

DEFENDR HAND SANITIZER- ethyl alcohol gel
TASTE BEAUTY 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.

DEFENDR+ Hand Sanitizer

Defendr Hand Sanitizer is a a human over the counter drug product labeled by Taste Beauty Llc. The generic name of Defendr Hand Sanitizer is alcohol. The product's dosage form is gel and is administered via topical form.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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 eyes, ears, and mouth. In case of contact with eyes, rinse eyes 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.

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 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

Deionized water, Acrylates/C10-30 alkyl acrylate crosspolymer, Triethanolamine, EDTA.

Package Label - Principal Display Panel

 HAND SANITIZER + Kills 99% of Germs + Anti Bacterial		unscented + moisturizing 8 FL OZ / 236 mL	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Ethyl alcohol 70% v/v</td> <td>Antiseptic</td> </tr> </table> <p>Use ● Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from fire and flames.</p> <p>Do not use ● In children less than 2 months of age. ● On open skin wounds</p> <p>When using this product ● Keep out of eyes, ears and mouth. ● In case of contact with eyes, rinse eyes thoroughly with water.</p>	Active ingredient	Purpose	Ethyl alcohol 70% v/v	Antiseptic	<p>Stop use and ask a doctor if ● Irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Other information ● Store between 15-30°C (59-86°F) ● Avoid freezing and excessive heat above 40°C(104°F)</p> <p>Inactive ingredients Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol</p>	 1 119 043 0103 889 113
Active ingredient	Purpose								
Ethyl alcohol 70% v/v	Antiseptic								

DEFENDR HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74825-5071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.75 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	33.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74825-5071-5	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

