THOMAS AND FRIENDS- sodium fluoride 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.

Thomas & Friends Toothpaste

Drug Facts

Active Ingredients

Sodium Fluoride 0.243% (0.15% w/v Fluoride Ion)

Purpose

Anticavity Toothpaste

Uses

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 Center immediately.

Directions

Adults and children 6 years of age and older:

- Brush teeth thoroughly after meals or at least twice a day. Use 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, Silica, Aqua, PEG-32, Xylitol, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Benzyl Alcohol, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, FD&C Blue #1, FD&C Red #40.

Other Information

Store at room temperature.

QUESTIONS? COMMENTS? / COMMENTAIRES?

1-877-274-8358 (U.S.A.) 1-909-434-0911 (INTERNATIONAL) 1-888-635-5337 (CANADA)

BUBBLE GUM GOMME À BULLES

ANTICAVITY FLUORIDE TOOTHPASTE DENTIFRICE ANTICARIE AU FLUORURE

make brushing fun!®

For more oral care information, visit us at / Pour d'autres rens eignements, visitez: www.brushbuddies.com

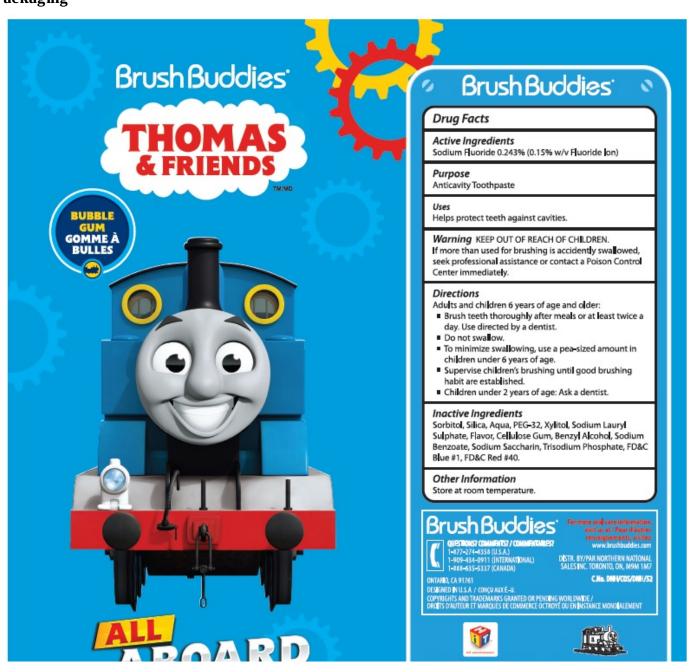
DISTR. BY/PAR NORTHERN NATIONAL SALES INC. TORONTO, ON, M9M 1M7

C.No. DNH/COS/DNH/52

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Packaging





THOMAS AND FRIENDS

sodium fluoride paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70108-015

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	243 mg in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
WATER (UNII: 059QF0KO0R)		
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)		
XYLITOL (UNII: VCQ006KQ1E)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM PHO SPHATE, TRIBASIC, ANHYDRO US (UNII: SX01TZO3QZ)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:70108-015-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/09/2018		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	05/09/2018		

Labeler - Ashtel Studios, Inc. (148689180)

Revised: 5/2018 Ashtel Studios, Inc.