

**MAESA - HEY HUMAN- clean mint rush 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%

(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](http://www.heyhumans.com)

## Package, Label

**Drug Facts**

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

Display Panel

## MAESA - HEY HUMAN

clean mint rush paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73333-200
<b>Route of Administration</b>	BUCCAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 g in 96 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.2801 g in 96 g
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	0.01678 g in 96 g
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	0.0016 g in 96 g
<b>SORBITOL</b> (UNII: 506T60A25R)	0.25 g in 96 g
<b>WATER</b> (UNII: 059QF0KO0R)	0.1474 g in 96 g
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	0.18 g in 96 g
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	0.1 g in 96 g
<b>TETRAGONIA TETRAGONIODES WHOLE</b> (UNII: 414NLG6K5S)	0.008 g in 96 g
<b>SODIUM COCOYL GLUTAMATE</b> (UNII: BMT4RCZ3HG)	0.005 g in 96 g
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	0.004 g in 96 g
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)	0.0035 g in 96 g
<b>MENTHOL</b> (UNII: L7T10EIP3A)	0.0011 g in 96 g
<b>SQUALANE</b> (UNII: GW89575KF9)	0.00002 g in 96 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73333-200-01	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(73333-200) , label(73333-200) , pack(73333-200)

Revised: 4/2021

Nutrix International, LLC.