

**LINHART- sodium fluoride toothpaste paste, dentifrice**  
**Linhart 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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**Drug Fact**

**Active ingredient**

Sodium Fluoride 0.25%

**Purpose**

Anticavity

**Uses**

Aids in the prevention of tooth 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 the reach of children under 6 years of age.**

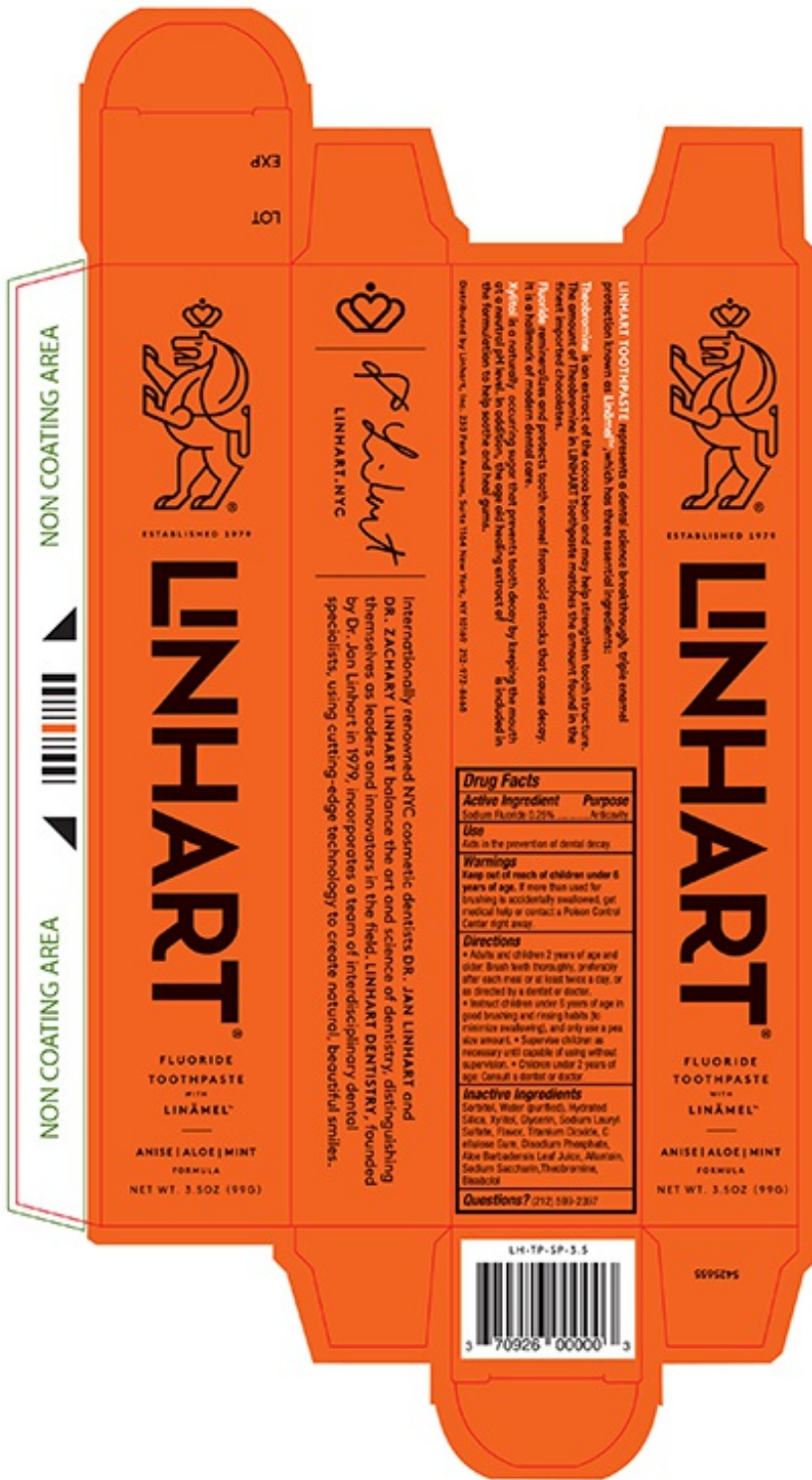
**Directions**

- 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.

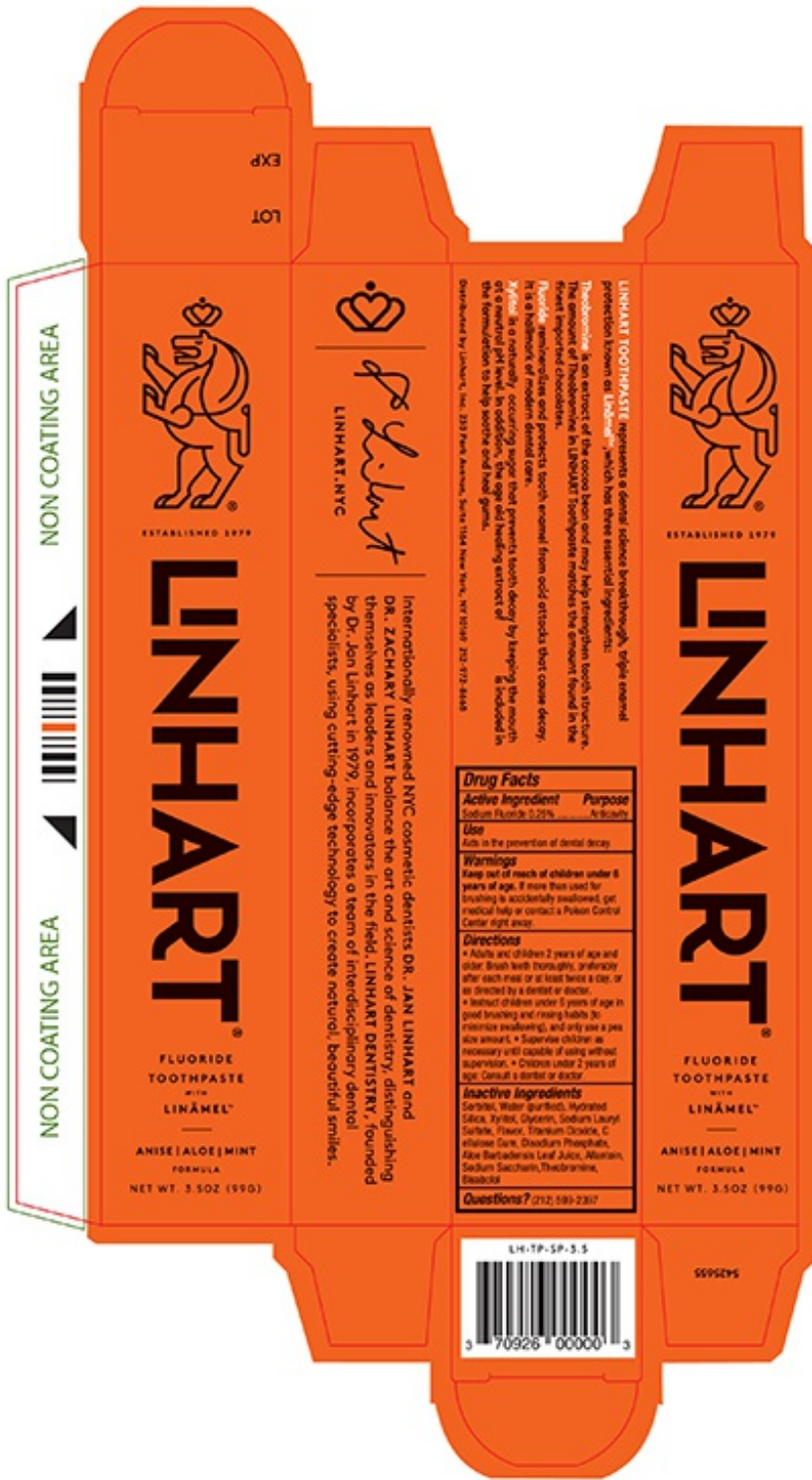
**Inactive ingredients**

Sorbitol, Water (purified), Hydrated Silica, Xylitol, Glycerin, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Cellulose gum, Disodium Phosphate, Aloe Barbadenias Leaf Juice, Allantoin, Sodium Saccharin, Theobromine, Bisabolol

**Principal Primary Panel - Carton 3.5oz**



LINHART with Linamel  
 Fluoride Toothpaste  
 NET WT 3.5oz(99g)



Principal Primary Panel - Tube 3.5oz



LINHART with Linamel  
 Fluoride Toothpaste  
 NET WT 3.5oz (99g)



# LINHART

sodium fluoride toothpaste paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70926-100
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.5 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>SODIUM PHOSPHATE DIBASIC DIHYDRATE</b> (UNII: 94255I6E2T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>.ALPHA.-BISABOLOL, (+/-)-</b> (UNII: 36HQN158VC)	
<b>THEOBROMINE</b> (UNII: OBD445WZ5P)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70926-100-64	1 in 1 CARTON	08/17/2017	
1		99 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70926-100-34	1 in 1 CARTON	08/17/2017	
3		28 g in 1 TUBE; Type 0: Not a Combination		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/17/2017	

**Labeler** - Linhart Inc (080343587)

Revised: 3/2021

Linhart Inc