MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Alcohol Antiseptic 80% Topical Solution (Solution, 100 mL)	FIN	F 008 676

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Alcohol (95%), USP	84.21	mL				
Glycerin, USP	1.45	mL				
Hydrogen Peroxide Concentrate (30% w/w), USP	0.42	mL				
Purified Water, USP	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Hydrogen Peroxide Concentrate*

Hygroscopic *(protect from moisture whenever possible):* *Glycerin*

Heat Sensitive *(protect from heat whenever possible):* *Hydrogen Peroxide Concentrate*

Flammable *(Keep away from heat and flame)* *Alcohol*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Alcohol (95%), USP §	84.21	mL			
Glycerin, USP §	1.45	mL			
Hydrogen Peroxide Concentrate (30% w/w), USP §	0.42	mL			
Purified Water, USP	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction	
1.	**Medium preparation:** A. In the given order, sequentially add the following ingredients to the Alcohol (95%): -Glycerin -Hydrogen Peroxide Concentrate (30% w/w) Specifications: Continuously mix. End result: Homogeneous liquid-like solution. Note: Add the next ingredient, once the previous one has been completely added and dissolved.
2.	**Filling to Volume:** A. Add Purified Water to the homogeneous liquid-like solution (Step 1A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		28 days, as per APF.	Packaging Requirements		- Tightly closed, light-resistant container. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5		Protect from light.
	2	Keep out of reach of children.	6		Cap tightly after use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7		For external use only.
	4	Keep at controlled room temperature (20°C – 25°C).	8		**If swallowed, get medical help or contact a Poison Control Center right away.**
Pharmacist Instructions					

IMPORTANT: Non-sterile preparation, do not use in the presence of an open wound.

As a therapeutic good, this formulation may be prepared under TGA Guidance or PBA Guidance.

Add any auxiliary labels specific to the API to the dispensing container as deemed compliant and necessary.

PER TGA GUIDANCE:

Please ensure appropriate ethanol is used.

During the COVID-19 Pandemic specified hand sanitiser formulations are excluded from TGA regulation a long as they only contain particular ingredients in particular quantities in the final formulation, and comply with certain manufacturing practices, and advertisement and labelling conditions. Manufacturers must also test the alcohol concentrations of each batch, manufacture under sanitary conditions and maintain production record-keeping.

Please see labeling requirements as stated in Schedules 1 and 2 of the TGA's Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020 for the duration of the COVID-19 Pandemic in which this exemption applies.

PER PHARMACY BOARD OF AUSTRALIA (PBA) GUIDANCE:

Intended for use in a pharmaceutical compounded preparation, as specified. Please ensure appropriate ethanol is used.

When prepared as a compounded medication for individual known patients under the compounding exemptions of the Therapeutic Goods Regulations 1990, the preparation must comply with *Guidelines on compounding of medicines* (PBA).

Labelling requirements as per Poisons Standard and State/Territory Legislation. Additional labelling requirements for the compounding of batches must comply with Therapeutic Goods Order No. 69

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	General requirements for labels for medicines . From 1st September 2020, each medicine to which this Order applies, must comply with the requirements specified in either: **(i) TGO 91, if that Order is applicable to the medicine; or** **(ii) TGO 92, if that Order is applicable to the medicine,** **instead of the requirements in Therapeutic Goods No. 69.**
Patient Instructions	Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.

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REFERENCES

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6.	Alcohol (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 114.
7.	Hydrogen Peroxide Concentrate (Monograph). *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2199.
8.	USP <795>. *United States Pharmacopeia XLII / National Formulary 37.* Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6951.

Appendix A. Labelling for Ethyl Alcohol Formulation as per TGA Guidance

PRINCIPAL DISPLAY LABEL (FRONT AND BACK OF PACKAGE):

The front and back labels may be combined into a single label.

Ethanol Hand Sanitiser 80% Topical Solution

1 Front Label

Ethanol hand sanitiser 80%

Hand rub (optional text: suitable for use in medical and health services)
(Insert volume of the product in mLs)
(Insert name of the manufacturer or supplier)
(Insert contact details of the manufacturer or supplier)

2 Back Label

Contains:

Ethanol 80% v/v, water, glycerol and hydrogen peroxide.

Use:

Antiseptic hand rub when soap and water are not available.

Directions for use:

Apply sufficient amount of product on hands to cover all surfaces. Rub hands together until dry.

Warnings:

For external use only. Flammable. Keep away from heat or flame.
Keep out of eyes,
ears and mouth.
Discontinue use if skin irritation or rash occurs.
Keep out of reach of children.
Store below 30 °C.
Date of manufacture: dd mm yyyy