

**MOJITO MINT DENTISTRY- sodium fluoride paste**  
**Yangzhou Hongshengding Chemical 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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**71035-901 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**

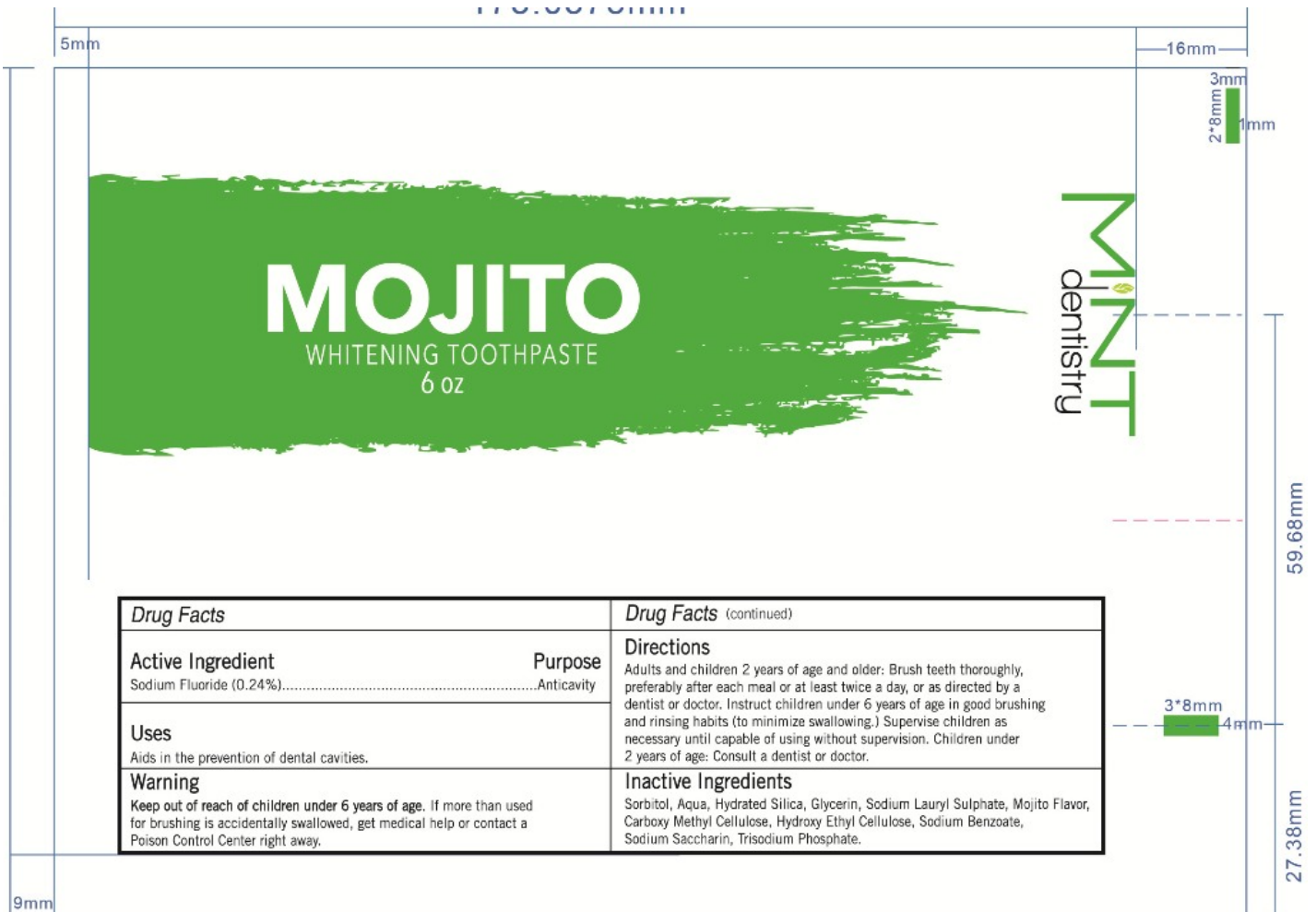
Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

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



## MOJITO MINT DENTISTRY

sodium fluoride paste

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71035-901 |
| <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)   |          |

|   |  |
|---|--|
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)       |  |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J) |  |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)      |  |

**Packaging**

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71035-901-01 | 72 in 1 CARTON                                       | 09/04/2016           |                    |
| 1 |                  | 1 in 1 BOX   |                      |                    |
| 1 |                  | 170.1 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:71035-901-02 | 288 in 1 CARTON                                      | 09/04/2016           |                    |
| 2 |                  | 1 in 1 BOX   |                      |                    |
| 2 |                  | 28.35 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** - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)

**Registrant** - Yangzhou Hongshengding Chemical Co.,Ltd. (543774755)

**Establishment**

| Name                                     | Address | ID/FEI    | Business Operations    |
|--|---------|-----------|------------------------|
| Yangzhou Hongshengding Chemical Co.,Ltd. |         | 543774755 | manufacture(71035-901) |

Revised: 9/2018

Yangzhou Hongshengding Chemical Co.,Ltd.