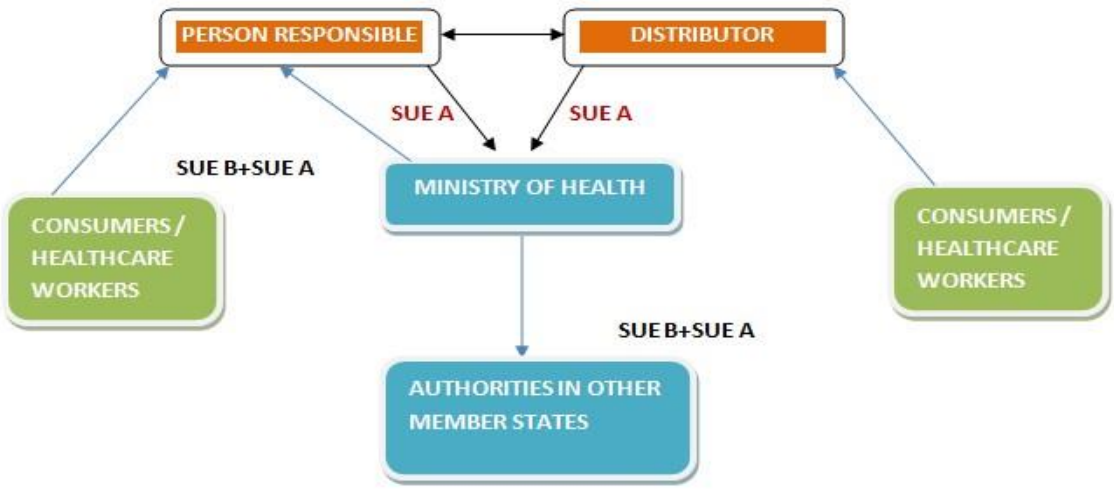


Examples of serious undesirable effects caused by cosmetic products

Such cases need to be reported by healthcare workers, distributors, and manufacturers to the Ministry of Health via email adddress: kozmetovigilancija@miz.hr

Three standardised forms are used for reporting:

- Form A (SUE Form A) is filled out by the responsible person or the distributor http://ec.europa.eu/DocsRoom/documents/13251/attachments/3/translations
- Form B (SUE Form B) is filled out by the authorised body
- Form (SUE Form C) is filled out by an authorised body based on the report submitted by healthcare workers or end users.



Reporting a serious undesirable effect by the responsible person or the distributor

Guidance for safe use of cosmetics:

- ✓ Always carefully read the instructions and pay attention to all warnings regarding use.
- ✓ Close the product lids when they are not in use.
- ✓ Use products that are within the expiration date indicated on the packaging.
- ✓ Keep products away from sulinght or heat sources.
- ✓ Never dilute products with water or mix them with other products, unless it is specifically indicated in the instructions for use.
- ✓ Apply products with clean hands or an applicator which must be regularly washed with soap, detergent, or mild shampoo after use.
- ✓ Use an applicator that is completely clean and dry.

The use of products whose action depends on correct application

Cosmetic products whose action depends on correct application (products for cold permanent curling, depilators, hair colors, color shampoos, neutralisators etc.) must have attached instructions for use, which should be carefully read and studied. In case of warnings, the user must be consulted.

Unless stated otherwise on the product label, hypersensitivity tests can be conducted:

→ For permanent hair curling products:

Apply the product to the skin behind the ear with a cotton ball. Thoroughly rinse the product after 20 minutes with water. If within 24 hours changes occur on this skin area (redness, swelling, itching), the product should not be used.

→ For hair colors:

A small amount of cream, prepared according to instructions, is applied to the skin behind the ear. After 30 minutes, the cream must be removed with cotton or rinsed with water. If after 24 hours changes occur in the affected skin area (redness, swelling, itching), the product should not be used.

→ For depilatory products:

A small amout of the depilatory product is applied to the inner forearm. Rinse with water after 10 minutes. If changes occur in this skin area after 24 hours (redness, swelling, itching), the depilatory product should not be used.

Before use, it is recommended to consult with the user on potential allergic reactions to ingredients of products used in treatments, as it is important to know what to do in such cases.

Useful links on tattoos and permanent makeup:

https://echa.europa.eu/hot-topics/tattoo-inks

https://www.edqm.eu/en/tattoos-and-permanent-make