# 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.

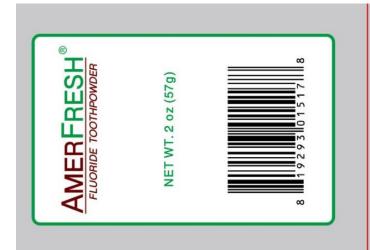
#### **Directions**

#### For Use:

- Wet toothbrush and dip into powder until brush is fully covered
- do not swallow.
- supervise children as necessary until capable of useing 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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70766-005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII: Q80 VPU408O)	FLUORIDE ION	0.1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
CALCIUM CARBO NATE (UNII: H0 G9 379 FGK)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	

]	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
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	2	50 in 1 BOX			
2	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