

2080 K ORIGINAL- 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.

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, Blue#1

CONFIRM SHEET		Printing Guide Line		
*본 도면은 인쇄용 사양으로, 인쇄 시에는 색상의 차이를 피하기 위하여 인쇄할 경우, 표기사항 부합을 1:1 또는 확대하여 남-남에 인쇄하여 제작하여야 합니다.				
제품명 2080 K ORIGINAL 2080 K ORIGINAL 55 X 37 X 180 (mm)	인쇄일시 Cyan Magenta Yellow Black	인쇄방식 PT 185 C	인쇄방법 4색 4단	최대인쇄크기
날짜 2017.01.10	인쇄방법 4색 4단			
표준규격 및 제품명 Illustrakr CSS 2080 K ORIGINAL 2080 K ORIGINAL 55 X 37 X 180 (mm)				

*주의사항 : 반드시 인쇄자가 확인 후 승인 한 후에 인쇄하면 제작비를 미정하며, 해외 사정이나 의사 결정이 어려운 사항은 확인 후에 기입하여 주시기 바랍니다. AEKYUNG DESIGN CENTER

투명



2080 K ORIGINAL

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0007
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

PANTHENOL (UNII: WV9CM0O67Z)	0.6 g in 120 g
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	0.006 g in 120 g
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	0.00156 g in 120 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GINKGO (UNII: 19FUJ2C58T)	
ERYTHRITOL (UNII: RA96B954X6)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67225-0007-1	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(67225-0007)

Establishment

Name	Address	ID/FEI	Business Operations
AK AMERICA		690064554	pack(67225-0007)

Revised: 4/2017

Aekyung Industrial Co., Ltd.