REGULATION AND STANDARDS

For all health, hygiene, care and disinfection products, an assessment of the benefit and/or risk must be carried out before they are placed on the market. Depending on the nature of the product, this assessment relates to different criteria and levels of requirements and may be carried out by the manufacturer or by a supervisory authority (Federal Office of Public Health (FOPH), Swiss Agency for Therapeutic Products (Swissmedic)).

REGULATION CONCERNING BIOCIDES: (UE) 528/2012

Definition: Preparations intended to destroy, repel or render harmful organisms harmless, prevent the action of or exert a controlling effect on by chemical or biological means.
Product categories:
Group 1: disinfectants and general biocidal products including
Type 1: products intended for human hygiene.
Type 2: disinfectants for the private domain and the public health field.
Type 3: veterinary hygiene.
Type 4: disinfectants for surfaces in contact with foodstuffs and animal feed.
Type 5: disinfectants for drinking water.
Group 2: protective products (wood, mildew, etc.).
Group 3: antiparasitic products.
Group 4: other biocide products (protection of foodstuffs, embalming, etc.).
Assessment criteria:
- User safety via toxicological studies.
- Environmental safety via eco-toxicological studies.
- Disinfectant efficacy of biocidal products via European disinfection standards.
Applicable standards: N/A.
Marketing decision-maker: The manufacturer and/or the notifying body according to the type of medical device.
Medical devices vigilance:
- Reporting adverse reactions to the Swissmedic, collection of information.
- Recording, assessment, use of this information for regular re-assessment of products.
- Implementation of actions: changes to information for healthcare professionals, patients, suspension, withdrawal from the market.

REGULATION CONCERNING MEDICAL DEVICES - DIRECTIVE 93/42/EEC

Definition: Instrument, device, equipment, material or other, used alone or in combination, for use in humans for the purposes of diagnosing, preventing, controlling, treating or alleviating a disease, disability, study or replacement or modification of anatomy or a physiological process.
Assessment criteria:
- Patient and user safety (care personnel).
- Effectiveness and reliability of the objectives for diagnosis, prevention, control, treatment or reduction of the impacts of a pathology.
Applicable standards: standard ISO 13485.
Marketing decision-maker: The manufacturer and/or the notifying body according to the type of medical device.
Medical devices vigilance:
- Reporting adverse reactions to the ANSM or the DGCCRF.
- Recording, assessment, use of this information.
- Implementation of actions: changes to information for healthcare professionals, patients, suspension, withdrawal from the market.

REGULATION CONCERNING COSMETICS: (EC) 1223/2009

Definition: 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.
Assessment criteria:
- User safety via studies and the assessment of an independent toxicologist.
- Effectiveness to be proven based on the allegations mentioned.
Applicable standards: ISO 22716 “Good cosmetic manufacturing practices”.
Marketing decision-maker: the manufacturer.
Cosmetovigilance:
- Reporting adverse events to the ANSM or the DGCCRF.
- Recording, assessment, use of this information.
- Implementation of actions: changes to information for healthcare professionals, users, suspension, withdrawal from the market.
**Temperature:**

- **Human medicine**
  - Surgical hand rubbing and washing: 20°C.
  - Disinfection of medical devices: 20°C.
  - Disinfection of surfaces: 20°C.

- **Industries**
  - Hygienic hand washing: 20°C.
  - Contact time: 5 min, 1 min for hand disinfection. Temperature: 20°C.

- **General/Centres**
  - Hygienic hand rubbing and washing: 20°C.
  - Disinfection of medical devices: 20°C.
  - Disinfection of surfaces: 20°C.

**En 1040**

Basic bactericidal activity - Phase 1. Microbial reduction ≥ 10^4 against 2 strains: Pseudomonas aeruginosa, Staphylococcus aureus. Contact time: 5, 15, 30, 45 or 60 min. Temperature: + 20°C.

**En 13727 + A2**

Assessment of the bactericidal activity - Phase 2, step 1. Microbial reduction ≥ 10^5 against Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli and hands only. Clean conditions: 0.3 g/l bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 5 or 60 minutes. Contact time: 5 or 60 minutes.

**En 13697**

Assessment of the bactericidal activity and/or fungicidal activity - Phase 2, step 2. Microbial reduction ≥ 10^4 against Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli. Clean conditions: 0.3 g/l of bovine albumin + 8.5 g/l of skimmed milk for P. aeruginosa. Dirty conditions: 3 g/l bovine albumin. Contact time: 5 min. Temperature: between 18 and 25°C.

**En 13687**

Assessment of the bactericidal and/or fungicidal activity - Phase 2, step 2. For fungicidal activity: Microbial reduction ≥ 10^4 against Candida albicans and Aspergillus Brasiliensis or C. albicans alone (yeasticidal). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 60 min, for 5, 15 or 30 min. Temperature: 20°C or 40°C (or additional temperature).

**En 14561**

Assessment of the activity of hygienic hand washing products under practical conditions of use - Phase 2, step 2. Microbial reduction ≥ 10^5 against Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae. Clean conditions: 0.3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 30 sec or 60 sec.

**En 1500**

Assessment of the activity of hygienic hand washing products under practical conditions of use - Phase 2, step 2. Antifungal activity of the hands of 18 to 22 volunteers by Escherichia coli and Candida albicans. Contact time: 30 sec. Total time of washing limited to either 30 sec or 60 sec.

**En 14348**

Assessment of the mycobactericidal activity - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Mycobacterium avium, Mycobacterium terrae (tuberculosis + M. terrae alone). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 60 min, 6, 15, 30 min. Temperature: 20°C (or additional temperature).

**En 14563**

Assessment of the mycobactericidal activity as per the germ cell method - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Mycobacterium avium, Mycobacterium terrae. Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 60 min, 6, 15, 30 min. Temperature: 20°C or 40°C.

**En 1275**

Basic fungicidal activity - Phase 1, step 1. Microbial reduction ≥ 10^4 against: Candida albicans, Aspergillus brasiliensis or C. albicans alone (yeasticidal). Contact time: 5, 15, 30, 60 min. Temperature: 20°C.

**En 14712**

Quantitative suspension test for the evaluation of the sporicidal activity of chemical disinfectants used in the medical field (phase 2, step 1). Test on C. difficile or B. subtilis A & B, cecum.

**En 14476 + A1**

Assessment of the virucidal activity - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Polioviruses, Adenovirus, Murine Norovirus and Panovirus (only for tests ≥ 40°C and for textile) and Vaccinia virus (only for hand disinfection). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin. Contact time: 5 min. Temperature: + 20°C.

**En 14476 + A1**

Assessment of the mycobacterial activity - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Polioviruses, Adenovirus, Murine Norovirus and Panovirus (only for tests ≥ 40°C and for textile) and Vaccinia virus (only for hand disinfection). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 g/l of sheep red blood cells. Contact time: 5 min. Temperature: + 20°C.

**En 14476 + A1**

Assessment of the bactericidal and/or fungicidal activity - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Candida albicans, Aspergillus brasiliensis or C. albicans alone (yeasticidal). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 5 min. Temperature: + 20°C.

**En 14476 + A1**

Assessment of the bactericidal and fungicidal activity on non-porous surfaces, with mechanical action using wipes - Phase 2, step 2. Microbial reduction ≥ 10^4 against: Staphylococcus aureus, Enterococcus hirae. Microbial reduction ≥ 10^4 against Pseudomonas aeruginosa and Candida albicans. Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin. Contact time: 5 min, 120 seconds. Temperature: 10°C.

**En 14562**

Microbial reduction ≥ 10^4 against Candida albicans, Aspergillus brasiliensis or C. albicans alone (yeasticidal). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml of sheep red blood cells. Contact time: 60 min, 5, 5, 15, 30 min (additional minutes). Temperature: 20°C (additionally 10°C and 40°C).

**En 17121**


**En 17121**

Determination of the bactericidal, fungicidal and sporicidal activity for the airborne disinfected surfaces. Microbial reduction ≥ 10^5 (Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae and Escherichia coli), mycobacterial- dic activity - Phase 1 basic standard. Contact time: 5 min. Temperature: + 20°C.

**PHEASE 1**

**En 13610**

Assessment of the virucidal activity - Phase 2, step 1. Microbial reduction ≥ 10^4 against: Lactococcus lactis PFO1 & PGO1. Clean conditions: 1% acidi whey. Contact time: 15 min. Temperature: 20°C.

**En 13610**

Assessment of the bactericidal and yeasticidal activity on non-porous surfaces, with mechanical action using wipes - Phase 2, step 2. Test conditions: temperature 21°C and 65% relative humidity or conditions defined by the manufacturer. Contact time: + 2°C.

**En 17272**

Determination of the bactericidal, fungicidal and sporicidal activity for the airborne disinfected surfaces. Microbial reduction ≥ 10^5 (Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae and Escherichia coli), mycobacterial- dic activity - Phase 1 basic standard. Contact time: 5 min. Temperature: + 20°C.

**ISO 11930**

Assessment of the antimicrobial protection of a cosmetic product.