VYDAL SCENTED HAND SANITIZER- vydal scented hand sanitizer liquid List Distillery, 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] Purpose

Alcohol 80% v/v.....Antiseptic

Do not use

- In children under 2 months of age.
- On open skin wounds.

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Warnings

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. NOT FOR CONSUMPTION. DO NOT INGEST.

Other Information

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

Inactive Ingredients

Gylcerin, Hydrogen Peroxide, Orange Oil, Eucalyptus Oil, English Lavender Oil, Purified Water USP

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.

Use [s]

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

Use [s]

- Hand sanitizer helps reduce bacteria that potentially causes disease.
- For use when soap and water are not available.

VYDAL

80% Alcohol **Scented Hand Sanitizer** Cleansing Zen

- WHO Recommended Hand Rub
 - Formulation #1
- FOR EXTERNAL USE ONLY
- NOT SAFE FOR CONSUMPTION
- NON-STERILE SOLUTION

3.4oz / 100mL



Drug Facts

Active ingredient(s)

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

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

In case of contact with eyes, rinse eyes thoroughly with water NOT FOR CONSUMPTION. DO NOT INGEST.

Stop use and ask a doctor if irritation or rash occur

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

Directions

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Inactive ingredients Glycerin,Hydrogen Peroxide,Orange Essential Oil, Eucalyptus Essential Oil, Lavender Essential Oil,Purified Water USP.

Product of List Distillery,LLC www.listdistillery.com



VYDAL

80% Alcohol

Scented Hand Sanitizer

Cleansing Zen

• WHO Rocommended Hand Rub

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3.4 fl oz/100 mL

MADE IN USA

VYDAL SCENTED HAND SANITIZER

vydal scented hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74563-003
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TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

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Ingredient Name		Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	800 mL in 1000 mL	

Inactive Ingredients				
Ingredient Name	Strength			
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)				
ORANGE OIL (UNII: AKN3KSD11B)				
EUCALYPTUS OIL (UNII: 2R040NI662)				
WATER (UNII: 059QF0KO0R)	184.2 mL in 1000 mL			
GLYCEROL FORMAL (UNII: 3L7GR2604E)	14.5 mL in 1000 mL			
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	1.3 mL in 1000 mL			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:74563-003- 01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/15/2020		

Labeler - List Distillery, LLC (087028906)

Registrant - List Distillery, LLC (087028906)

Establishment					
Name	Address	ID/FEI	Business Operations		
List Distillery, LLC		087028906	manufacture(74563-003)		

Revised: 6/2020 List Distillery, LLC