



Hand Sanitisers & Cosmetics Quality & Compliance

Hand hygiene is an extremely important step in preventing the spread and transmission of viruses and bacteria causing illnesses. Cosmetics products and alcohol-based hand rubs, often referred to as hand sanitisers, are means of rapidly and effectively inactivating a wide array of potentially harmful microorganisms which can be found on hands and skin.

Product and regulatory scenario

Cosmetics and personal care products are applied to the human body for the purposes of cleaning, beautifying, promoting attractiveness or changing appearance.

To ensure product safety and compliance with regulation, a Product Ingredients File (PIF) is absolutely essential, and is a legal requirement. It is an overview of many mandatory processes such as the safety assessment, label and label ingredients review, and the cosmetic product safety report. It also contains key information on raw materials, suppliers, production methods, products, producers, brand owners, and the history of consumer use of the products. The PIF must be updated on a continuous basis.

Hand gels and sanitisers, may be considered either as a cosmetic or a biocide, dependent. On the product's primary function, claims, composition and purpose of use. A product cannot be both a cosmetic and a, biocidal product. This means that if a product has even just one biocidal claims it is a biocidal product.

- **Cosmetics products** are designed to primarily clean and / or moisturize the skin. They are categorized as a cosmetic, the product would be referred to as a hand rub or hand gel, and would fall within the cosmetics regulations with efficacy testing to support their claims.
- **Biocide products** have the sole purpose of killing germs, disinfecting or sanitising hands or preventing cross contamination as their primary functions. The active substances in the products, as well as, the biocidal products themselves, are subject to Biocidal Products Regulation.

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
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
- “Brookfield viscosity” test
- Ethanol – GC/FID Default variation; Digital photography – Default variation
- Glycerol, Isopropanol, Benzalkonium chloride, alcohol, “H2O2” dosage
- Labelling – In accordance with national and international regulations

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 be 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

Europe (Biocidal Products Regulation (BPR) Regulation (EU) 528/2012) PT1		Hygienic Handrub (hydroalcoholic hand sanitisers)	Hygienic handwash (not hydroalcoholic 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
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	

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.

