

**MAESA - HEY HUMANS- wintermint mint chill 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%

(0.15%w/v fluoride ion)

Purpose

Anticavity

Use

Helps protect against cavities.

Warnings

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

If more than use 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 doctor.

Children 2 to 6 years:

To minimize swallowing, use only a pea-size 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, water, Hydrate Silica, Sorbitol, Xylitol, Cocamidopropyl Betaine, Flavor, Xanthan Gum, Stevia Rebaudiana leaf/steam extract, Cellulose gum, Sodium cocoyl Glutamate, Menthol and Squalane.

Questions or Comments

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

For more Information, please visit www.heyhumans.com

Package, Label

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.

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Questions or Comments
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 c/o Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.
 DIST. BY MAESA LLC, NEW YORK, NY 10281.

Drug Facts

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

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Display Panel

MAESA - HEY HUMANS		
wintermint mint chill paste, dentifrice		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:73333-199
Route of Administration	BUCCAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.25 g in 96 g
Inactive Ingredients		
Ingredient Name	Strength	
MINT (UNII: FV98Z8GITP)	0.008 g in 96 g	

XANTHAN GUM (UNII: TTV12P4NEE)	0.004 g in 96 g
CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)	0.0016 g in 96 g
MENTHOL (UNII: L7T10EIP3A)	0.0011 g in 96 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	0.01678 g in 96 g
GLYCERIN (UNII: PDC6A3C0OX)	0.2801 g in 96 g
WATER (UNII: 059QF0KO0R)	0.1474 g in 96 g
XYLITOL (UNII: VCQ006KQ1E)	0.1 g in 96 g
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	0.0035 g in 96 g
SQUALANE (UNII: GW89575KF9)	0.00002 g in 96 g
SORBITOL (UNII: 506T60A25R)	0.25 g in 96 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.18 g in 96 g
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	0.005 g in 96 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73333-199-01	96 g in 1 TUBE; Type 0: Not a Combination Product	02/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/14/2021	

Labeler - Nutrix International, LLC. (117341868)

Establishment

Name	Address	ID/FEI	Business Operations
Nutrix International. LLC.		117341868	manufacture(73333-199) , label(73333-199) , pack(73333-199)

Revised: 4/2021

Nutrix International, LLC.