

**AMERFRESH TOOTH- sodium monofluorophosphate powder**  
**Yangzhou SION Commodity 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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**Amerfresh Fluoride Toothpaste**

**Active ingredients**

SODIUM MONOFLUOROPHOSPHATE 0.76%(0.1 w/v Fluoride ion)

**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 accidently swallowed,get medical help or contact a Poison Control Center immediately.

Keep out of reach of children.

**Directions**

For Use:

- Wet toothbrush and dip into powder until brush is fully covered
- do not swallow .
- supervise children as necessary until capable of using without supervision
- instruct children under 12 years of age in good brushing and rinsing habits(to minimize swallowing).
- 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.
- Children under 6 years of age:do not use unless directed by a doctor or dentist.

**INACTIVE INGREDIENT**

calcium carbonate, silica,sodium lauryl sulfate, flavor, sodium sacharine, methylisothiazolinone



## AMERFRESH TOOTH

sodium monofluorophosphate powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70766-005
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70766-005-01	40 in 1 CARTON	04/20/2018	
1		454 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:70766-005-02	4 in 1 CARTON	04/20/2018	
2		50 in 1 BOX		
2		57 g in 1 POUCH; 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	04/20/2018	

**Labeler** - Yangzhou SION Commodity Co.,Ltd (546806042)

**Registrant** - Yangzhou SION Commodity Co.,Ltd (546806042)

## Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou SION Commodity Co., Ltd		546806042	manufacture(70766-005)

Revised: 12/2020

Yangzhou SION Commodity Co.,Ltd