GOBY PEPPERMINT- sodium fluoride paste
BGLG, 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.

Goby peppermint Toothpaste

Drug Facts

Active Ingredients

sodium fluoride, .24%
(0.15% w/v fluoride ion)

Purpose

Anticavity

Use

Helps prevent cavities

Warning

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

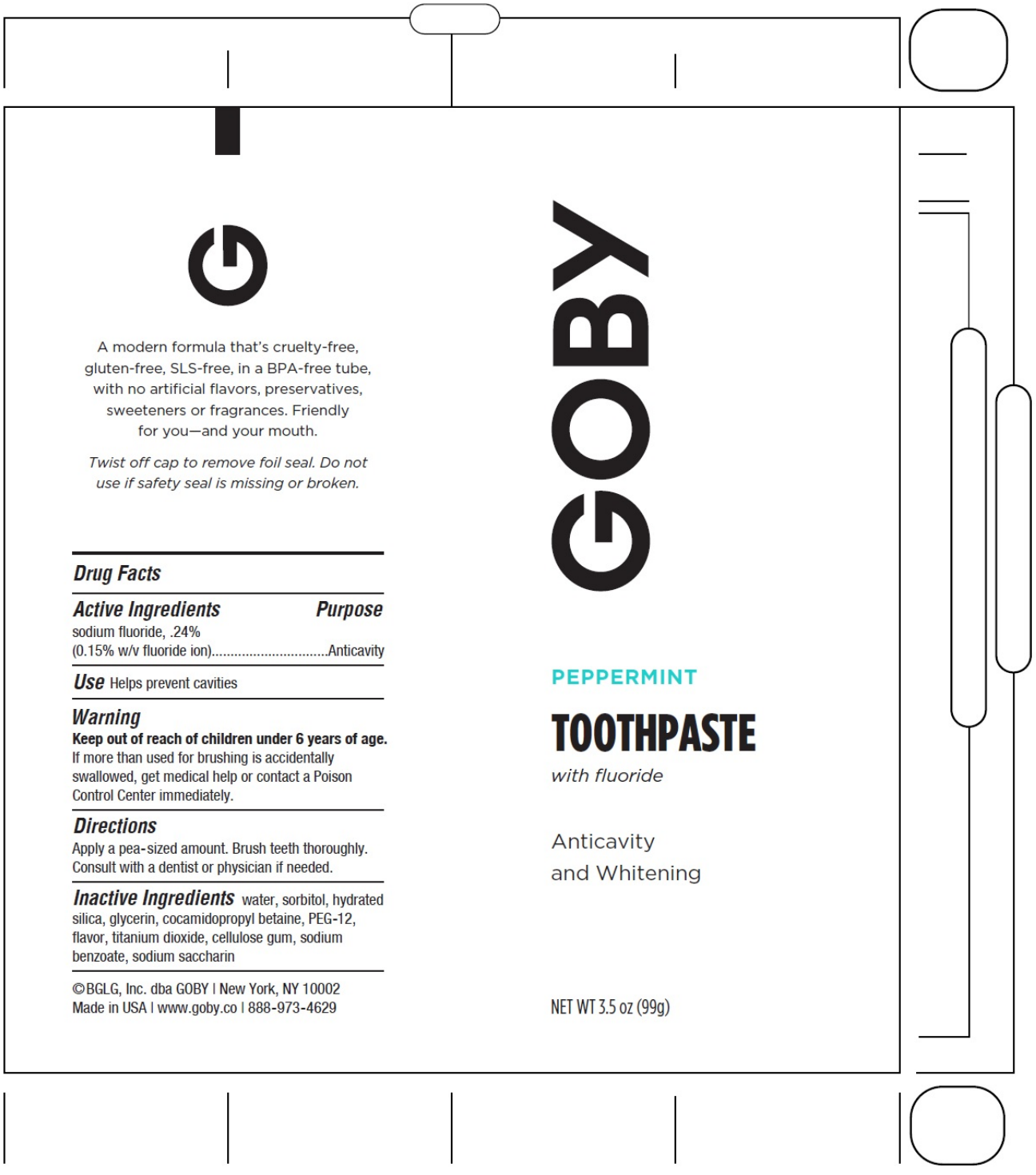
Apply a pea-sized amount. Brush teeth thoroughly. Consult with a dentist or physician if needed.

Inactive Ingredients

water, sorbitol, hydrated silica, glycerin, cocamidopropyl betaine, PEG-12, flavor, titanium dioxide, cellulose gum, sodium benzoate, sodium saccharin

Package Labeling:

ALBÉA
Inspired packaging solutions - REYNOSA, MEXICO



GOBY PEPPERMINT

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81788-001

Route of Administration	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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81788-001-00	99 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2021	

Labeler - BGLG, Inc. (074391154)

Revised: 4/2021 BGLG, Inc.