



REME•SENSE™

Dipotassium Oxalate 3%

TOOTH DESENSITIZER

Rx Only

PRESCRIBING INFORMATION

Description: Reme•sense™ consists of a tray and foam strips impregnated with a desensitizing gel. These strips are designed to relieve dental hypersensitivity by patient application to the affected tooth (teeth). The impregnated foam strips are held in place with a tray.

Composition: Reme•sense™ contains glycerin, water, dipotassium oxalate, aroma, EDTA, methylparaben, citric acid and saccharin.

Indications and Usage: Reme•sense™ is indicated for the local management of dental sensitivity by patient application of foam strips impregnated with a desensitizing gel.

DOSAGE: Use two strips per treatment.

A treatment consists of one 10 minute application in the mouth and relieves dental hypersensitivity immediately with results lasting up to four weeks.

DIRECTIONS FOR USE:

- Gently brush your teeth without toothpaste before applying Reme•sense™
- Tear open two foam strips placing one on the ledge inside the tray for the top teeth and one on the ledge for the bottom teeth.
- Place the tray in your mouth for 10 minutes. Make sure the tray fits closely around your teeth and pull your lips over the tray. The notch in the tray should face up.
- Do not bite or press too hard on the tray.
- It is recommended that you not remove the tray during treatment. If you must spit out, remove the tray, spit out and then reinsert the tray for the remaining time.
- After ten minutes, remove the tray from the mouth and immediately remove and throw the foam strips away. Clean the tray with soap and water. Save the tray.
- Do not eat, rinse or brush the teeth for 30 minutes.
- If you have any questions consult your Dentist.

CONTRAINDICATIONS:

Do not use this product if you are allergic to any of the ingredients.

WARNINGS:

- For Dental use only.
- Avoid swallowing the liquid.
- Avoid any contact with the eyes. In the event of contact with the eyes, rinse thoroughly with water. Seek medical attention if irritation or discomfort persists.
- Keep out of the reach of children. Not recommended for children under age 12.
- Not recommended for use if you are pregnant or breast feeding.
- Do not bite into the tray.
- Every foam strip is for one use only and the tray is to be used by one person only.
- If the packaging for the individual foam strips are damaged, the strips should not be used.

- Do not use the product after expiry date on the packaging.
- The product contains potassium. Excessive consumption of potassium can cause hypertension.
- It is not recommended to perform more than 16 treatments per year.
- Consult with your Dentist.

PRECAUTIONS:

- If hypersensitivity persists after three treatments, or you experience continuous pain, it is advisable to consult your Dentist.
- It is advisable not to lay down while carrying treatment.

STORAGE: Store the product in a cool, dry place away from heat. Avoid direct sunlight

LOT NUMBER AND EXPIRATION DATE:

Note lot number on any inquiry to identify product. Do not use the product after expiry date on the packaging.



DO NOT REUSE



EXPIRATION DATE



LOT NUMBER



CONSULT INSTRUCTIONS FOR USE



STORE AWAY FROM DIRECT SUNLIGHT

MATERIAL SAFETY DATA SHEET

The data are based on the information of the hazardous ingredient present in the product

1. PRODUCT AND COMPANY IDENTIFICATION

Name of product: Reme•sense™ Tooth Desensitizer
 General Use: Dental hypersensitivity
 Distributor: Nuline Pharmaceuticals, LLC
 Rye Brook NY 10573

Emergency Telephone (24 HR)

For emergency involving spill, leak, fire, exposure
Call CHEMTREC
(800) 424-9300

Medical Emergency involving this product

Call (877)- NULINE1
(685-4631)

2. HEALTH HAZARD DATA

Handling this product in its final form presents minimal risk from occupational exposure.

Health effects information is based on hazards of components.

This mixture has not been tested as a whole.

POTENTIAL HEALTH EFFECTS DURING ACUTE OVEREXPOSURE

- EYES:** Mildly irritating to the eyes.
- Skin:** May cause skin irritation.
- INGESTION:** Substance maybe harmful if swallowed.

3. HAZARDS IDENTIFICATION

Name of Product	CAS Number	Concentration
Potassium oxalate monohydrate	6487-48-5	3%

(yellowing). This does not affect the foam quality. Protect from visible and UV light to prevent this process.

4.FIRST AID MEASURES

Eye Contact with large amounts of the specific ingredient:

Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Seek medical attention immediately.

Skin Contact with large amounts of the specific ingredient:

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cover the irritated skin with an emollient. Wash clothing before reuse. Seek medical attention immediately.

Serious Skin Contact with large amounts of the specific ingredient:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

Inhalation of large amounts of the specific ingredient:

Physical form suggests that risk of inhalation exposure is negligible

Ingestion of large amounts of the specific ingredient:

Do NOT induce vomiting unless directed to do so by medical personnel.

Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

5.FIREFIGHTING MEASURES

Flammability of large amounts of the specific ingredient:

May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: Carbon oxides (CO, CO₂). Some metallic oxides

Fire Hazards large amounts of the specific ingredient in Presence of Various Substances:

Slightly flammable to flammable in presence of heat.

Non-flammable in presence of shocks.

Explosion Hazards large amounts of the specific ingredient in

Presence of Various Substances:

Slightly explosive in presence of open flames and sparks.

Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:

- SMALL FIRE: Use DRY chemical powder.
- LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

6.ACCIDENTAL RELEASE MEASURES

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7.HANDLING AND STORAGE

Avoid exposure to direct sunlight or temperatures above room temperature and prevent contamination. Store away from heat sources (match, cigarette, open fire, electrical heater,). UV Rays may cause surface discoloration

8.PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: impregnated foam strips.
- Smell: mint.
- Color: white.
- pH: between 4- 5,6
- Solubility in water: soluble.

9.STABILITY AND REACTIVITY

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, dust generation, incompatible materials. Incompatibility with various substances: Reactive with oxidizing agents, acids, alkalis.

10.TOXICOLOGY INFORMATION

Routes of exposure: Eyes, skin, absorption through skin, swallowing.

Short term effects of exposure: Irritation of eyes and skin and possible damage.

Avoid contact with eyes and skin and do not swallow.

Long term effects of exposure: Irritation of eyes and skin and possible damage.

Avoid contact with eyes and skin and do not swallow.

11.ECOLOGICAL INFORMATION

- Biodegradability: dependent on the type, the product is not degradable or degrades slowly. Decomposition products are not harmful to the environment.
- Additional ecological data: in case of a fire with polyurethane foams, the particles that fall in the water are harmless. They are sieved out of the water and/or disintegrated in the water treatment plant. Living organisms in the water are not endangered.

12.DISPOSAL CONSIDERATIONS

Local regulations are applicable. Rinse recipients used for removal with water before use.

13.TRANSPORT INFORMATION

Not regulated.

14 LEGALLY REQUIRED INFORMATION

Store in a cool, dry place away from heat. Avoid direct sunlight.

Federal and State Regulations: No products were found
Other Regulations: OSHA: Hazardous by definition of Hazardous Communication Standard (29 CFR 1910.1200)

SARA 313 Title III:

Section 302 Extremely Hazardous Substances: None

Section 311/312 Hazardous Categories: None

Section 313 Toxic Chemicals: None

15.OTHER INFORMATION

For Dental use only.

Use as directed in prescribing information.

DISCLAIMER: The information on this sheet is limited to the material identified and is believed by Nuline Pharmaceuticals, LLC to be correct based on its knowledge and information as of the date noted. Nuline Pharmaceuticals makes no representation, guarantee or warranty, expressed or implied, as to the accuracy, reliability or completeness of the information and assumes no responsibility for injury, damage or loss resulting from the use of this material.

HRI 89100 033 11 3 Month Supply

