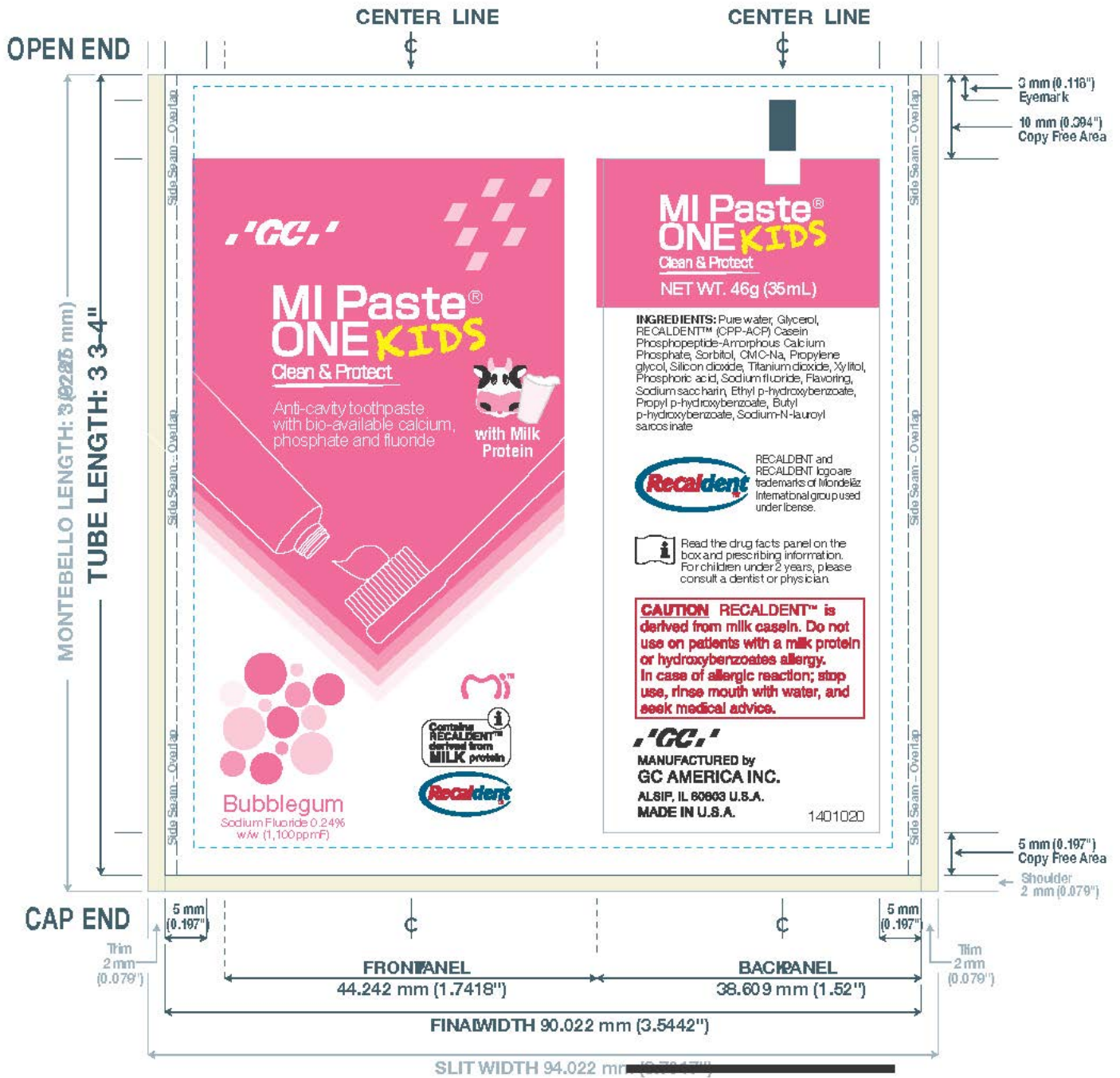


MIPASTE ONE KIDS BUBBLE GUM- mipaste one kids bubble gum paste, dentifrice
GC America Inc.



Active ingredient
 Sodium Fluoride
 0.24% w/w

Anti-cavity

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.

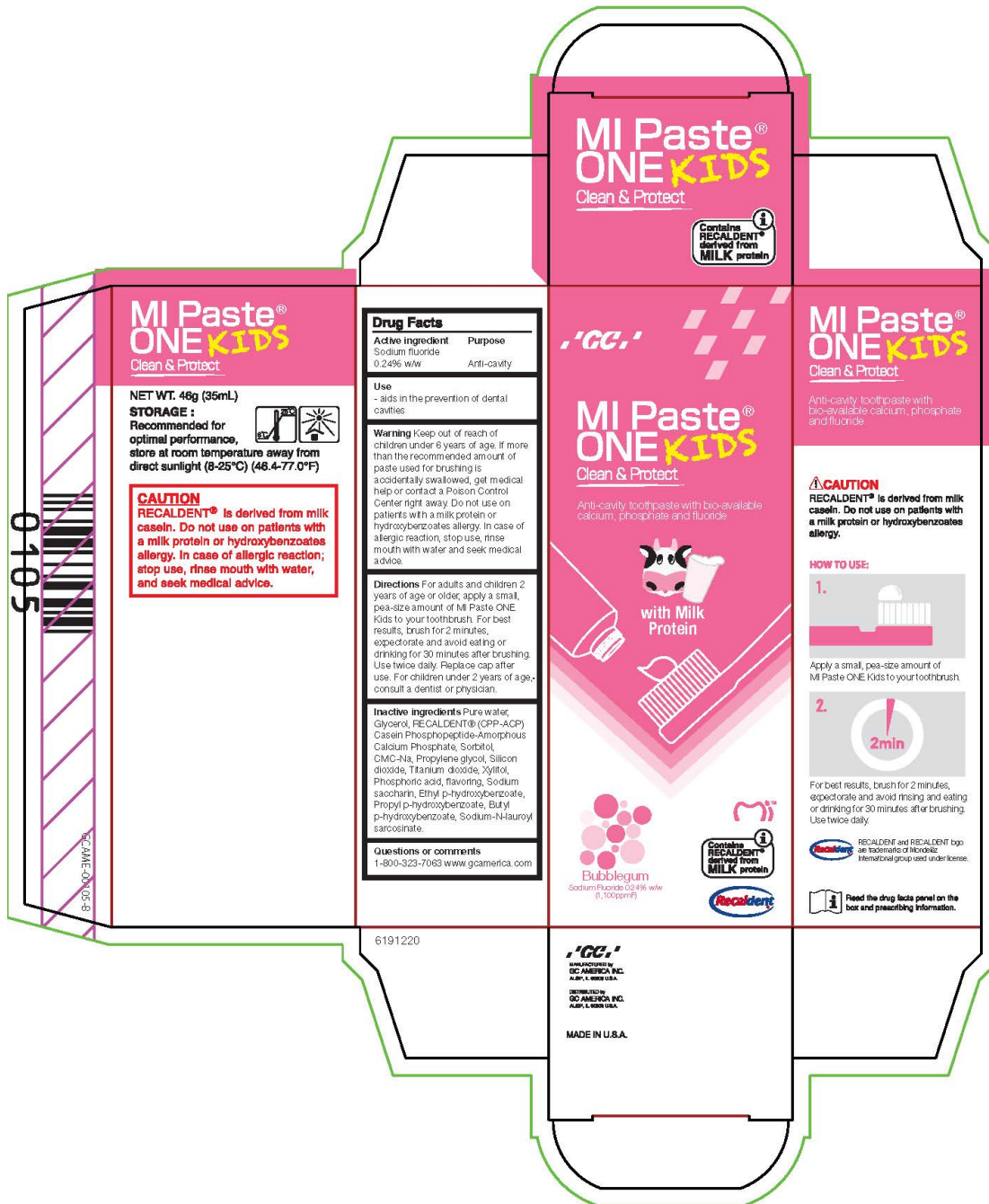
Use

- aids in the prevention of dental cavities

Anti-cavity toothpaste with bio-available calcium, phosphate and Fluoride

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.



MIPASTE ONE KIDS BUBBLE GUM

mipaste one kids bubble gum paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61596-101
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
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYLPARABEN (UNII: 14255EXE39)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CALCIUM PHOSPHATE, UNSPECIFIED FORM (UNII: 97Z1W3NDX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61596-101-10	10 in 1 BOX	04/21/2021	
1	NDC:61596-101-02	1 in 1 BOX, UNIT-DOSE		
1	NDC:61596-101-01	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
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Revised: 1/2024

GC America Inc.