

**HEY HUMANS WHITENING WINTERMINT CHILL- sodium fluoride paste,  
dentifrice  
Maesa 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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**Hey Humans Whitening Wintermint Chill**

***Drug Facts***

**Active Ingredients**

Sodium Fluoride 0.25% (0.15% w/v fluoride ion)

**Purpose**

Anticavity

**Uses**

- 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 and older:
  - Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- Children 2 to 6 years:
  - To minimize swallowing, use only a pea-sized amount.
  - Supervise children's brushing and rinsing until good habits are established.
- Children under 2 years of age: Consult a dentist or physician.

**Inactive Ingredients**

Glycerin, Sorbitol, Hydrated Silica, Water, Xylitol, Cocamidopropyl Betaine, Flavor, Sodium Cocoyl Glutamate, Xanthan Gum, Stevia Rebaudiana Leaf/Stem Extract, Cellulose Gum, Menthol, Squalene.

**Questions or Comments**

You may report an adverse reaction to: HEY HUMANS c/o Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.

DIST. BY MAESA LLC, NEW YORK, NY 10281

**PRINCIPAL DISPLAY PANEL - 96 g Tube Carton**

Naturally Derived  
Toothpaste

With Fluoride

Hey  
Humans

Everice™  
Technology

WHITENING, ANTICAVITY,  
ANTI-PLAQUE, ANTI-TARTAR

Wintermint  
Chill

NET WT.  
96 g / 3.4 OZ.

# Hey Humans

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EXP XX/XXXX  
XXXXXXXXXX (batch code)

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For more information,  
please visit [www.heyhumans.com](http://www.heyhumans.com)  
DIST. BY MAESA LLC, NEW YORK, NY 10261



# HEY HUMANS WHITENING WINTERMINT CHILL

sodium fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71899-201
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O)	fluoride ion	1.5 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Hydrated Silica</b> (UNII: Y607T4G8P9)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3O11KX)	
<b>Sodium Cocoyl Glutamate</b> (UNII: BMT4RCZ3HG)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Carboxymethylcellulose Sodium, Unspecified</b> (UNII: K679OBS311)	
<b>Menthol, Unspecified Form</b> (UNII: L7T10EIP3A)	
<b>Squalene</b> (UNII: 7QWM220FJH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71899-201-01	1 in 1 CARTON	01/31/2021	
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	01/31/2021	

**Labeler** - Maesa LLC (144282311)

## Establishment

Name	Address	ID/FEI	Business Operations
Nutrix International LLC		117341868	MANUFACTURE(71899-201)

Revised: 3/2021

Maesa LLC