

**DENTAL CLINIC 2080 CAVITY PROTECTION- sodium monofluorophosphate paste**  
**Aekyung Industrial 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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 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 under 6 years of age

Sodium monofluorophosphate 0.75% (0.13% w/v Fluoride ion)

Sodium carboxymethylcellulose, Sodium lauryl sulfate, Sodium saccharin, Sorbitol, Titanium dioxide, Tocopheryl acetate, water

Purpose Anticavity

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 of age

Consult a dentist or doctor

Aids in the prevention of dental cavities



sodium monofluorophosphate paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67225-0001
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.208 g in 160 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
SORBITOL (UNII: 506T60A25R)	92.8 g in 160 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	3.52 g in 160 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.64 g in 160 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.4 g in 160 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.208 g in 160 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.4 g in 160 g

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67225-0001-2	1 in 1 PACKAGE	04/01/2015	
1		160 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	04/01/2015	

**Labeler** - Aekyung Industrial Co., Ltd. (687995647)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aekyung Ind. Co., Ltd._Chungyang Factory		690511126	manufacture(67225-0001)

Revised: 7/2016

Aekyung Industrial Co., Ltd.