

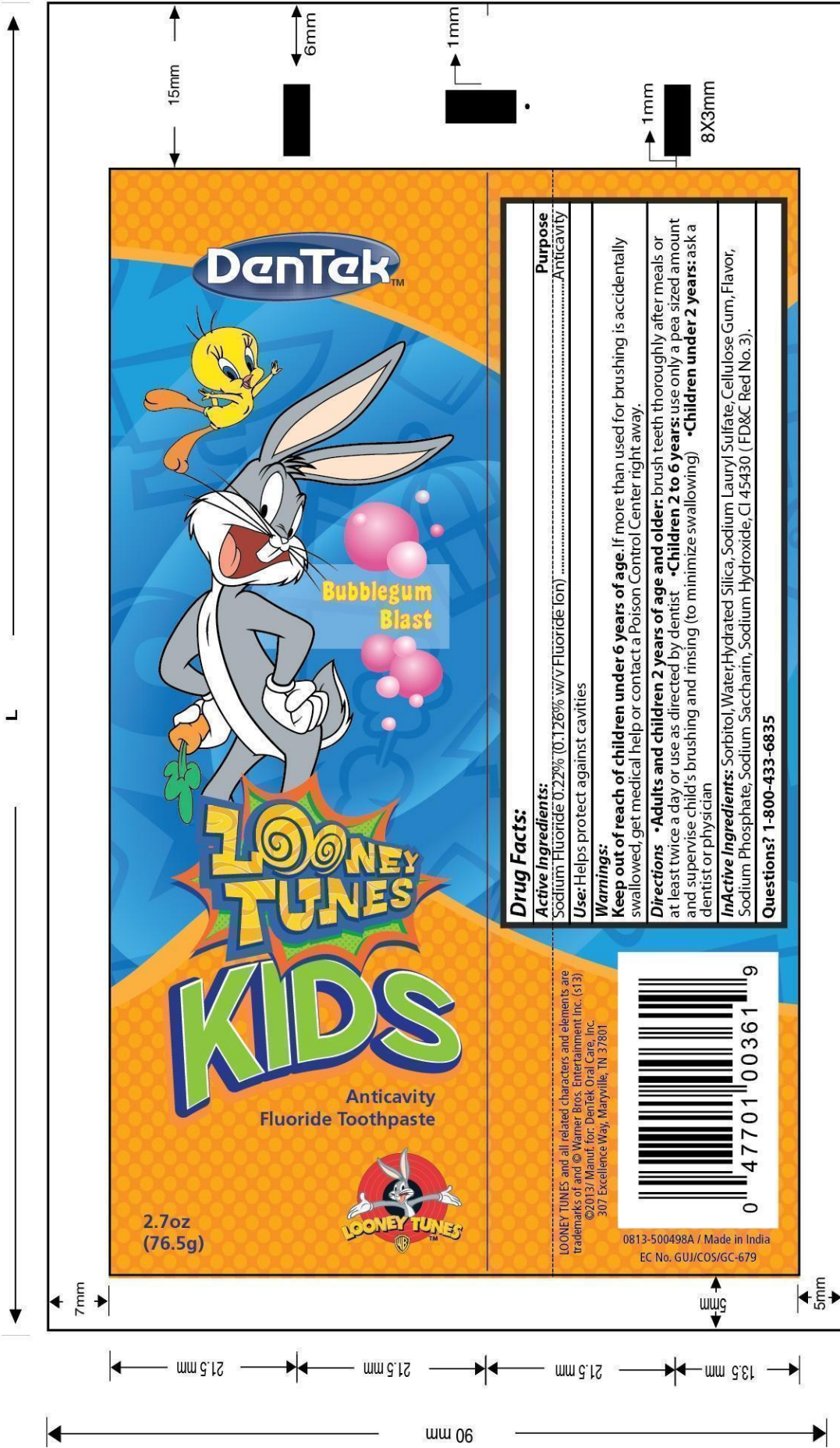
DENTEK KIDS ANTICAVITY FLUORIDE LOONEY TUNES BUBBLEGUM BLAST- sodium fluoride paste, dentifrice
DenTek Oral Care, Inc.

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.

Kids Toothpaste with sodium fluoride

toothpaste tube label

LAYOUT FOR DIA 28 mm x 150mm
 L (Tube Length) = Final tube Length



Active Ingredients

Sodium Fluoride 0.22% (0.126% w/v Fluoride Ion)

Purpose

Anticavity

Indications and Use

Use: Helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

.Adults and children 2 years of age and older: brush teeth thoroughly after meals or at least twice a day or use as directed by dentist **.Children 2 to 6 years:** use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) **.Children under 2 years:** ask a dentist or physician

Inactive Ingredients

Sorbitol, Water, Hydrated Silica, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Phosphate, Sodium Saccharin, Sodium Hydroxide, CI 45430 (FD&C Red No. 3).

Questions

Questions? 1-800-433-6835

Keep Out of Reach of Children

Keep out of reach of children under 6 years of age.

DENTEK KIDS ANTICAVITY FLUORIDE LOONEY TUNES BUBBLEGUM BLAST

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60630-498
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0964 g in 76.5 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	42.075 g in 76.5 g
WATER (UNII: 059QF0K00R)	15.34 g in 76.5 g
HYDRATED SILICA (UNII: Y6O7T4G8P9)	15.3 g in 76.5 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	1.3 g in 76.5 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.918 g in 76.5 g
SODIUM PHOSPHATE (UNII: SE337SVY37)	0.38 g in 76.5 g
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	0.176 g in 76.5 g
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.0765 g in 76.5 g

Product Characteristics

Color	red (CI 45430 (FD&C Red No. 3))	Score	
Shape		Size	
Flavor	BUBBLE GUM (Proprietary blend)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60630-498-01	76.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2014	

Labeler - DenTek Oral Care, Inc. (153818646)**Registrant** - DenTek Oral Care, Inc. (153818646)

Revised: 10/2013

DenTek Oral Care, Inc.