# DENTOVATIONS- lavender hand sanitizer 10oz liquid 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[s]

Alcohol 65%

## Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## **Warnings**

For external use only. Flammable. Keep away from heat or flame.

#### Do not use

Do not use

- On children less than 2 months of age.
- On open skin wounds.

## When using

**When using** this product keep out of eyes, ears, mouth. In case of contact with eyes, rinse thoroughly with water.

## Stop use

Stop use section and ask a doctor if irritation or rash occurs.

## Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Purpose

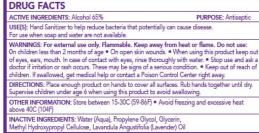
Activa Advanced Hand Sanitizer kills 99.9% of harmful germs and bacteria.

Made in USA

Dentovations Inc. Boston, MA 02108







#### **Directions**

- Place enough product on hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under age of 6 when using this product to avoid swallowing.

## Other Information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

## **Inactive Ingredients**

Water (Aqua), Propylene Glycol, Glycerin, Methyl hydroxypropyl Cellulose, Lavandula Angustifolia (lavender Oil)

## Package

#### DRUG FACTS PURPOSE: Antiseptic ACTIVE INGREDIENTS: Alcohol 65% USE(S): Hand Sanitizer to help reduce bacteria that potentially can cause disease For use when soap and water are not available. WARNINGS: For external use only. Flammable. Keep away from heat or flame. Do not use: On children less than 2 months of age . On open skin wounds. . When using this product keep out of eyes, ears, mouth. In case of contact with eyes, rinse thoroughly with water. . Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. . Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away DIRECTIONS: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under age 6 when using this product to avoid swallowing. OTHER INFORMATION: Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) INACTIVE INGREDIENTS: Water (Aqua), Propylene Glycol, Glycerin, Methyl Hydroxypropyl Cellulose, Lavandula Angustifolia (Lavender) Oil



Front Label

## **DENTOVATIONS**

lavender hand sanitizer 10oz liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73333-283	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.65 g in 283 g

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSES (UNII: 3NXW29V3WO)	0.0075 g in 283 g			
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.0005 g in 283 g			
GLYCERIN (UNII: PDC6A3C0OX)	0.01 g in 283 g			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.01 g in 283 g			
WATER (UNII: 059QF0KO0R)	0.322 g in 283 g			

ı	Pac	ckaging			
ı	# Item Code Package Description		Package Description	<b>Marketing Start Date</b>	Marketing End Date
	1 N	DC:73333-283-01	283 g in 1 BOTTLE; Type 0: Not a Combination Product	05/02/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/02/2020	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Nutrix International, LLC.		117341868	manufacture(73333-283), pack(73333-283), label(73333-283)	

Revised: 5/2020 Nutrix International, LLC.