



# Hand Sanitisers & Disinfectants

## Quality & Compliance

Disinfectants and alcohol-based hand rubs, often referred to as hand sanitisers, are a means of rapidly and effectively deactivating a wide variety of potentially harmful microorganisms on hands, skin and surfaces.

### Product and regulatory scenario

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

For disinfection claims relating to microorganisms we refer to: vegetative bacteria, yeasts, mould spores, bacterial spores and viruses.

Disinfectants do not necessarily kill all organisms (sterilisation) but reduce them to a harmless level for human and/or animal health. Disinfectants are applied to inanimate objects and materials such as instruments, containers and surfaces. They may also be used to disinfect hands and skin or other living tissues.

**Hand sanitisers, gels and rubs** can be categorised as cosmetics or biocide products, depending on the product's primary function, claims, ingredients and intended use.

- **Cosmetics products** are designed to primarily clean and / or moisturise the skin. When categorised as cosmetics, the product would be referred to as a hand rub or hand gel, and would fall within the cosmetics regulations with efficacy testing required to support claims.
- **Disinfectants** or **Biocides** are basically conceived to kill germs, disinfect, sanitise hands (or other parts of the body) and prevent cross contamination as primary functions. The product and its active substances need to comply with the Biocidal Products Regulation.

### Regulatory overview

Field	Europe	US
Disinfectants (Surface)	Biocidal Products Regulation (BPR) Regulation (EU) 528/2012) PT2	EPA Antimicrobial pesticides OCSPP performance test guidelines 810.2000 series
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
Cosmetics	Cosmetic Products Regulation (EC) No 1223/2009	Federal Food, Drug, and Cosmetic Act (FD&C Act) and Fair Packaging and Labeling Act (FPLA)

## Test methods and requirements for hand hygiene products

### 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
- “Brookfield viscosity” test
- “H<sub>2</sub>O<sub>2</sub>” 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, in order to avoid risk of allergic reactions
- Labelling – In accordance with national and international regulations
- Flammability

### In Vitro testing

These tests can assess the impact of raw materials used as well as finished product, using cells and reconstructed tissues. Irritation, skin-sensitisation and/or endocrine disrupting effects can be evaluated using these non-animal testing models.

### Test methods

Dependent on a product’s classification and claims, some specific test methods should applied, the following tests are required for disinfectants:

- Germ kill efficacy test
- Hand rub and hand wash studies
- Minimum Inhibitory Concentration (MIC)
- Virucidal activity versus standard and specific human viruses including Betacoronavirus models

### Efficacy testing standards

Field	Europe	US
Bactericidal activity (Antimicrobial)	EN 1276, EN 14348, EN 13727, EN 1500, EN 1040, EN 1499	ASTM E2752, ASTM E2755, ASTM E1174, ASTM E1115, ASTM E2315
Fungicidal / yeasticidal activity	EN 1650, EN 13624	ASTM E2613
Virucidal activity	EN 14476	ASTM E1052

## Toxicology and Regulatory

Eurofins offers you personalized support for your products compliance procedures.

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.*

