

**PLAK SMACKER GREAT WHITE SHARK COOL BERRY FLAVOR ANTI CAVITY
FLUORIDE GEL TOOTH- sodium fluoride paste, dentifrice
Yangzhou ONE & ONLY Personal Care Products Co., LTD**

85162-003

Active ingredients

SODIUM FLUORIDE 0.24% (0.11 w/v Fluoride ion)

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Purpose

Anti-cavity toothpaste

Uses

Aids in the prevention of cavities.

Warnings

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

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

Keep out of reach of children.

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 physician
- Do not swallow
- To minimize wallowing, use a pea sizes amount in children under 6 years
- Supervise children's brushing until good habits are established
- Children under 2 years of age: consult a dentist or physician

INACTIVE INGREDIENT

Sorbitol, Water, Silica, PEG-400, Sodium lauryl sulfate, Cellulose gum, Xanthan gum, flavor, Xylitol, Sodium saccharine, Sodium benzoate, Trisodium phosphate, CI 42090

3mm
1mm
2.6mm

4mm
3*7mm



Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24%	Anti-Cavity
(0.10% w/v fluoride ion)	Toothpaste

Use Aids in the prevention of cavities.

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

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

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 physician.
- Do not swallow.
- To minimize swallowing use a pea sized amount in children under 6 years.
- Supervise children's brushing until good habits are established.
- Children under 2 years of age, consult a dentist or physician.

Inactive Ingredients

Sorbitol, Water, Silica, PEG-400, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Xylitol, Sodium Saccharin, Sodium Benzoate, Trisodium Phosphate, CI 42090

Questions or comments?
1-800-558-6684

Distributed by:
Young Innovations, Inc.
2260 Wendt Street
Algonquin, IL 60102 USA
www.plaksmacker.com

REF 100050

Made in China

SHARK24G Rev.A

PLAK SMACKER GREAT WHITE SHARK COOL BERRY FLAVOR ANTI

CAVITY FLUORIDE GEL TOOTH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85162-003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRISODIUM PHOSPHIDE (UNII: A360RQX9W2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85162-003-01	144 in 1 BOX	01/16/2025	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:85162-003-02	5 in 1 CARTON	01/16/2025	
2		24 in 1 BOX		
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:85162-003-06	480 in 1 BOX	01/16/2025	
3		28 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:85162-003-03	144 in 1 BOX	01/16/2025	
4		50 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:85162-003-04	72 in 1 BOX	01/16/2025	
5		100 g in 1 TUBE; Type 0: Not a Combination Product		

6	NDC:85162-003-05	144 in 1 BOX	01/16/2025	
6		100 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:85162-003-07	72 in 1 BOX	01/16/2025	
7		120 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:85162-003-08	144 in 1 BOX	01/16/2025	
8		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 Drug	M021	01/16/2025	

Labeler - Yangzhou ONE & ONLY Personal Care Products Co., LTD (458091296)

Registrant - Yangzhou ONE & ONLY Personal Care Products Co., LTD (458091296)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou ONE & ONLY Personal Care Products Co., LTD		458091296	manufacture(85162-003)

Revised: 1/2025

Yangzhou ONE & ONLY Personal Care Products Co., LTD