

12.

WHO-recommended handrub formulations

12.1 General remarks

To help countries and health-care facilities to achieve system change and adopt alcohol-based handrubs as the gold standard for hand hygiene in health care, WHO has identified formulations for their local preparation. Logistic, economic, safety, and cultural and religious factors have all been carefully considered by WHO before recommending such formulations for use worldwide (see also Part I, Section 14).

At present, alcohol-based handrubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.^{60,221,329,484-487}

WHO recommends alcohol-based handrubs based on the following factors:

1. evidence-based, intrinsic advantages of fast-acting and broad-spectrum microbicidal activity with a minimal risk of generating resistance to antimicrobial agents;
2. suitability for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene (including clean water, towels, etc.);
3. capacity to promote improved compliance with hand hygiene by making the process faster and more convenient;
4. economic benefit by reducing annual costs for hand hygiene, representing approximately 1% of extra-costs generated by HCAI (see also Part III, Section 3);⁴⁸⁸⁻⁴⁹⁰
5. minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products (see also Part I, Section 14).⁴⁹¹⁻⁴⁹⁸

For optimal compliance with hand hygiene, handrubs should be readily available, either through dispensers close to the point of care or in small bottles for on-person carriage.^{335,485}

Health-care settings currently using commercially-available handrubs should continue to use them, provided that they meet recognized standards for microbicidal efficacy (ASTM or EN standards) and are well accepted/tolerated by HCWs (see also Implementation Toolkit available at <http://www.who.int/gpsc/en/>). It is obvious that these products should be regarded as acceptable, even if their contents differ from those of the WHO-recommended formulations described below. WHO recommends the local production of the following formulations as an alternative when suitable commercial products are either unavailable or too costly.

12.1.1 Suggested composition of alcohol-based handrub formulations for local production

The choice of components for the WHO-recommended handrub formulations takes into account cost constraints and microbicidal activity. The following two formulations are recommended for local production with a maximum of 50 litres per lot to ensure safety in production and storage.

Formulation I

To produce final concentrations of ethanol 80% v/v, glycerol 1.45% v/v, hydrogen peroxide (H₂O₂) 0.125% v/v.

Pour into a 1000 ml graduated flask:

- a) ethanol 96% v/v, 833.3 ml
- b) H₂O₂ 3%, 41.7 ml
- c) glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Formulation II

To produce final concentrations of isopropyl alcohol 75% v/v, glycerol 1.45% v/v, hydrogen peroxide 0.125% v/v:

Pour into a 1000 ml graduated flask:

- a) isopropyl alcohol (with a purity of 99.8%), 751.5 ml
- b) H₂O₂ 3%, 41.7 ml
- c) glycerol 98%, 14.5 ml

Top up the flask to 1000 ml with distilled water or water that has been boiled and cooled; shake the flask gently to mix the content.

Only pharmacopoeial quality reagents should be used (e.g. *The International Pharmacopoeia*) and not technical grade products.

12.1.2 Method for local production

12.1.2.1 Volume of production, containers

- **10-litre** preparations: glass or plastic bottles with screw-threaded stoppers can be used.
- **50-litre** preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to 100 litre capacity should be used to allow for mixing without overflowing.

The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 litres. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

12.1.2.2 Preparation

- 1) The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.