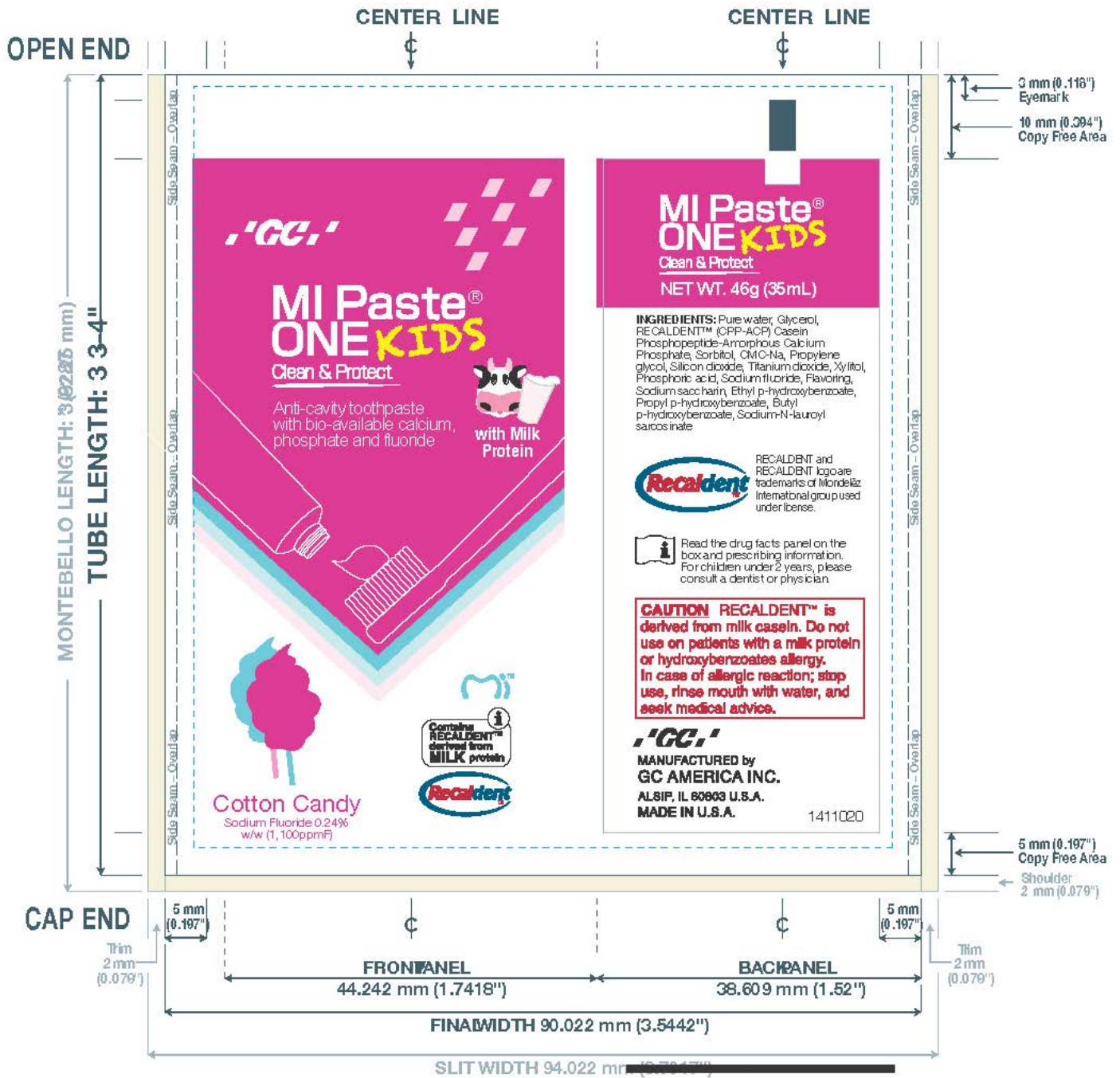


MIPASTE ONE KIDS COTTON CANDY- mipaste one kids cotton candy paste, dentifrice
GC America Inc.



Directions For adults and children 2 years of age or older, apply a small, pea-size amount of MI Paste ONE Kids to your toothbrush. For best results, brush for 2 minutes, expectorate and avoid eating or drinking for 30 minutes after brushing.

Use twice daily. Replace cap after use. For children under 2 years of age, consult a dentist or physician.

Warning Keep out of reach of children under 6 years of age. If more than the recommended amount of paste used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. Do not use on patients with a milk protein or hydroxybenzoates allergy. In case of allergic reaction, stop use, rinse mouth with water and seek medical advice.

Inactive ingredients Pure water, Glycerol, RECALDENT CPP-ACP Casein Phosphopeptide-Amorphous Calcium Phosphate, Sorbitol, CMC-Na, Propylene glycol, Silicon dioxide, Titanium dioxide, Xylitol, Phosphoric acid, Flavoring, Sodium saccharin, Ethyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Butyl p-hydroxybenzoate, Sodium-N-lauroyl sarcosinate.

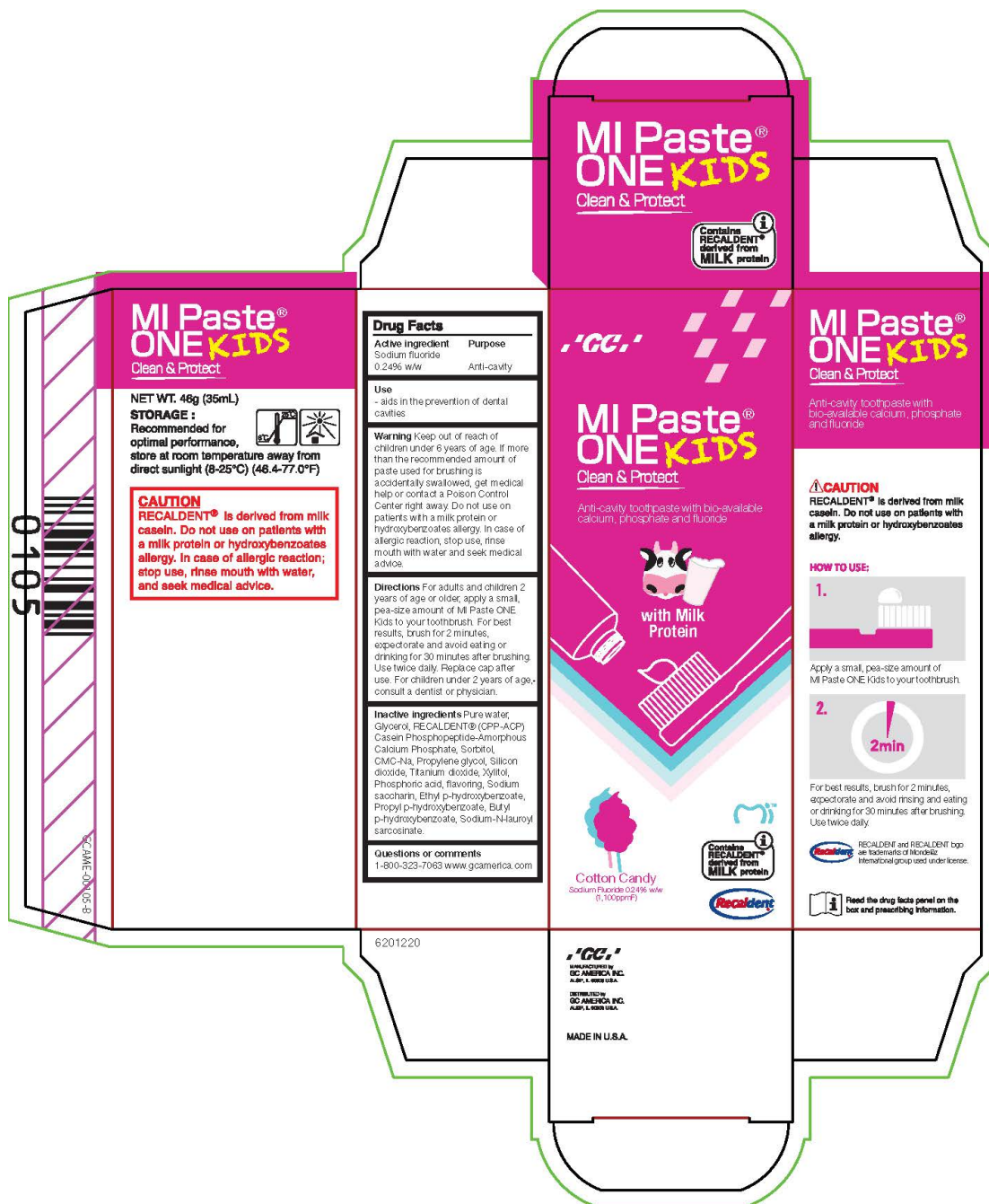
Use

- aids in the prevention of dental cavities

Warning Keep out of reach of children under 6 years of age. If more than the recommended amount of paste used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. Do not use on patients with a milk protein or hydroxybenzoates allergy. In case of allergic reaction, stop use, rinse mouth with water and seek medical advice.

Purpose: Anticavity

Active ingredient
Sodium Fluoride
0.24% w/w



MIPASTE ONE KIDS COTTON CANDY

mipaste one kids cotton candy paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61596-102
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.24 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYLPARABEN (UNII: 14255EXE39)	
CALCIUM PHOSPHATE, UNSPECIFIED FORM (UNII: 97Z1W3NDX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596-102-10	10 in 1 BOX	04/21/2021	
1	NDC:61596-102-02	1 in 1 BOX, UNIT-DOSE		
1	NDC:61596-102-01	0.46 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	04/21/2021	

Labeler - GC America Inc. (005473608)

Establishment

Name	Address	ID/FEI	Business Operations
GC America Inc.		005473608	manufacture(61596-102)

