# DENTAL CLINIC 2080 K STRONG WINTER GREEN- 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.

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## Dental Clinic 2080 K Toothpaste Strong Winter Green

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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 Strong Winter Green, 100g (67225-0002-1)





## **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.

## **Drug Facts**

## Active ingredient

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

Use aids in the prevention of dental cavities

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

Purpose

Anticavity

of using without 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

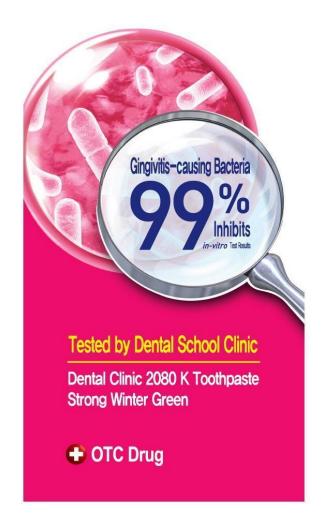
Liquid Sorbitol, Dental-Type Silica, Sodium Chloride, Sodium Lauryl sulphate, Sodium carboxymethylcellulose, Panthenol, Polyethylene Glycol 1500, Saccharin Sodium Hydrate, Phosphoric acid, Water

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



Dental Clinic **2080** 





## DENTAL CLINIC 2080 K STRONG WINTER GREEN

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67225-0002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
POLYGLUCOSE SORBITOL CARBOXYMETHYL ETHER (UNII: Y8P5S7CF2S)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHO SPHORIC ACID (UNII: E4GA8884NN)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	WINTERGREEN (Strong Winter Green)	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:67225-0002-1	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(67225-0002)	

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