Disinfectants and biocides Quality & Compliance

Biocides are chemical agents aimed to reduce, destroy, deter, render harmless, or exert a controlling effect on any harmful organism. These substances can be found in household or professional cleaning and personal care products, considered as means of rapidly and effectively inactivating a wide array of potentially harmful microorganisms on inanimate materials (instruments, containers, surfaces), or living tissues such as hands and skin.

Product and regulatory scenarios

Chemical disinfection refers to the reduction of the number of microorganisms in- or on- a matrix, achieved by irreversible action to a metabolism or product's structure, to a level judged to be appropriate for a defined purpose.

Disinfection claims refer to: vegetative bacteria, yeasts, mould spores, bacterial spores, viruses and other microorganisms.

During the so called sterilization process, disinfectants do not necessarily kill all organisms, but reduce them to a harmless level for human and/or animal health.

Disinfectants or Biocides are classified in different types, based on their intended use (human hygiene, surface or water disinfection, among other). Basically conceived to kill germs, disinfect surfaces, sanitize hands and body skin and prevent cross contamination, these products and each of the active substances in their composition should comply with the Biocidal Products Regulation.

Important note: when applied to disinfect medical devices or directly on wounds or skin before surgery, disinfectants are considered medical products and should additionally comply with the corresponding legislation.

Regulatory overview

Field	Europe	US
Disinfectants / Hands sanitisers (not wounded skin)	Biocidal Products Regulation (BPR) Regulation (EU) 528/2012) PT1*	FDA Over-the-Counter Monographs for Consumer and Healthcare Personnel Handwashes and Handrubs
Disinfectants (Surface)	Biocidal Products Regulation (BPR) Regulation (EU) 528/2012) PT2-3-4	EPA Antimicrobial pesticides OCSPP performance test guidelines 810 series
Disinfectants (water)	Biocidal Products Regulation (BPR) Regulation (EU) 528/2012) PT5	EPA – Drinking water regulations

* For products specifically intended for the cleaning, disinfection or sterilisation of medical devices the applicable document is REGULATION (EU) 2017/745

Test methods and requirements

Basic quality control

- Chemical product appearance - Visual examination
- Weight or Volume - Gravimetry
- Density at 20 °C - PE 2.2.5
- pH – Potentiometry
- Ethanol - GC/FID Default variation; Digital photography - Default variation
- Glycerol
- Isopropanol
- Benzalkonium chloride
- “Brookfield viscosity” test
- “H_2O_2” dosage
- Alcohol concentration of raw materials and final product
- Additives - Should be as non-toxic as possible (considering accidental ingestion)
- Perfumes or dyes - Not recommended, to avoid risk of allergic reactions
- Labelling - in accordance with national and international regulations
- Flammability
- Virucidal activity versus standard and specific human viruses including Betacoronavirus models

Test methods

Test methods should applied based on a product’s classification and claims. Below, test methods specifically applicable to disinfectant products are outlined.

Germ kill efficacy test

Measurement of the time required for a certain product concentration to kill a certain level of bacteria/ fungi. Include (Phase 1 tests are not permitted to support a biocidal claim) phase2/step1 and/or step2 CEN tests as well as ASTM E 2315 time-kill tests.

Hand rub and hand wash studies

Simulated in-use hand rub/wash procedures based on EN 12791, EN 1500 and EN 1499, ASTM E2755 and ASTM E1174 to evaluate the products’ efficacy.

Minimum Inhibitory Concentration (MIC)

Benchmark the lowest concentration of an antimicrobial drug (Antifungal, Antibiotic or Bacteriostatic) that will inhibit the visible growth of a microorganism after overnight incubation. MICs can be determined on plates of solid growth medium or broth dilution methods after a pure culture is isolated.

Virucidal activity

The aim of the test is to evaluate the capability of a chemical disinfectant formulation to reduce the number of infecting viral particles on suitable human / animal-derived host cells.

Toxicology and Regulatory

Eurofins offers personalised support to assurance the compliance of your products.

Our toxicologists and regulatory experts can assist you from the choice of ingredients according to legislation, validation of labeling, claims, audit of the dossier, signature of the safety report and monitoring entire compliance lifecycle of the product.

Eurofins can support its clients, through testing and consultancy services, to claim the product’s efficacy against coronavirus, based on the client’s benchmark and the regulations of the targeted country.

Efficacy testing standards

Please note, in order to put a biocidal product on the market, the supplier has to perform all mandatory tests ("Basic requirements" in the table). The supplier cannot simply perform optional tests without performing the mandatory tests.

Europe (Biocidal Products Regulation (BPR) Regulation (EU) 528/2012))

PT1		Hygienic Handrub (hydroalcoolic hand sanitisers)	Hygienic handwash (not hydroalcoolic hand sanitisers)	Surgical hand disinfection
Bacteria	**Basic requirements- 2,1 test**	EN 13727 / EN 1276	EN 13727 / EN 1276	EN 13727
Bacteria	**Basic requirements- 2,2 test**	EN 1500	EN 1499	EN 12791
Yeast	**Basic requirements- 2,1 test**	EN 13624 / EN 1650	EN 13624 /EN 1650	EN 13624
Mycobacteria/ tuberculosis	**Optional – 2,1 test**	EN 14348	EN 14348	EN 14348
Viruses	**Optional – 2,1 test**	EN 14476	EN 14476	EN 14476
Fungal spores	**Optional – 2,1 test**	EN 13624 / EN 1650	EN 13624 / EN 1650	EN 13624

PT2	Hard surfaces and other uses (use in healthcare)		Hard surfaces and other uses (use other than in healtcare)	
Bacteria	**Basic requirements- 2,1 test**	EN 13727 / EN 1276	**Basic requirements- 2,1 test**	EN 13727 / EN 1276
Bacteria	**Basic requirements- 2,2 test**	EN 13697 / EN 16615	**Basic requirements- 2,2 test**	EN 13697 / EN 16615
Yeast	**Basic requirements- 2,1 test**	EN 13624 / EN 1650	**Optional – 2,1 test**	EN 13624 / EN 1650
Yeast	**Basic requirements- 2,2 test**	EN 13697 / EN 16615	**Optional – 2,2 test**	EN 13697 / EN 16615
Mycobacteria/ tuberculosis	**Optional – 2,1 test**	EN 14348	**Optional – 2,1 test**	EN 14348
Viruses	**Optional – 2,1 test**	EN 14476	**Optional – 2,1 test**	EN 14476
Viruses	**Optional – 2,2 test**	EN 16777	**Optional – 2,2 test**	EN 16777
Fungal spores	**Optional – 2,1 test**	EN 13624 / EN 1650	**Optional – 2,1 test**	EN 13624 / EN 1650
Fungal spores	**Optional – 2,2 test**	EN 13697	**Optional – 2,2 test**	EN 13697

PT2	Room disinfection (including use in healthcare)		Instrument Disinfestation by immersion or filling		Textiles	
Bacteria	**Basic require-ments- 2,1 test**	EN 13727 / EN 1276	**Basic require-ments- 2,1 test**	EN 13727	**Basic require-ments- 2,1 test**	EN 13727 / EN 1276
Bacteria	**Basic require-ments- 2,2 test**	EN 17272:2020	**Basic require-ments- 2,2 test**	EN 14561	**Basic require-ments- 2,2 test**	EN 16616 / ASTM E2406 / ASTM E2274
Yeast	**Basic require-ments- 2,1 test**	EN 13624 / EN 1650	**Basic require-ments- 2,1 test**	EN 13624	**Basic require-ments- 2,1 test**	EN 13624 / EN 1650
Yeast	**Basic require-ments- 2,2 test**	EN 17272:2020	**Basic require-ments- 2,2 test**	EN 14562	**Basic require-ments- 2,2 test**	EN 16616 / ASTM E2406 / ASTM E2274
Mycobacteria/ tuberculosis	**Optional – 2,1 test**	EN 14348	**Optional – 2,1 test**	EN 14348	**Optional – 2,1 test**	EN 14348
Mycobacteria/ tuberculosis	**Optional – semi-field trial**	EN 17272:2020	**Optional – 2,2 test**	EN 14563	**Optional – 2,2 test**	EN 16616 / ASTM E2406 / ASTM E2274
Viruses	**Optional – 2,1 test**	EN 14476	**Basic require-ments- 2,1 test**	EN 14476	**Optional – 2,1 test**	EN 14476
Viruses	**Optional – 2,2 test**	EN 17272:2020	**Optional – 2,2 test**	EN 16777	**Optional – 2,2 test**	EN 16616 / ASTM E2406 / ASTM E2274
Fungal spores	**Optional – 2,1 test**	EN 13624 / EN 1650	**Basic require-ments- 2,1 test**	EN 13624	**Optional – 2,1 test**	EN 13624 / EN 1650
Fungal spores	**Optional – 2,2 test**	EN 17272:2020	**Basic require-ments- 2,2 test**	EN 14562	**Optional – 2,2 test**	EN 16616 / ASTM E2406 / ASTM E2274

Note: EN 14476 includes additional test conditions allowing us to test product against specific strains which present an interest in this context i.e. Human coronavirus HCOV 229E.

US

FDA Over-the-Counter Monographs for Consumer and Healthcare Personnel Handwashes and Handrubs		
	Efficacy testing on handrub	**Efficacy testing on handwash**
Bactericidal activity (Antimicrobial)	ASTM E2752 ASTM E2755 ASTM E1115 ASTM E2315	ASTM E1174
Fungicidal / yeasticidal activity	ASTM E2613	ASTM E2613
Virucidal activity	ASTM E1052	ASTM E1052

EPA guidelines OCSPP 810.2200 Disinfectants for Use on Environmental Surfaces		
Summary of Testing for Base Disinfectant Claims		
Claim	Formulation / Test Methods	
Limited spectrum disinfectant / hard non-porous surfaces Broad spectrum disinfectant/hard non-porous surfaces Hospital or healthcare disinfectant / hard non-porous surfaces	Water soluble powders / liquids	AOAC Use-Dilution Method (ref. 1)
	Spray products	AOAC Germicidal Spray Products as Disinfectants Test (ref. 2)
	Towelettes	AOAC Germicidal Spray Products as Disinfectants Test modified for towelettes or ASTM E2362 (ref. 3)
Summary of Testing for Additional Disinfectant Claims		
Claim	Formulation/Test Methods	
Additional bacteria /hard non-porous surfaces	Water soluble powders / liquids	AOAC Use-Dilution Method (ref. 1)
	Spray products	AOAC Germicidal Spray Products as Disinfectants Test (ref. 2)
	Towelettes	AOAC Germicidal Spray Products as Disinfectants Test modified for towelettes or ASTM E2362 (ref. 3)
Internal toilet and urinal bowl surfaces (refer to section (F)(1) for guidance on above vs. below the waterline claims)	Water-soluble powders / liquid	AOAC Use-Dilution Test to include a 5% organic soil challenge added to the bacterial inoculum
	Spray products (for above waterline and dry flush only)	AOAC Germicidal Spray Products as Disinfectants Test (ref. 2)
Virucidal disinfectant/hard non-porous surfaces	Water soluble powders / liquids	ASTM E1053 (ref. 5) modified for the formulation type
	Spray products	
	Towelettes	
Fungicidal disinfectant/hard non-porous surfaces	Water soluble powders / liquids	AOAC Use-Dilution Method modified for fungi or AOAC Fungicidal Activity of Disinfectants (ref. 4)
	Spray products	AOAC Germicidal Spray Products as Disinfectants Test modified for fungi
	Towelettes	AOAC Germicidal Spray Products as Disinfectants Test modified for towelettes or ASTM E2362 (ref. 3)
Tuberculocidal disinfectant/hard non-porous surfaces	Water soluble powders / liquids	AOAC Tuberculocidal Activity of Disinfectants (ref. 8), Quantitative Tuberculocidal Activity Test (ref. 9)
	Spray products	AOAC Germicidal Spray Products Test modified for tuberculocidal activity
	Towelettes	AOAC Germicidal Spray Products as Disinfectants Test modified for towelettes or ASTM E2362

EPA guidelines OCSPP 810.2300 Sanitizers for Use on Hard Surfaces Tests for basic claims		
Level of efficacy	Test methods	
Non-food Contact Sanitizer	Water soluble powders / liquids Spray products	ASTM E-1153 99.9% reduction within 5 minutes
	Towelettes	Reserved 99.9% reduction within 5 minutes
Sanitizers for Urinal and Toilet Bowl Water and In-tank Sanitizers	Water soluble powders/liquids/tablets Simulated-use study	Simulated-use study 99.9% reduction over parallel control counts
Residual Selfsanitizing – wet surfaces		Simulated-use study 99.9% reduction over parallel control counts

EPA guidelines OCSPP 810.2400 Disinfectants and Sanitizers for Use on Fabrics and Textiles Efficacy Data Recommendations		
Type of product	Test procedures	
Disinfecting pre-soak treatments / Hospital or healthcare disinfectants	AOAC International Use-Dilution Methods1 (Ref. 1), modified to include 5% organic soil	
Sanitizing pre-soak treatments	Inanimate Non-Food Contact Surfaces (ASTM E1153) modified to include 5% organic soil, (Ref.2)	
Laundry Sanitizers and Disinfectants Sanitizing laundry additives Disinfecting laundry	Basic bacteriological procedure (Simulated-use study): • ASTM E 2274 (Ref. 3) or • Use in High Efficiency Washing Operations (ASTM E 2406) (Ref. 4)	
Laundry additives (Residual) Self-sanitizing additives	Test Method: • 100-2004 Quantitative Procedure: Assessment of Antibacterial Finishes on Textile Materials (Ref. 5) or • Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions (ASTM E2149-01) (Ref. 6)	
Impregnated self-sanitizing fabrics and textiles	Carpet sanitizers	There is no standard test method. contact the Agency (EPA).
	Mattress, pillows and upholstered furniture treatments	Simulated- Page 7 use studies, in which artificially contaminated articles.
Surface Sanitization of Fabrics and Textiles	Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03) (Ref. 2)