

**CHARCOAL 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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**73297-001 charcoal 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**

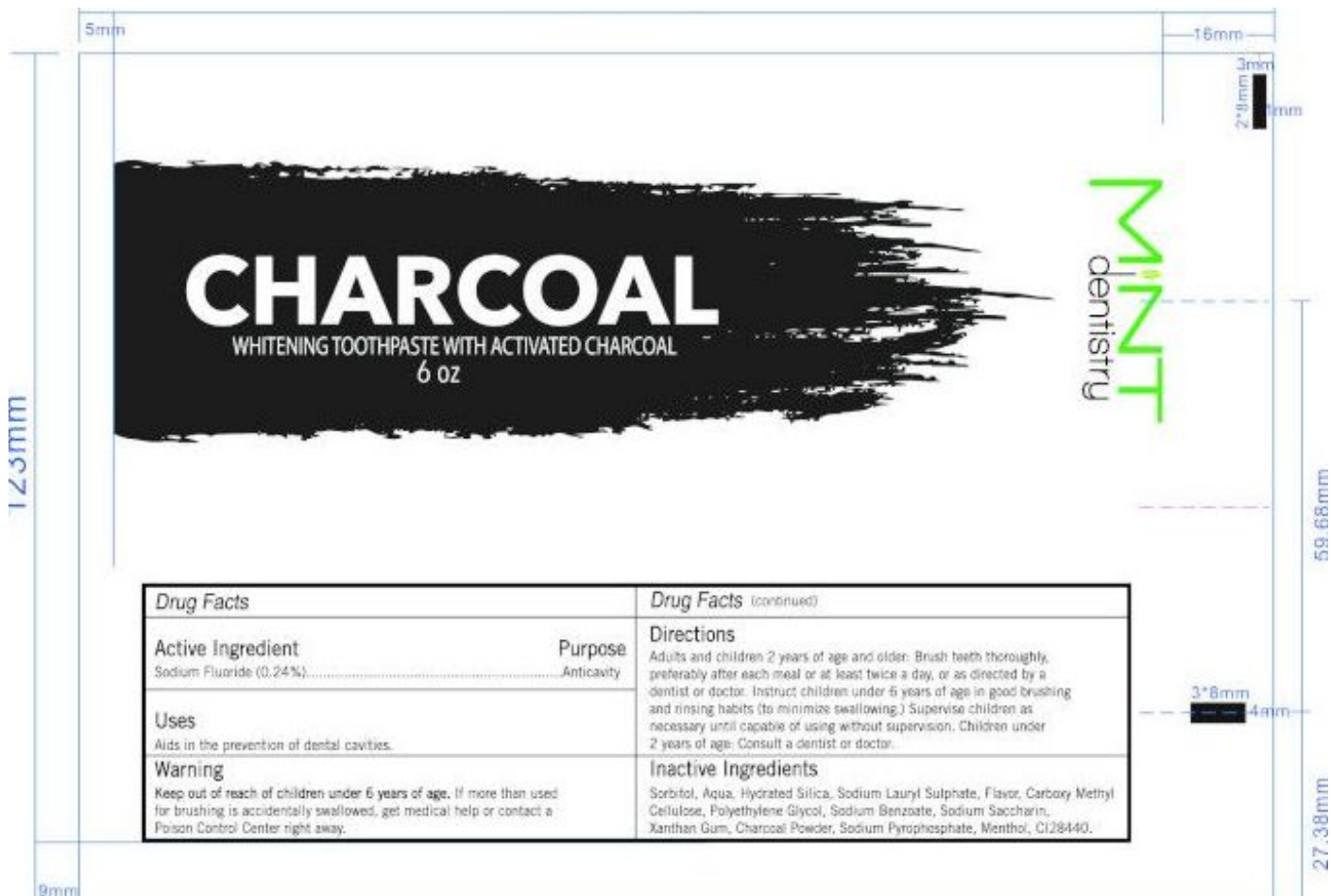
Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

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



## CHARCOAL MINT DENTISTRY

sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73297-001
<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)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
WATER (UNII: 059QF0K00R)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	

### Product Characteristics

<b>Color</b>	black	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73297-001-01	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	08/28/2019	

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

**Registrant** - Jiangsu Shushi Biotechnology Co., Ltd. (543774755)

### Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Shushi Biotechnology Co., Ltd.		554500950	manufacture(73297-001)

Revised: 8/2019

Jiangsu Shushi Biotechnology Co., Ltd.