MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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| Suggested Formula | Benzocaine 10%, Lidocaine 10%, Tetracaine 4% Dental Paste (Suspension, 30 g) | FIN | F 009 577 |
|---|---|---|---|

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Benzocaine, USP | 3.000 | g | | | | |
| Lidocaine, USP | 3.000 | g | | | | |
| Tetracaine, USP | 1.200 | g | | | | |
| Stevia Powder | 0.10 | g | | | | |
| Butylated Hydroxytoluene (BHT), NF | 0.03 | g | | | | |
| Bubble Gum Flavor | 0.3 | mL | | | | |
| Polyethylene Glycol 400, NF | 12.0 | mL | | | | |
| Polyethylene Glycol 3350, NF | 8.98 | g | | | | |

## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

| | |
|---|---|
| ***Light Sensitive*** *(protect from light whenever possible):* | *Benzocaine, Tetracaine, Butylated Hydroxytoluene* |
| ***Narrow Therapeutic Index*** | *Lidocaine* |
| ***Eutectic Mixture when combined:*** | *Lidocaine, Tetracaine* |
| ***Hygroscopic*** *(protect from moisture whenever possible):* | *Stevia Powder, Polyethylene Glycol 400* |
| ***Moisture Sensitive*** *(protect from humidity whenever possible):* | *Butylated Hydroxytoluene* |
| ***Heat Sensitive*** *(protect from heat whenever possible):* | *Butylated Hydroxytoluene* |

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## SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

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 **12 to 15%** 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).

**Lidocaine has a Narrow Therapeutic Index.**

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 30 g)

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing | Qty. | Unit | Multiplication factor (*): ____ | Processing Error | Qty. to measure |
|---|---|---|---|---|---|
| Benzocaine, USP § | 3.000 | g | | | |
| Lidocaine, USP | 3.000 | g | | | |
| Tetracaine, USP § | 1.200 | g | | | |
| Stevia Powder § | 0.10 | g | | | |
| Butylated Hydroxytoluene (BHT), NF § | 0.03 | g | | | |
| Bubble Gum Flavor | 0.3 | mL | | | |
| Polyethylene Glycol 400, NF § | 12.0 | mL | | | |
| Polyethylene Glycol 3350, NF | 8.98 | g | | | |

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

| Preparatory Instruction | |
|---|---|
| 1. | **Preparatory step:**<br><br>A. Prepare a hot water bath.<br><br>Specifications: Temperature: 60 to 65°C. |
| 2. | **Powder-liquid preparation:**<br><br>A. Combine and triturate the following ingredients together to form a fine homogeneous powder blend:<br><br>-Benzocaine<br>-Lidocaine<br>-Tetracaine<br>-Stevia Powder<br>-Butylated Hydroxytoluene (BHT)<br><br>B. Levigate the fine, homogeneous powder blend (Step 2A) with the Polyethylene Glycol 400.<br><br>End result: Homogeneous paste-like dispersion. |

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3. **Medium preparation:**

A. Using the hot water bath, melt the Polyethylene Glycol 3350.

Specifications: Continuously mix.
Maintain temperature between 60 to 65°C

End result: Homogeneous liquid-like solution.

IMPORTANT: Do not allow the temperature to exceed 65°C.

4. **Phase Integration:**

A. Using the hot water bath, in the given order, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 3A):

-Homogeneous paste-like dispersion (Step 2B)
-Bubble Gum Flavor

Specifications: Continuously mix.
Maintain temperature between 60 to 65°C

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.

IMPORTANT: Do not allow the temperature to exceed 65°C.

5. **Cooling:**

A. Remove the mixture (Step 4A) from the hot water bath and gently stir as it cools down to room temperature (20°C – 25°).

End result: Homogeneous paste-like dispersion.

6. **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 unit-dose syringe. |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | 7 | | Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use. |
| | 2 | Keep out of reach of children. | 8 | | Protect from light. |
| | 3 | Keep in a dry place. | 9 | | Cap tightly after use. |
| | 4 | Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants. | 10 | | May impair mental and/or physical ability. Use care when operating a car or machinery. |
| | 5 | **For dental office use only.** | 11 | | Do not swallow. |
| | 6 | Keep at controlled room temperature (20°C – 25°C). | | | |
| Pharmacist Instructions | Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.<br><br>**IMPORTANT: TO BE ADMINISTERED ONLY BY THE PRESCRIBING PHYSICIAN.**<br><br>**IMPORTANT: Non-sterile preparation, do not use in the presence of an open wound.**<br><br>**IMPORTANT:** - Small batch is prepared due to inherent potential of systemic toxicity.<br>- Limits as to the total amount of product used should be established by a physician.<br>- You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas.<br>- Continued application of this product might produce systemic side effects. Advise patient accordingly.<br><br>**IMPORTANT: DRUG-DRUG INTERACTIONS EXIST BETWEEN DIFFERENT DRUG COMBINATIONS WITHIN THIS FORMULATION. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.** | | | | |
| Patient Instructions | Contact your pharmacist in the event of adverse reactions.<br><br>**IMPORTANT:** - Do not cover the site of application.<br>- 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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| 16. | Tetracaine (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 4292. |
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