

EAGLE PROMOTIONS- hand sanitizer 128oz gel
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[S]

Alcohol 70% v/v

PURPOSE

Antiseptic

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

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

STOP USE

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 6 years of age. When using this product 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, Melaleuca Alternifolia (Tea Tree) Leaf Oil.

DISPLAY PANEL

INSTANT HAND SANITIZER GEL

Kills 99.9% of Germs


70% Alcohol

Tea Tree Scented

128 FL OZ (3,785 ML)


Drug Facts

Active Ingredient(s) Alcohol 70% v/v	Purpose Antiseptic
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 - in children less than 2 months of age - on open skin wounds	
When using this product keep out of the eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask 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 6 years of age 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, Melaleuca Alternifolia (Tea Tree) leaf Oil.	



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Eagle Promotions
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MADE IN
U. S. A.

Label

EAGLE PROMOTIONS

hand sanitizer 128oz gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73333-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 g in 3974 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.01 g in 3974 g
WATER (UNII: 059QF0KO0R)	0.273 g in 3974 g
HYPROMELLOSES (UNII: 3NXW29V3WO)	0.007 g in 3974 g
TEA TREE OIL (UNII: VIF565UC2G)	0.002 g in 3974 g
GLYCERIN (UNII: PDC6A3C0OX)	0.008 g in 3974 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:73333-128-01	3974 g in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		07/08/2020	

Labeler - Nutrix International, LLC. (117341868)

Establishment			
Name	Address	ID/FEI	Business Operations
Nutrix International, LLC.		117341868	manufacture(73333-128) , pack(73333-128) , label(73333-128)

Revised: 7/2020

Nutrix International, LLC.