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:
Minister of the Environment.
Toxicovigilance:
- Submission of product information to the FOPH

to respond to immediate risks of poisoning.

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 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 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 (General Directorate for Competition Policy,. Consumer affairs and Fraud control).
- Recording, assessment, use of this information.
- Implementation of actions: changes to information for healthcare professionals, users, suspension, withdrawal from the market.

DISINFECTION STANDARDS*

SECTORS	PHASES STEPS	MICROORGANISMS				
		BACTERIA	FUNGI/YEAST	MYCOBACTERIA	VIRUS	SPORES
General	Phase 1 basic standard	EN 1040	EN 1275			EN 14347
Human medicine	Phase 2 - Step 1	EN 13727 + A2	EN 13624	EN 14348	EN 14476+A1	EN 17126
	Phase 2 - Step 2	Hands: EN 1499 EN 1500 - EN 12791 Instruments: EN 14561 Wipes: EN 16615	Instruments: EN 14562 Wipes: EN 16615	Instruments: EN 14563	EN 17111 EN 16777	
Industries Community centres General Public	Phase 2 - Step 1	EN 1276	EN 1650 + A1		EN 13610	EN 13704
	Phase 2 - Step 2	Surfaces: EN 13697 ADS: NF T72-281	Surfaces: EN 13697 ADS: NF T72-281	ADS: NF T72-281	ADS: NF T72-281 EN 17111	ADS: NF T72-281

PHASE 1
Basic standards: 1st step to be taken, demonstrates the existence of activity in the most favourable conditions for the product.

PHASE 2
Application standards: trying to reproduce, for each use, the conditions close to the real conditions of use.
Phase 2/step 1.
In vitro application standard.
Phase 2/step 2.
Application standard that models usage.

PHASE 3
Field tests in practical conditions

EN 1040
Basic bactericidal activity - Phase 1. Microbial reduction ≥ 105 against 2 strains : Pseudomonas aeruginosa, Staphylococcus aureus. Contact time : 1, 5, 15, 30, 45 or 60 min. Temperature : +20°C.

EN 13727 + A2
Assessment of the bactericidal activity - Phase 2, step 1. Microbial reduction ≥ 105 against : Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherischia coli (hands only). Clean conditions : 0.3 g/l of bovine albumin. Dirty conditions : 3 g/l of bovine albumin + 3 ml/l of sheep red blood cells.
Contact time :
- Hygienic hand rubbing : maximum 60 seconds.
- Hygienic hand washing : maximum 75 seconds.
- Surgical hand rubbing and washing: maximum 5 minutes.
- Disinfection of medical devices: maximum 60 minutes.
- Disinfection of surfaces : 5 or 60 minutes.

Temperature :
- Surgical hand rubbing and washing : maximum 20°C.
- Disinfection of medical devices : from 20 to 60°C.
- Disinfection of surfaces : maximum 30°C.

EN 14561
Assessment of the bactericidal activity as per the germ cell method - Phase 2, step 2. Microbial reduction ≥105 against : Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae. Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml/l of sheep red blood cells. Contact time : 60 min. (or 5, 15 or 30 min.).Temperature: 20°C or 10°C (additional temperature level).

EN 1499
Assessment of the activity of hygienic hand washing products under practical conditions of use - Phase 2, step 2. Artificial contamination of the hands of 12 to 15 volunteers by Escherichia coli. Comparison of the reduction factor obtained during the test, to the one obtained under the same conditions with a reference washing (mild soap). Total time of washing limited to either 30 sec. or 60 sec.

EN 1500
Assessment of the activity of hygienic hand treatment products under practical conditions of use - Phase 2, step 2. Artificial contamination of the hands of 18 to 22 volunteers by Escherichia coli. Comparison of the reduction factor obtained during the test, to the one obtained under the same conditions with a reference product (60% 2-propanol solution). Total time of rubbing limited to either 30 sec. or 60 sec.

EN 12791
Assessment of the activity of surgical hand disinfectants - Phase 2, step 2. Treatment of the clean hands of 23 to 26 volunteers. Assessment of an immediate effect after surgical hand disinfection and a residual effect after wearing surgical gloves for 3 hours after disinfection. Reference = 60% propan-1-ol (v/v).

EN 1276
Assessment of the bactericidal activity - Phase 2, step 1. Microbial reduction ≥105 against: Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus hirae. Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin. Contact time: 5 min, 1 min for hand disinfection. Temperature: 20°C.

EN 13697
Assessment of the bactericidal and/or fungicidal; activity - Phase 2, step 12 For bactericidal activity: Microbial reduction ≥104 against: Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli. Clean conditions: 0.3 g/l of bovine albumin and 8.5 g/l of skimmed milk for P. aeruginosa. Dirty conditions: 3 g/l bovine albumin. Contact time: 5 mins. Temperature: between 18 and 25°C. For fungicidal activity: Microbial reduction ≥103 against: Candida albicans and Aspergillus brasiliensis or C. albicans alone (yeasticidal). Clean conditions: 0.3 g/l bovine albumin. Dirty conditions: 3 g/l bovine albumin. Contact time: 15 mins. Temperature: between 18 and 25°C.

EN 14348
Assessment of the mycobacterial activity - Phase 2, step 1. Microbial reduction ≥104 against: Mycobacterium avium, Mycobacterium terrae (tuberculocidal = M.terrae alone). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml/l of sheep red blood cells. Contact time: 60 min. 5, 15, 30 min. Temperature: 20°C (10°C additional temperature).

EN 14563
Assessment of the mycobactericidal activity as per the germ cell method - Phase 2, step 2. Microbial reduction ≥104 against: Mycobacterium avium, Mycobacterium terrae. Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml/l of sheep red blood cells.
Contact time: 60 min. or 5, 15, 30 min. Temperature: 20°C or 10°C.

EN 1275
Basic fungicidal activity - Phase 1, step 1. Microbial reduction ≥104 against: Candida albicans, Aspergillus brasiliensis or C. albicans alone (yeasticidal). Contact time: 5, 15, 30 or 60 min. Temperature: 20°C.

EN 13624
Assessment of the fungicidal activity - Phase 2, step 1. Microbial reduction ≥104 against: Candida albicans, Aspergillus brasiliensis or C. albicans alone (yeasticial or hand disinfection). Clean conditions: 0.3 g/l of bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 ml/l of sheep red blood cells.
Contact time:
- Hygienic hand rubbing: maximum 60 seconds.
- Hygienic hand washing: maximum 75 seconds.
- Surgical hand rubbing and washing: maximum 5 minutes.
- Disinfection of medical devices : maximum 60 minutes.
- Disinfection of surfaces: 5 or 60 minutes.

Temperature:
- Hygienic and surgical rubbing and hand washing: maximum 20°C.
- Disinfection of medical devices: from 20 to 60°C.
- Disinfection of surfaces : maximum 30°C.

EN 1650 + A1
Assessment of the fungicidal activity - Phase 2, step 1. Microbial reduction ≥104 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. Contact time: 15 min. (1, 5, 30 and 60 additional minutes). Temperature: 20°C (additional 4, 10 and 40°C).

EN 14562
Assessment of the fungicidal activity as per the germ cell method - Phase 2, step 2. Microbial reduction ≥104 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/l of sheep red blood cells. Contact time: 60 min. (5, 15 and 30 of additional time). Temperature: 20°C compulsory to choose < 60°C.

EN 14347
Basic sporicidal activity - Phase 1. Microbial reduction ≥104 against: Bacillus subtilis, Bacillus cereus. Contact time: 30 min., 60 min., 120 min. Temperature: 20°C.

EN 13704
Assessment of the sporicidal activity - Phase 2, step 1. Microbial reduction ≥ 103 against: Bacillus subtilis. Clean conditions: 0.3 g/l bovine albumin. Contact time: 60 mins
Temperature: 20°C.

EN 17126
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 & B. cereus

EN 14476 + A1
Assessment of the virucidal activity - Phase2, step 1. Microbial reduction ≥ 104 against: Poliovirus, Adenovirus, Murine Norovirus and Parvovirus (only for tests at ≥ 40°C and for textiles) 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:
- Hygienic treatment and hand washing: between 30 seconds and 120 seconds.
- Disinfection of instruments: maximum 60 min.
- Disinfection of surfaces: between 5 min. and 60 min.
- Disinfection of textiles: maximum 20 min.

Temperature:
- Hygienic hand treatment and washing: 20°C.
- Disinfection of instruments: between 20°C and 70°C.
- Disinfection of surfaces: between 4°C and 30°C.
- Disinfection of textiles: between 30°C and 70°C.

EN 17111
Assesment of the virucidal activity, Phase 2, step 2. Quantitative germ-holder assay for the evaluation of virucidal activity for instruments used in medicine. Envelopped virus: Vaccinia virus. Non envelopped virus: Adenovirus & norovirus. Clean or dirty conditions. Activity against enveloped viruses Efficacy based on the protocol for standard EN 14476 limited to Adenovirus and murine Norovirus or Vaccinia virus for the hand disinfection, covers all enveloped viruses such as HIV-1, Herpes virus, hepatitis B and C virus, Coronavirus, Influenza virus, etc. Activity against other viruses Efficacy based on the protocol for standard EN 14476 with a microbial reduction ≥ 104 on naked viruses such as Rotavirus, BDVD, Vaccinia virus, hepatitis A and E virus, Caliciviridae, Rhinovirus, etc.

EN 16777
Quantitative test of non-porous surface without mechanical action for the evaluation of the virucidal activity of chemical disinfectants used in the medical field (phase 2/Step 2).
Envelopped virus, vaccinia virus. Non-envelopped virus Adenovirus & Norovirus.

EN 13610
Assessment of the virucidal activity - Phase 2, step 1. Microbial reduction ≥104 against: Lactococcus lactis P001 & P008. Clean conditions: 1% acid whey.Contact time: 15 mins. Temperature: 20°C.

EN 16615
Assessment of the bactericidal and yeasticidal activity on non-porous surfaces, with mechanical action using wipes - Phase 2, step 2. Microbial reduction ≥105 against: Staphylococcus aureus and Enterococcus hirae. Microbial reduction ≥104 against: Pseudomonas aeruginosa and Candida albicans. Clean conditions: 0.3 g/l bovine albumin. Dirty conditions: 3 g/l of bovine albumin + 3 g/l of sheep red blood cells. Contact time: maximum 60 min. Temperature: between 4 and 30°C.

NF T 72-281 (prEN 17272)
Determination of the bactericidal, fungicidal and sporicidal activity for the airborne disinfection of surfaces. Microbial reduction: bactericidal ≥105 (Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae and Escherichia coli). mycobactericidal ≥104 (Mycobacterium avium and Mycobacterium terrae). fungicidal ≥104 (Candida albicans, Aspergillus brasiliensis). sporicidal ≥103 (Bacillus subtilis). virucidal ≥104 (Enterovirus bovin, murine Norovirus, Adenovirus and Bacteriophage Lactococtus lactis). Test start conditions: temperature 21°C and 60% relative humidity or conditions defined by the manufacturer. Contact time < 12 h.

Effectiveness of antimicrobial preservation
Test as per the European Pharmacopoeia. Test to demonstrate the efficacy of a product's preservative system against artificial contamination (106 bacteria/ml).

ISO 11930
Assessment of the antimicrobial protection of a cosmetic product.