

2080 K HERBAL 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.

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 Sorbitor, 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		
상기 내용을 신중히 검토하신 후, 인쇄 전 최종 확인을 부탁드립니다. (인쇄 전 최종 확인을 위해, 인쇄 전 최종 확인을 위해, 인쇄 전 최종 확인을 위해)				
제품명	2080 K HERBAL MINT	사이즈(mm)	55 X 37 X 180 (mm)	인쇄 일자
날짜	2017.01.10	인쇄 방법	온풍기 인쇄	반도체 및 구조물부
표준재 박판 및 포장재	Illustrator CS5	색상	Cyan PT 7487 C Magenta PT 7459 C Yellow Black White	최대 인쇄 기량
*주의사항 : 반드시 담당자가 확인 후 승인 한 후에 인쇄를 시작하십시오. (인쇄 전 최종 확인을 위해, 인쇄 전 최종 확인을 위해, 인쇄 전 최종 확인을 위해)				



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2080 K HERBAL MINT

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0006
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:67225-0006-1	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(67225-0006)

Revised: 1/2017

Aekyung Industrial Co., Ltd.