

**PRODUCTION REPORT**

**ALCOHOL-BASED HANDRUB SOLUTION  
WHO-RECOMMENDED FORMULATION 1**

Batch number	Amounts	Date	Operator
	.....Bottles of.....mL		

**1. COMPOSITION**

	RAW MATERIALS			AMOUNTS (in mL)	VISA		DOUBLE CHECK	
	Description	Batch number	Analysis control N°		Identifica tion	measure	Identifica tion	measure
				10 litres				
1	Ethanol ..... % (Ethanol 96%)			.....mL (8333 mL)				
2	Hydrogen peroxide 3%			417 mL				
3	Glycerol 98%			145 mL				
4	Sterile distilled or boiled cold water			qsp ad for 10 litres				

**2. EQUIPMENT**

Packaging material	Amounts	Visa of clean material use
Bottles of 100 mL		
Leak-proof screw tops		
Labels (with required data)		

Other material: please see production sheet

**LABEL**  
(stick a label of the prepared batch)

**3. PREPARATION**

3.1 NOTE: Put on gloves, safety glasses and clean outfit (blouse, cap)

**Mode of operation:** Before, during and after production, it is essential to work in an ordered, methodical, tidy way.

1. Before starting production, check that the factory line is clean. That is to say, ensure that the working area is completely clear of any unnecessary raw ingredients and materials, and that it has been cleaned with alcohol.
2. Measure the quantity of alcohol (measuring cylinder or beaker)
3. Measure the quantity of hydrogen peroxide 3% (measuring cylinder)
4. Measure the quantity de glycerol (measuring cylinder)
5. If distilled water is not available, boil water for 15 to 20 minutes and let it cool to room temperature (between 15-25°C), and measure the required quantity (measuring cylinder). The volume depends on the initial percentage of alcohol (cf. document "Component amounts based on initial alcohol content")
6. Pour into the container :
  - a. The measured quantity of glycerol 98% and then rinse the cylinder that was used for the glycerol with some ethanol (using ethanol from the amount already measured), until all glycerol residues have been removed.
  - b. The measured quantity of hydrogen peroxide 3%.
  - c. Add boiled cold water or distilled water
  - d. Gradually incorporate, the measured amount of ethanol (in 3-4 additions), and mix well between each addition (homogenization).

7. Mix the solution:
  - a. Close the container with the screw cap as quickly as possible to prevent any evaporation and then gently mix by shaking the recipient for 5 minutes.
  - b. If no container is available with a screw cap, mix the solution with a spatula for 5 minutes then cover the container with a lid to prevent evaporation.
8. Check the final volume of the solution and if necessary complete to the desired volume with water (due to solution contraction of water / alcohol mixture) and mix again
9. Distribute the solution into bottles **immediately**.
10. Label the bottles:
  - a. Check that the labelling table is free of any material from previous productions
  - b. Stick a label on each bottle, so that each one is identifiable
11. Put the whole batch **in quarantine** (= every bottle) for **at least 72 hours**
12. Tidy up and clean the work place, as well as the equipment used
13. Give samples to the laboratory for analysis

**Packaging and labelling:** Amount by packaging of 100 mL

Number of prepared labels	
Number of used labels	
Number of destroyed labels	

**4. CLEANING PREPARATION EQUIPMENT:**

Date and Visa	
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**5. EXPIRY DATE:**  **(+ 2 YEARS)**

**6. STORAGE CONDITIONS:** ROOM TEMPERATURE (15-25°C)

**7. QUARANTINE:**

Date when put in quarantine		Visa operator :	
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**8. QUALITY CONTROL ANALYSIS**

Total number of units to be analysed	
Samples to be archived	

**9. NUMBER OF UNITS MANUFACTURED**

<b>Total manufactured</b>	
Eliminated due to defect	
Samples for analysis and archives	
Placed in storage	

<b>Entry in storage</b>	<b>Visa</b>	<b>Date</b>

**10. RELEASE OF THE PRODUCTION**

	<b>Date</b>		<b>Visa</b>
Production		Operator	
Quality control		Laboratory	
End of quarantine		Quality control manager	
Authorisation from responsible person		Person responsible for production	

**ATTACH THE ANALYICAL REPORT TO THE PRODUCTION REPORT**