

**TOOTHPOWDER- sodium fluoride powder**  
**Yangzhou Hengyuan Daily Chemical Plastic 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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**Charm-TEX toothpowder**

**Active ingredients**

Sodium Fluoride 0.24%(0.1 w/v Fluoride ion)

**Purpose**

anticavity

**Uses**

helps protect against 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 immediately.

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 a physician.

Children 2-6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years: Ask a dentist or a physician.

**INACTIVE INGREDIENT**

calcium carbonate, silica, mint flavour, sodium lauryl sulfate, sodium benzoate

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Toothpowder, 2 oz. (by volume)

Active Ingredient:

.024% Sodium fluoride

MADE IN CHINA

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DRUG FACTS	DIRECTIONS
Active ingredient: <span style="float: right;">Purpose</span> Sodium Fluoride 0.24% (0.1% w/v fluoride ion) ----- Antioavity	Adults and children 6 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 a physician.
Use: helps protect against cavities.	
Warning: 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 centre immediately.	Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing.
Inactive Ingredient : Calcium carbonate ,Silica,Mint flavour, Sodium lauryl sulfate, Sodium Benzoate.	
Product of China,Exclusive Distributor: Charm-Tex, Inc. USA, WWW.CHARM-TEX.COM	Children under 2 years: Ask a dentist or physician.

N.C.No: DD/COS/DD/C/340

Mfg. Date & Bath No.: 20190901

Expiry: 2 years from the date of Mfg.

## TOOTHPOWDER

sodium fluoride powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51289-500
Route of Administration	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
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM SILICATE (UNII: IJF18F77L3)	
MINT (UNII: FV98Z8G1TP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51289-500-03	250 in 1 CARTON	09/09/2016	
1		85 g in 1 BAG; Type 0: Not a Combination Product		
2	NDC:51289-500-02	250 in 1 CARTON	09/09/2016	
2		57 g in 1 BAG; Type 0: Not a Combination Product		
3	NDC:51289-500-01	250 in 1 CARTON	09/09/2016	
3		28 g in 1 BAG; 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 Hengyuan Daily Chemical Plastic Co.,Ltd (527127383)

**Registrant** - Yangzhou Hengyuan Daily Chemical Plastic Co.,Ltd (527127383)

## Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Hengyuan Daily Chemical Plastic Co., Ltd.		527127383	manufacture(51289-500)

Revised: 9/2016

Yangzhou Hengyuan Daily Chemical Plastic Co.,Ltd