

GUIDE TO LOCAL PRODUCTION

This is intended to guide a local producer in the actual preparation of the formulation.

Materials required (small volume production)**REAGENTS FOR FORMULATION 1:**

- Ethanol 96%
- Hydrogen peroxide 3%
- Glycerol 98%
- Sterile distilled or boiled cold water

REAGENTS FOR FORMULATION 2:

- Isopropyl alcohol 99.8%
- Hydrogen peroxide 3%
- Glycerol 98%
- Sterile distilled or boiled cold water

- 10-litre glass or plastic bottles with screw-threaded stoppers (1), or
- 50-litre plastic tanks (preferably in polypropylene or high density polyethylene, translucent so as to see the liquid level) (2), or
- Stainless steel tanks with a capacity of 80–100 litres (for mixing without overflowing) (3, 4)
- Wooden, plastic or metal paddles for mixing (5)
- Measuring cylinders and measuring jugs (6)
- Plastic or metal funnel
- 100 ml and 500 ml plastic bottles with leak-proof tops (7)
- An alcoholometer: the temperature scale is at the bottom and the ethanol concentration (percentage v/v and w/w) at the top (8)

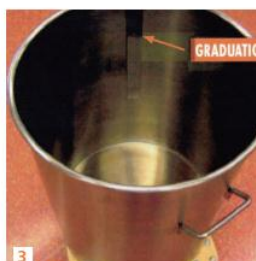
NOTE

- Glycerol: used as humectant, but other emollients may be used for skin care, provided that they are cheap, widely available and miscible in water and alcohol and do not add to toxicity, or promote allergy.
- Hydrogen peroxide: used to inactivate contaminating bacterial spores in the solution and is not an active substance for hand antiseptics.
- Any further additive to both formulations should be clearly labelled and be non-toxic in case of accidental ingestion.
- A colorant may be added to allow differentiation from other fluids, but should not add to toxicity, promote allergy, or interfere with antimicrobial properties. The addition of perfumes or dyes is not recommended due to risk of allergic reactions.

General information

Labelling should be in accordance with national guidelines and should include the following:

- Name of institution, date of production and batch number
- WHO-recommended handrub solution
- For external use only
- Avoid contact with eyes
- Keep out of the reach of children
- Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry
- Composition: ethanol or isopropanol, glycerol and hydrogen peroxide
- Flammable: keep away from flame and heat

**Production and storage facilities:**

- Production and storage facilities should ideally be air conditioned or cool rooms. **No naked flames or smoking should be permitted in these areas.**
- WHO-recommended handrub formulations should not be produced in quantities exceeding 50-litres locally or in central pharmacies lacking specialised air conditioning and ventilation.
- Since undiluted ethanol is highly flammable and may ignite at temperatures as low as 10°C, production facilities should directly dilute it to the above-mentioned concentration. The flashpoints of ethanol 80% (v/v) and of isopropyl alcohol 75% (v/v) are 17.5°C and 19°C, respectively.
- National safety guidelines and local legal requirements must be adhered to the storage of ingredients and the final product.

METHOD: 10-LITRE PREPARATIONS

These can be prepared in 10-litre glass or plastic bottles with screw-threaded stoppers.

Recommended amounts of products:

FORMULATION 1:

- Ethanol 96%: **8333 ml**
- Hydrogen peroxide 3%: **417 ml**
- Glycerol 98%: **145 ml**

FORMULATION 2:

- Isopropyl alcohol 99.8%: **7515 ml**
- Hydrogen peroxide 3%: **417 ml**
- Glycerol 98%: **145 ml**

Final products:

FORMULATION 1:

- Final concentrations:
- Ethanol 80% (v/v)
 - Glycerol 1.45% (v/v)
 - Hydrogen peroxide 0.125% (v/v)

FORMULATION 2:

- Final concentrations:
- Isopropyl alcohol 75% (v/v)
 - Glycerol 1.45% (v/v)
 - Hydrogen peroxide 0.125% (v/v)

Step by step preparation:



1. The alcohol for the formula to be used is poured into the large bottle or tank up to the graduated mark.



2. Hydrogen peroxide is added using the measuring cylinder.



3. Glycerol is added using a measuring cylinder. As glycerol is very viscous and sticks to the wall of the measuring cylinder, it should be rinsed with some sterile distilled or cold boiled water and then emptied into the bottle/tank.



4. The bottle/tank is then topped up to the 10-litre mark with sterile distilled or cold boiled water.
5. The lid or the screw cap is placed on the tank/bottle as soon as possible after preparation, in order to prevent evaporation.



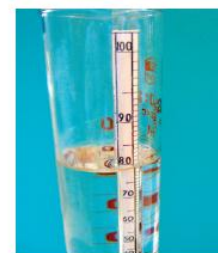
6. The solution is mixed by shaking gently where appropriate or by using a paddle.



7. Immediately divide up the solution into its final containers (e.g. 500 or 100 ml plastic bottles), and place the bottles in quarantine for 72 hours before use. This allows time for any spores present in the alcohol or the new/re-used bottles to be destroyed.

Quality control

1. Pre-production analysis should be made every time an analysis certificate is not available to guarantee the titration of alcohol (i.e. local production). Verify the alcohol concentration with the alcoholmeter and make the necessary adjustments in volume in the preparation formulation to obtain the final recommended concentration.



2. Post-production analysis is mandatory if either ethanol or an isopropanol solution is used. Use the alcoholmeter to control the alcohol concentration of the final use solution. The accepted limits should be fixed to $\pm 5\%$ of the target concentration (75%–85% for ethanol).



3. The alcoholmeter shown in this information pamphlet is for use with ethanol; if used to control an isopropanol solution, a 75% solution will show 77% ($\pm 1\%$) on the scale at 25°C.

Source: Guide to Local Production: WHO-recommended Handrub Formulations, http://www.who.int/gpsc/5may/tools/system_change/en/