

**2080 K GINGER MINT- sodium fluoride 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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Active Ingredient: Sodium Fluoride 0.22% (0.1% w/v fluoride)

Purpose: anticavity

Do not use this product for purposes other than those described on the label. In case of eye contact, rinse off immediately with water. If irritation persists, seek medical help.

Keep out of the reach of children under 6 years of age

Stop using this product and consult your dentist if irritation to gums, teeth, or oral mucosa occurs

Do not swallow. Rinse mouth with water after brushing.

Children under 6 years:

- To minimize swallowing, use a pea-sized amount. Supervise brushing until good habits are established.

- If swallowed more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.

This toothpaste contains 1,000 ppm fluoride

Inactive Ingredients: Liquid Sorbitol, Water, Silicon Dioxide, Polyethylene Glycol 1500, Sodium Lauryl Sulfate Flavor, Sodium Chloride, Sodium Carboxymethylcellulose, Saccharin Sodium Hydrate, Phosphoric Acid, Panthenol, Ginkgo Biloba Leaf Extract, Erythritol, Yellow#203, Ginger Essential Oil

CONFIRM SHEET		Printing Guide Line	
<p>본시 디자인은 디자인사 또는 인쇄업자와의 협업을 통해 제작되며, 디자인사로부터 제공된 디자인은 본시 디자인과 다를 수 있습니다. 디자인사로부터 제공된 디자인은 본시 디자인과 다를 수 있습니다. 디자인사로부터 제공된 디자인은 본시 디자인과 다를 수 있습니다.</p>			
<p>제품명 2080 K GINGER MINT 10g (100g)</p>	<p>사이즈(mm) 55 X 37 X 190 (mm)</p>	<p>인쇄일 Cyan Magenta Yellow Black</p>	<p>인쇄일 PT 10/25 C 온도 최대 인쇄 기온</p>
<p>날짜 2017.01.10</p>	<p>인쇄방법 온풍기 인쇄</p>	<p>주요사항 : 본시 디자인이 확인 후 승인 한 것에 대해서는 책임을 지지 않으며, 해외 시장이나 의사 결정이 어려운 사항은 확인 후에 기입하여 주시기 바랍니다.</p>	
<p>표준재판 및 표지판 등록 2080 K GINGER MINT 디자인 등록 번호</p>		<p>등록번호 등록일자</p>	



## 2080 K GINGER MINT

sodium fluoride paste

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0008
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.12 g in 120 g

### Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	72 g in 120 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	3.12 g in 120 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.6 g in 120 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	0.156 g in 120 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.12 g in 120 g
PHOSPHORIC ACID (UNII: E4GA8884NN)	22.8 g in 120 g
WATER (UNII: 059QF0K00R)	12.07 g in 120 g

<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	0.6 g in 120 g
<b>POLYETHYLENE GLYCOL 1500</b> (UNII: 1212Z7S33A)	0.006 g in 120 g
<b>GINGER OIL</b> (UNII: SAS9Z1SVUK)	0.00156 g in 120 g
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>GINKGO</b> (UNII: 19FUJ2C58T)	
<b>ERYTHRITOL</b> (UNII: RA96B954X6)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67225-0008-1	1 in 1 PACKAGE	07/07/2016	
1		120 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 final	part355	07/07/2016	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Aekyung Ind. Co., Ltd._Chungyang Factory		690511126	manufacture(67225-0008)

Revised: 1/2017

Aekyung Industrial Co., Ltd.