

**SORBET RINSE- sodium fluoride concentrate**  
**Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak**  
**Products Inc**

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**Active Ingredient (before dilution):**

Fluoride Ion 1.5%

Available from 3.3% Sodium fluoride.

**Purpose:**

Anticaries Treatment

**Indications and Usage:**

- To be used under the direction of or as prescribed by a dental professional.
- This is a prescription fluoride rinse used to help prevent dental decay.

**Warnings:**

- Do not use before diluting with water.
- Keep out of reach of children. Children under 6 years of age: Consult a dentist or doctor prior to use.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a rinse, seek medical help or contact a Poison Control Center right away.

**Dilution Instructions:**

Use only after properly diluting according to one of the following formulas. Mix with distilled water only.

A. For 0.2% fluoride ion, neutral pH mouth rinse (weekly treatment):

Pour entire contents of concentrate bottle (4oz or 113.5mL) into clean mixing quart bottle. Add 28oz (286mL) of distilled water and blend.

B. For 0.5% fluoride ion, neutral pH mouth rinse (for use as prescribed):

Pour entire contents of concentrate bottle (4oz or 113.5mL) into clean mixing bottle. Add 8oz (227mL) of distilled water and blend.

**Dosage and Administration:**

1. At bedtime, brush and floss teeth thoroughly.
2. Pour out one tablespoon (1/3oz or 10mL) of the diluted solution.
3. Place in mouth and rinse for 60 seconds and expectorate (spit out).

4. Do not eat or drink for 30 minutes.

**Other Information:**

Store at controlled room temperature 59-86°F (15-30°C). Protect from freezing.

**Inactive Ingredients:**

DMDM Hydantoin, FD&C Blue #1, Flavoring, Polysorbate 20, Saccharin and Water.

<b>DESCRIPTION</b>	
<i>Active Ingredient (before dilution)</i>	<i>Purpose</i>
Fluoride Ion 1.5% .....	Anticaries treatment
Available from 3.3% sodium fluoride.	
<b>Indications and Usage:</b>	
<ul style="list-style-type: none"> <li>• To be used under the direction of or as prescribed by a dental professional.</li> <li>• This is a prescription fluoride rinse used to help prevent dental decay.</li> </ul>	
<b>Warnings:</b>	
<ul style="list-style-type: none"> <li>• Do not use before diluting with water.</li> <li>• Keep out of reach of children. Children under 6 years of age: Consult a dentist or doctor prior to use.</li> <li>• Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a rinse, seek medical help or contact a Poison Control Center right away.</li> </ul>	
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<b>Dosage and Administration:</b>	
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<b>Other Information:</b> Store at controlled room temperature 59-86°F (15-30°C). Protect from freezing.	
<b>Inactive Ingredients:</b> DMDM Hydantoin, FD&C Blue #1, Flavoring, Polysorbate 20, Saccharin and Water.	
Manufactured by:	Keystone Industries 480 S Democrat Road Gibbstown, NJ 08027 USA 1-800-333-3131 www.keystoneind.com NATLAB-0595 REV 03/2017

**Sorbet**

NDC#68400-328-40

**FLUORIDE ION 1.5%**

**SODIUM FLUORIDE RINSE CONCENTRATE**

**IMPORTANT: READ DIRECTIONS ON BACK FOR PROPER DILUTION AND USE**

**Rx Only**

**PEPPERMINT**

REF 9054520

Net Weight: 4 oz. (113.5 ml)

<b>SORBET RINSE</b>			
sodium fluoride concentrate			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68400-328
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1702.5 mg in 113.5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-328-40	113.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/10/2013	

**Labeler** - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc (014769301)

**Establishment**

Name	Address	ID/FEI	Business Operations
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc		014769301	manufacture(68400-328) , label(68400-328)