VORTEX - toothpaste paste, dentifrice
DSC Laboratories, Div. of DSC Products 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.

Drug Facts

Active Ingredients
Sodium Fluoride 0.20%

Purpose

Anticavity

Use

Aids in prevention of dental decay.

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

- Twist off cap and remove foil seal
- Adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or use as directed by dentist.
- Do not swallow
- To minimize swallowing use a pea-sized amount in children under 6.
- Supervise children's brushing until good habits are established.
- Children under 2 yrs.: ask a dentist

Inactive Ingredients

Purified water, Glycerin, Xylitol, Hydrated Silica, Carbomer Homopolymer Type C, Natural Grape Flavor, Xanthan Gum, D and C Red #28, FD and C Blue #1, D and C Red #33.

Questions?

Call 1-314-436-3332

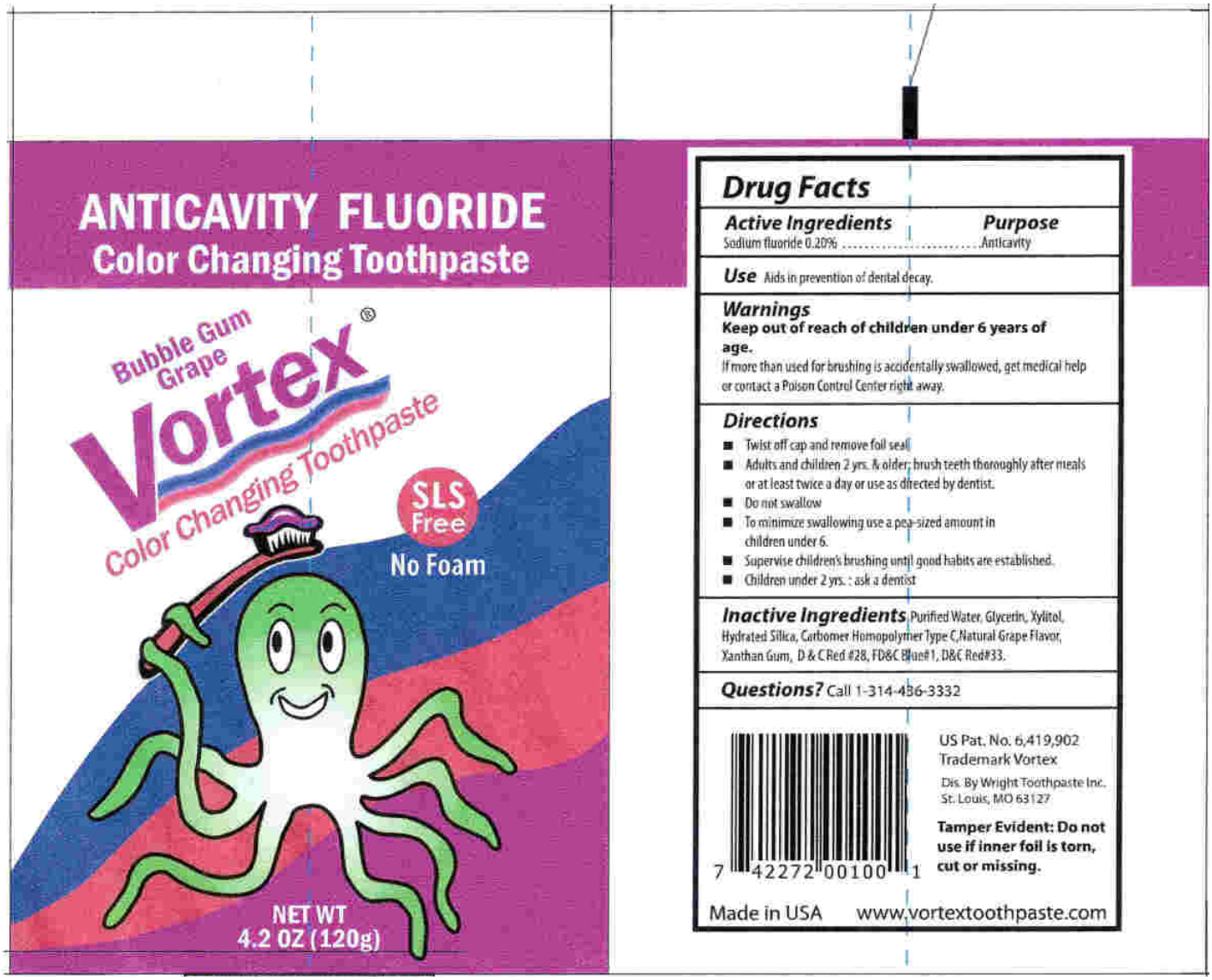
VORTEX TOOTHPASTE 120G TUBE

Vortex Anti-Cavity Fluoride Toothpaste

Net Wt. 4.2 oz (120g)

Distributed by: Wright Toothpaste Inc.

St. Louis, MO 63127



VORTEX

toothpaste paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52316-028
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.0 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52316-028-42	120 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/30/2011	

Labeler - DSC Laboratories, Div. of DSC Products Inc. (097807374)

Establishment

Name	Address	ID/FEI	Business Operations
DSC Laboratories, Div. of DSC Products Inc.		097807374	manufacture

Revised: 12/2011 DSC Laboratories, Div. of DSC Products Inc.