DENTAL CLINIC 2080 K CITRUS COOL MINT- sodium fluoride paste, dentifrice Aekyung Ind. 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.

Dental Clinic 2080 K Toothpaste Citrus Cool Mint

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Active Ingredient

Sodium Fluoride 0.22% (0.1% w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

do not swallow.

supervise children as necessary until capable of using 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 doctor.

Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Liquid Sorbitol, Dental-Type Silica, Sodium Chloride, Sodium Lauryl sulphate, Sodium carboxymethylcellulose, Panthenol, Polyethylene Glycol 1500, Saccharin Sodium Hydrate, Phosphoric acid, Water

Dental Clinic 2080 Gingivalis Project K

Gingivitis-causing Bacteria

99% Inhibits

in-vitro test Results

Tested by Dental School Clinic

Dental Clinic 2080 K Toothpaste Citrus Cool Mint

OTC Drug

Customer Center:060-024-1357 (Nationwide Toll-Free)

We accept returns in compliance with the Consumer Protection Act of Fair Trade Commission.

AEKYUNG

MADE IN KOREA

www.aekyung.co.kr

Net Weight: 100g

Dental Clinic 2080 K Toothpaste Citrus Cool Mint, 100g (67225-0003-1)





Gingivalis Project K

2080's gum health-promoting project that inhibits P.gingivalis, the major cause of gingivitis, periodontitis, and other periodontal disease, for strong, healthy gums.

> **Purpose** Anticavity

Drug Facts

Active ingredient

Sodium Fluoride 0.22% (0.1% w/v fluoride ion)

Use aids in the prevention of dental cavities

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do not swallow. supervise children as necessary until capable of using 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 doctor. Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients

Liquid Sorbitol, Dental-Type Silica, Sodium Chloride, Sodium Lauryl sulphate, Sodium carboxymethylcellulose, Panthenol, Polyethylene Glycol 1500, Saccharin Sodium Hydrate, Phosphoric acid, Water

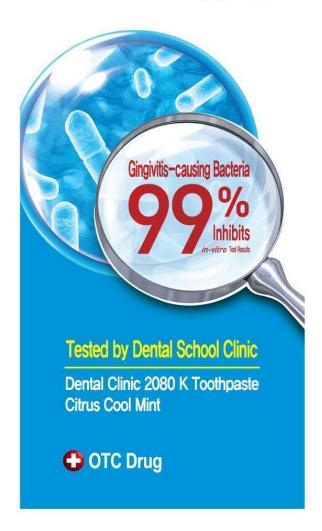
Customer Center: 080-024-1357 (Nationwide Toll-Free) We accept returns in compliance with the Consumer Protection Act of Fair Trade Commission.



MADE IN KOREA www.aekyung.co.kr Net Weight: 100g

2080





DENTAL CLINIC 2080 K CITRUS COOL MINT

sodium fluoride paste, dentifrice

Product Information

HUMAN OTC DRUG NDC:67225-0003 Product Type Item Code (Source)

DENTAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM ELLIORIDE (LINII: 87YO1474W7) (ELLIORIDE ION - LINII: O80 VPLI4080)	ELLIORIDE ION	0.1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
POLYGLUCOSE SORBITOL CARBOXYMETHYL ETHER (UNII: Y8 P5S7CF2S)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
PHO SPHO RIC ACID (UNII: E4GA8884NN)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	CITRUS (Citrus Cool Mint)	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67225-0003-1	1 in 1 PACKAGE		
1		100 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/16/2014	

Labeler - Aekyung Ind. Co., Ltd. (690511126)

Registrant - Aekyung Ind. Co., Ltd. (690511126)

Establishment			
Name	Address	ID/FEI	Business Operations
Aekyung Ind. Co., Ltd.		690511126	manufacture(67225-0003)

Revised: 5/2014 Aekyung Ind. Co., Ltd.