LINHART- sodium fluoride toothpaste paste, dentifrice Nutrix International,LLC

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 Fluoride 0.25%

Purpose

Anticavity

Indications and Usage

Aids in the prevention of dental decay.

Warnings

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach section

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

Directions

- Adults and Children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
- Instruct children 6 years of age in good brushing and rinsing habits (to minimize swallowing), and and only use a pea size amount.
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

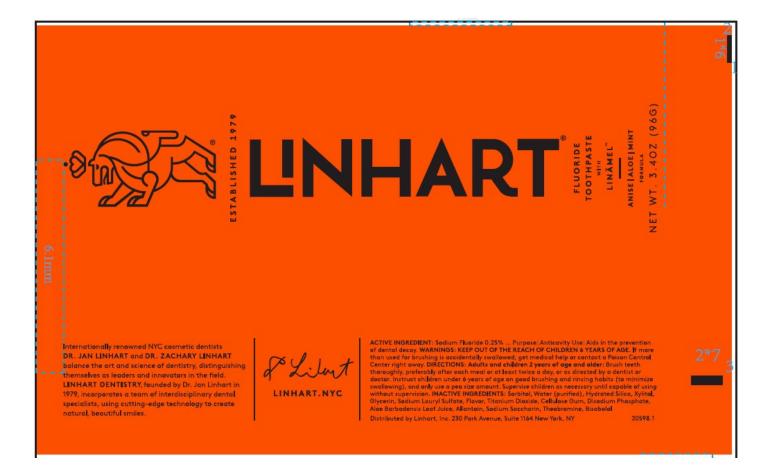
Inactive Ingredients

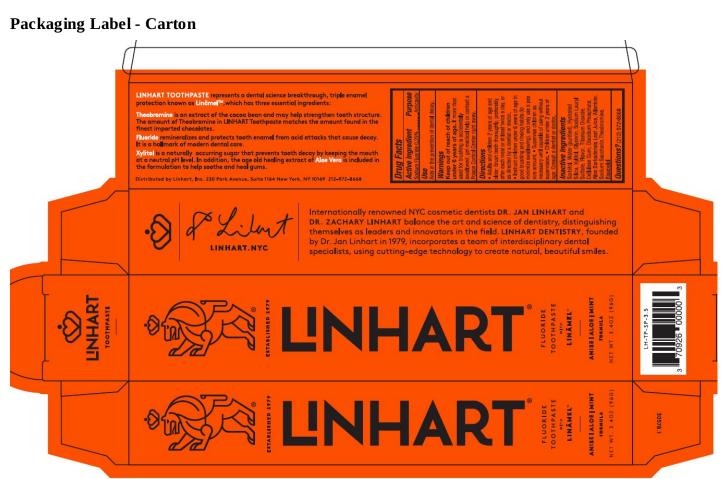
Sorbitol, Water (Purified), Hydrated Silica, Xylitol, Glycerin, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose Gum, Disodium Phosphate, Aloe Barbadensis Leaf Juice, Allantoin, Sodium Saccharin, Theobromine, Bisobolol.

Questions

(212) 599-2397

Primary Packaging Label





LINHART

sodium fluoride toothpaste paste, dentifrice

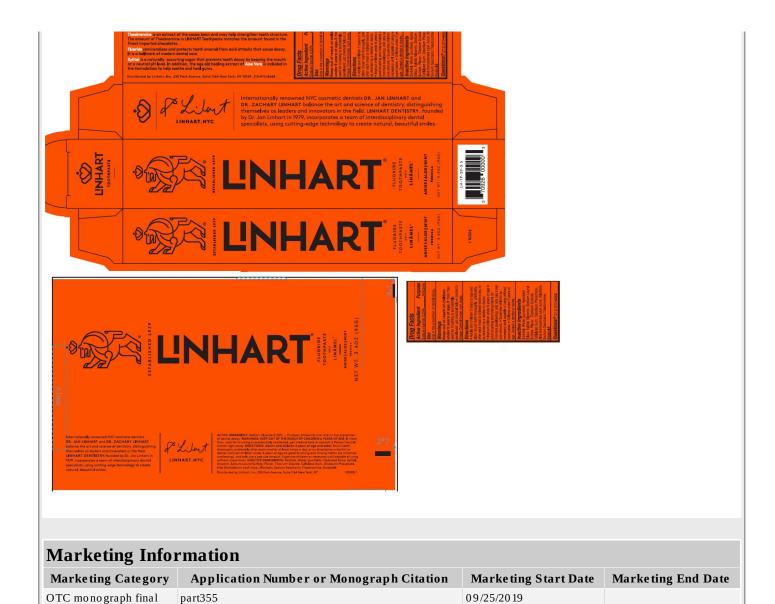
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73333-096
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	2.5 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SO DIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
CARBO XYMETHYLCELLULO SE (UNII: 05JZI7B19 X)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
.ALPHABISABOLOL, (+/-)- (UNII: 36 HQN158 VC)				
THEOBROMINE (UNII: OBD445WZ5P)				
XYLITOL (UNII: VCQ006KQ1E)				
ALLANTO IN (UNII: 344S277G0Z)				

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73333-096-03	1 in 1 CARTON	09/25/2019	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		



Labeler - Nutrix International, LLC (117341868)

Establishment			
Name	Address	ID/FEI	Business Operations
Nutrix International, LLC		117341868	manufacture(73333-096)

Revised: 1/2020 Nutrix International,LLC