BRUSHBUDDIES THOMAS FRIENDS ANTICAVITY FLURORIDE TOOTH- sodium monofluorophosphate paste, dentifrice Foshan Nanhai JiaChun Biology Engineering Co., Ltd

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.

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose:

Anticavity Toothpaste

Uses: Help protect teeth and roots against cavities

Warnings:

If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately

Keep out of reach of children

Directions:

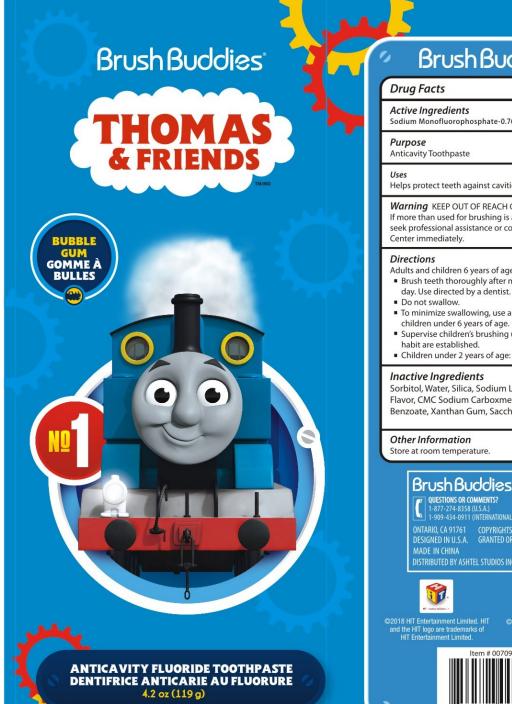
- Adults and children 2 years and older:
- Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- Do not swallow
- To minimize swallowing use a pea-sized amount in children under 6 years of age,
- Supervise children's brushing untill good habits are established.

Children under 2 years of age:

• Ask a dentist

Inactive Ingredients:

Sorbitor, Water, Silica, Sodium N-Lauroylsarcosinate, Xylitol, Flavor, Sodium Carboxymethylcellulose, Sodium Benzoate, Xanthan Gum, Saccharin Sodium, Rose Red 1



make brushing fun!®

BrushBuddies[®]

Sodium Monofluorophosphate-0.76%

Helps protect teeth against cavities.

Warning KEEP OUT OF REACH OF CHILDREN. If more than used for brushing is accidently swallowed,

seek professional assistance or contact a Poison Control

- Adults and children 6 years of age and older: Brush teeth thoroughly after meals or at least twice a
- To minimize swallowing, use a pea-sized amount in children under 6 years of age.
- Supervise children's brushing until good brushing habit are established.
- Children under 2 years of age: Ask a dentist.

Inactive Ingredients

Sorbitol, Water, Silica, Sodium Lauryl Sulfate, Xylitol, Flavor, CMC Sodium Carboxmethyl Cellulose, Sodium Benzoate, Xanthan Gum, Saccharin Socium, Rose Red.

Store at room temperature.

BrushBuddies[®]

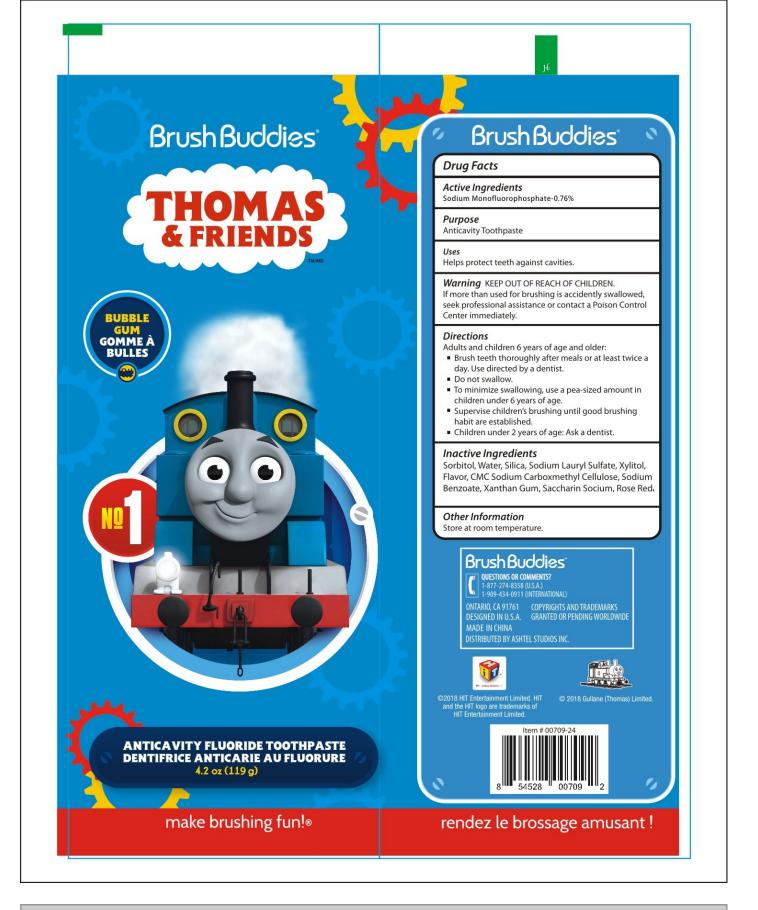
QUESTIONS OR COMMENTS? 1-877-274-8358 (U.S.A.) 1-909-434-0911 (INTERNATIONAL) ONTARIO, CA 91761 COPYRIGHTS AND TRADEMARKS DESIGNED IN U.S.A. GRANTED OR PENDING WORLDWIDE



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BRUSHBUDDIES THOMAS FRIENDS ANTICAVITY FLURORIDE TOOTH

sodium monofluorophosphate paste, dentifrice

Product Informati	on						
Product T ype	1	HUMAN OTC DRUG Item Code (Source)				NDC:71106-004	
Route of Administrati	on (DRAL					
Active Ingredient/	Active Moie	y					
Ingredient Name Basis Stren							Strengtl
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)						E ION	0.1 g in 100 g
Inactive Ingredien	ts						
Ingredient Name							
WATER (UNII: 059QF0k	KOOR)						
SORBITOL (UNII: 506T	60A25R)						
XYLITOL (UNII: VCQ00)6KQ1E)						
CARBOXYMETHYLCE	LLULOSE SOD	UM (UNII: K679OBS311)					
SODIUM BENZOATE (U	JNII: OJ245FE5E	J)					
XANTHAN GUM (UNII: 1	TTV12P4NEE)						
SACCHARIN SODIUM (UNII: SB8ZUX40	TY)					
Packaging							
# Item Code	Pa	ickage Description		Marketing Star	t Date	Marketi	ing End Dat
1 NDC:71106-004-01		Type 0: Not a Combination)8/02/2018			0
	0						
Marketing Info	rmation						
Marketing Category	Application	Number or Monograph	Citation	Marketing Star	rt Date	Market	ing End Dat
OTC monograph final	part355			08/02/2018			

Labeler - Foshan Nanhai JiaChun Biology Engineering Co., Ltd (527935253)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Nanhai JiaChun Biology Engineering Co., Ltd		527935253	manufacture(71106-004)

Revised: 8/2018

Foshan Nanhai JiaChun Biology Engineering Co., Ltd