

**MOJITO MINT DENTISTRY- sodium fluoride paste**  
**Jiangsu Shushi Biotechnology Co., Ltd.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**73297-002 mojito MINT dentistry**

**Active ingredients**

Sodium Fluoride 0.24%

**Purpose**

anticavity

**Uses**

aids in the prevention of dental cavities.

**Warnings**

Keep out of the reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

**Directions**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Children under 2 years: Consult a dentist or doctor.

**INACTIVE INGREDIENT**

HYDRATED SILICA, HYDROXYETHYL  
CELLULOSE, WATER, CARBOXYMETHYLCELLULOSE, SACCHARIN SODIUM, SODIUM  
PHOSPHATE, TRIBASIC, ANHYDROUS. SODIUM BENZOATE, SODIUM LAURYL  
SULFATE, SORBITOL, GLYCERIN

|   |                              |  |  |
|---|------------------------------|--|--|
| <b>Drug Facts</b>   |                              | <b>Drug Facts</b> (continued)  |  |
| <b>Active Ingredient</b><br>Sodium Fluoride (0.24%).....  | <b>Purpose</b><br>Anticavity | <b>Directions</b><br>Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing.) Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor. |  |
| <b>Uses</b><br>Aids in the prevention of dental cavities.   |                              | <b>Inactive Ingredients</b><br>Sorbitol, Aqua, Hydrated Silica, Glycerin, Sodium Lauryl Sulphate, Mojito Flavor, Carboxy Methyl Cellulose, Hydroxy Ethyl Cellulose, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate.  |  |
| <b>Warning</b><br>Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. |                              |  |  |

## MOJITO MINT DENTISTRY

sodium fluoride paste

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:73297-002 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 0.24 g in 100 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| SORBITOL (UNII: 506T60A25R)                                |          |
| HYDRATED SILICA (UNII: Y6O7T4G8P9)                         |          |
| HYDROXYETHYL CELLULOSE (40 MPA.S AT 2%) (UNII: I2N4ZF9233) |          |
| WATER (UNII: 059QF0K00R)                                   |          |
| CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)                  |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                |          |
| SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)   |          |

|  |  |
|--|--|
| SODIUM BENZOATE (UNII: OJ245FE5EU)       |  |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)      |  |

| Packaging |                  |  |                      |                    |
|-----------|------------------|--|----------------------|--------------------|
| #         | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
| 1         | NDC:73297-002-01 | 72 in 1 CARTON                                       | 08/28/2019           |                    |
| 1         |                  | 1 in 1 BOX   |                      |                    |
| 1         |                  | 170.1 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part356                                  | 09/04/2016           |                    |

**Labeler** - Jiangsu Shushi Biotechnology Co., Ltd. (554500950)

**Registrant** - Jiangsu Shushi Biotechnology Co., Ltd. (554500950)

| Establishment                          |         |           |                        |
|--|---------|-----------|------------------------|
| Name                                   | Address | ID/FEI    | Business Operations    |
| Jiangsu Shushi Biotechnology Co., Ltd. |         | 554500950 | manufacture(73297-002) |

Revised: 8/2019

Jiangsu Shushi Biotechnology Co., Ltd.