MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Salicylic Acid 40% Topical Paste (Suspension, 100 g)	FIN	F 009 634

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Salicylic Acid, USP	40.000	g				
Mineral Oil (light), NF	14.0	mL				
Medisca Ointment Base (Emulsifying)	48.11	g				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Salicylic Acid , Mineral Oil*

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.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

All work must be carried out inside an appropriate fumehood.

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 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Salicylic Acid, USP §	40.000	g			
Mineral Oil (light), NF §	14.0	mL			
Medisca Ointment Base (Emulsifying)	48.11	g			

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Triturate the Salicylic Acid to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Mineral Oil (Light). End result: Homogeneous paste-like dispersion.
2.	**Medium Integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) into the Ointment Base (Emulsifying). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous ointment-like dispersion. B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
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		6 months, as per USP 795*.	Packaging Requirements		Tightly closed, light-resistant ointment tube or wide-mouth container.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6		Protect from light.
	2	Keep out of reach of children.	7		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	For external use only.	8		Cap tightly after use.
	4	Do not touch the medication with your hands.	9		Do not allow to come into contact with eyes/ears/nose/mouth.
	5	Keep at controlled room temperature (20°C – 25°C).	10		Do not allow applicator tip to come into contact with surrounding tissue.
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
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.			

*** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.**

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REFERENCES

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5. Salicylic Acid (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition.* Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #8469.
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7. Salicylic Acid (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 3970.
8. USP <795>. *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.