

PLAK SMACKER- sodium fluoride paste, dentifrice
Dental Technologies, Inc

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.

Drug Facts

Active Ingredient

Sodium Fluoride 0.24%
(0.14% w/v fluoride ion)

Purpose

Anticavity toothpaste

Uses

Helps aid in the prevention of dental cavities.

Warnings

Do not use if inner foil is torn, cut or missing.

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 right away.

Directions

- Adults and children 2 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.
- Do not swallow
- To minimum swallowing use a pea sized amount in children under 6
- Instruct children under 6 years of age in good brushing and rinsing habits
- Supervise children as necessary until capable of using without supervision

Inactive Ingredients

Sorbitol, Water, Hydrated Silica, PEG-32, Cellulose Gum, Sodium Lauryl Sulfate, PEG-6, Flavor, Sodium Saccharin, Methylparaben, Propylparaben, Blue 1

Questions or comments?

1-800-558-6684

Principal Display Panel

PLAK SMACKER®

GREAT WHITE

SHARK

NO

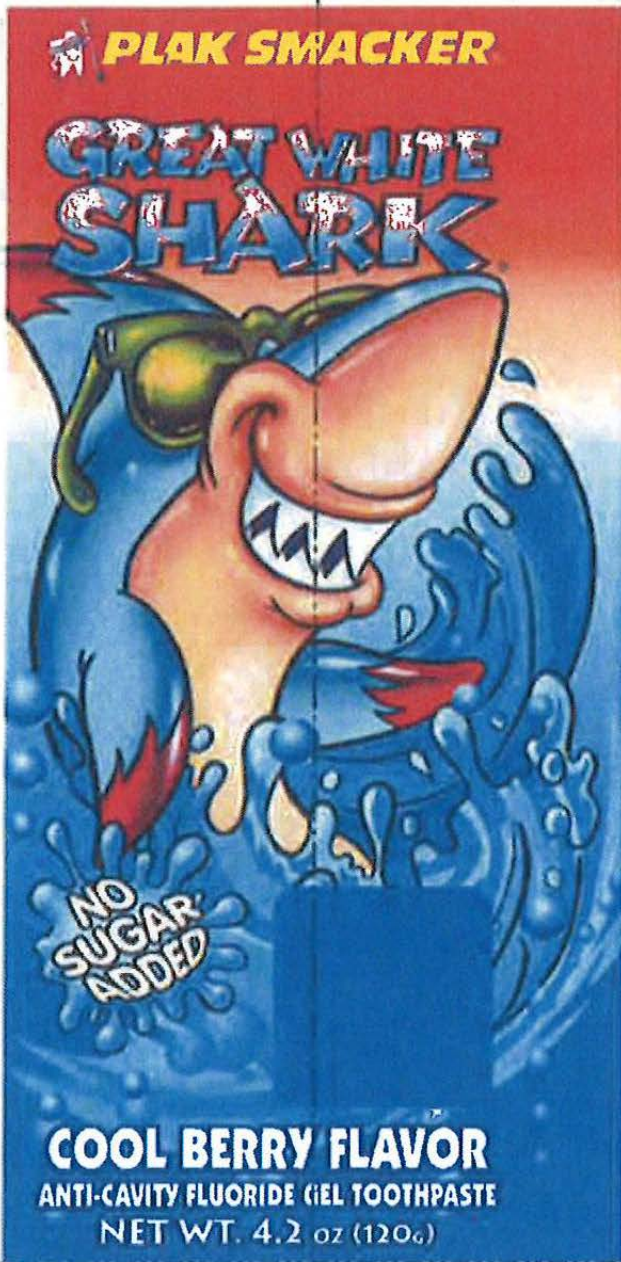
SUGAR

ADDED

COOL BERRY FLAVOR

ANTI-CAVITY FLUORIDE GEL TOOTHPASTE

NET WT. 4.2 OZ (120G)



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Questions or comments? 1-800-558-6684	

Distributed by: PLAK SMACKER®
 2260 Wendt St.
 Algonquin, IL 60102
 (800) 558-6684 www.plaksmacker.com

00157
REV 2

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55346-0718
Route of Administration	ORAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (Cool Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-0718-2	120 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:55346-0718-1	24 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	12/31/2007	

Labeler - Dental Technologies, Inc (148312838)

