# THOMAS AND FRIENDS- sodium monofluorophosphate paste, dentifrice Ashtel Studios, 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.

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# Thomas & Friends Toothpaste

#### **Drug Facts**

### **Active Ingredients**

Sodium Monofluorophosphate-0.76%

#### **Purpose**

Anticavity Toothpaste

#### Uses

Helps protect teeth against cavities.

## Warning

If more than used for brushing is accidently swallowed, seek professional assistance or contact a Poison Control Center immediately.

KEEP OUT OF REACH OF CHILDREN.

#### Directions

Adults and children 6 years of age and older:

- Brush teeth thoroughly after meals or at least twice a day. 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 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 Carboxymethyl Cellulose, Sodium Benzoate, Xanthan Gum, Saccharin Sodium, Rose Red

#### **Other Information**

Store at room temperature.

**BUBBLE GUM** 

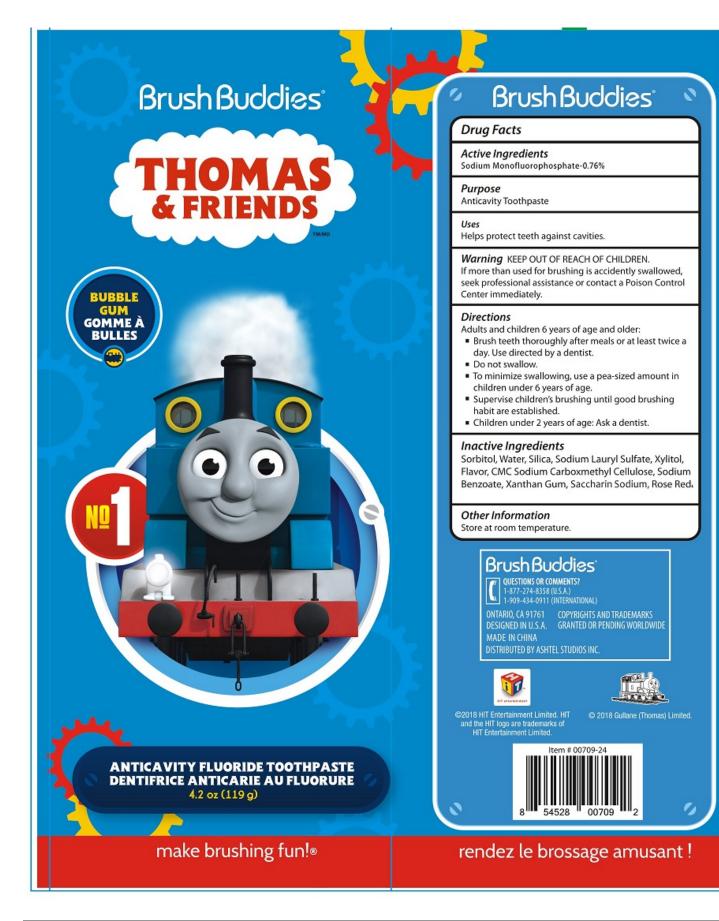
ANTICAVITY FLUORIDE TOOTHPASTE

Make brushing fun!®

**QUESTIONS OR COMMENTS?** 

1-877-274-8358 (U.S.A.)
1-909-434-0911 (INTERNATIONAL)
ONTARIO, CA 91761
DESIGNED IN U.S.A.
MADE IN CHINA
DISTRIBUTED BY ASHTEL STUDIOS INC.

# **Packaging**



## THOMAS AND FRIENDS

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70108-017
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.76 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
XYLITOL (UNII: VCQ006KQ1E)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
XANTHAN GUM (UNII: TTV12P4NEE)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
ROSE BENGAL SODIUM (UNII: 956575SN5L)		

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>	
ı	1 NDC:70108-017-01	119 g in 1 TUBE; Type 0: Not a Combination Product	08/16/2018		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/16/2018	

# Labeler - Ashtel Studios, Inc. (148689180)

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