

**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.*

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**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**

6.1mm

ESTABLISHED 1979



# LINHART®

FLUORIDE  
TOOTHPASTE  
WITH  
LINÄMEL™  
ANISE|ALOE|MINT  
FORMULA

NET WT. 3.4OZ. (96G)

9.1

Internationally renowned NYC cosmetic dentists DR. JAN LINHART and DR. ZACHARY LINHART balance the art and science of dentistry, distinguishing themselves as leaders and innovators in the field. LINHART DENTISTRY, founded by Dr. Jan Linhart in 1979, incorporates a team of interdisciplinary dental specialists, using cutting-edge technology to create natural, beautiful smiles.



LINHART.NYC

**ACTIVE INGREDIENT:** Sodium Fluoride 0.25% ... **Purpose:** Anticavity Use: Aids in the prevention of dental decay. **WARNINGS:** KEEP OUT OF THE REACH OF CHILDREN 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, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age on good brushing and rinsing habits (to minimize swallowing), and only use a pea size amount. Supervise children as necessary until capable of using without supervision. **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, Bisabolol

Distributed by Linhart, Inc. 230 Park Avenue, Suite 1164 New York, NY 20598.1

## Packaging Label - Carton

LINHART TOOTHPASTE represents a dental science breakthrough, triple enamel protection known as Linämel™, which has three essential ingredients:

**Theobromine** is an extract of the cocoa bean and may help strengthen tooth structure. The amount of Theobromine in LINHART Toothpaste matches the amount found in the finest imported chocolates.

**Fluoride** remineralizes and protects tooth enamel from acid attacks that cause decay. It is a hallmark of modern dental care.

**Xylitol** is a naturally occurring sugar that prevents tooth decay by keeping the mouth at a neutral pH level. In addition, the age old healing extract of **Aloe Vera** is included in the formulation to help soothe and heal gums.

Distributed by Linhart, Inc. 230 Park Avenue, Suite 1164 New York, NY 10169 212-972-8668

**Drug Facts**

**Active Ingredient** Purpose  
Sodium Fluoride 0.25% Anticavity



**Use**  
Aids in the prevention of dental decay.

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

**Inactive Ingredients**  
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**Questions?** 212.972.8668

LINHART.NYC

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LINHART  
TOOTHPASTE




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FLUORIDE  
TOOTHPASTE  
WITH  
LINÄMEL™  
ANISE|ALOE|MINT  
FORMULA

NET WT. 3.4OZ. (96G)



LH-TP-SP-3.5  
3 70926 00000 3



ESTABLISHED 1979

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1.850E

# LINHART

sodium fluoride toothpaste paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73333-096
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

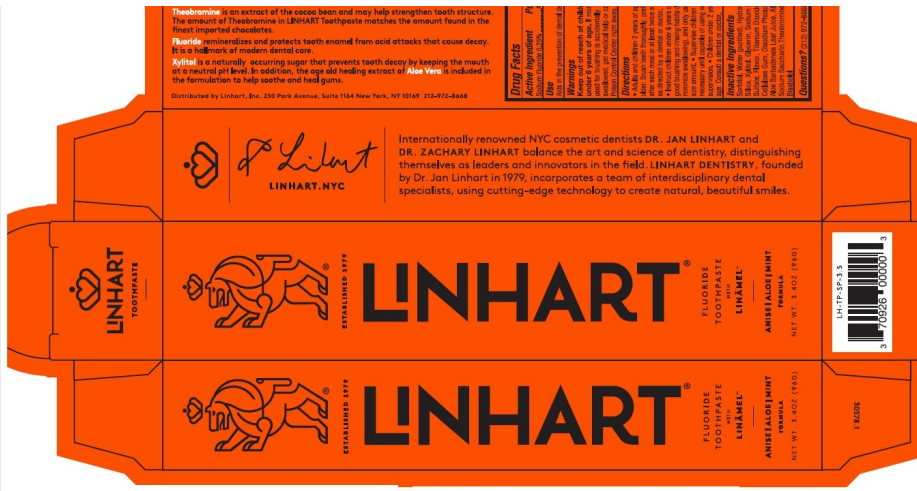
<b>Ingredient Name</b>	<b>Strength</b>
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
THEOBROMINE (UNII: OBD445WZ5P)	
XYLITOL (UNII: VCQ006KQ1E)	
ALLANTOIN (UNII: 344S277G0Z)	

## 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:73333-096-02	1 in 1 CARTON	09/25/2019	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/25/2019	

**Labeler** - Nutrix International,LLC (117341868)

## Establishment

Name	Address	ID/FEI	Business Operations
Nutrix, LLC		079833114	manufacture(73333-096)

Revised: 1/2020

Nutrix International,LLC