

HAND SANITIZER- alcohol gel
Weckerle Cosmetics 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.

HAND SANITIZER

Drug Facts

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Anti-microbial

Use

- Hand Sanitizer to help reduce bacteria on skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using the product.

Other Information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

Water , Glycerin, Propanediol, Panthenol, Aminomethyl Propanol, Carbomer, Fragrance, Carthamus Tinctorius (Safflower) Seed Oil, Cucumis Sativus (Cucumber) Fruit Extract, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Sodium Hyaluronate, Green 5, Tocopheryl Acetate.

PRINCIPAL DISPLAY PANEL - 100 mL Bottle Label

precos

HAND
SANITIZER
GEL

KILLS
99.9%
OF GERMS
& BACTERIA

WITH ALOE VERA
& PRO VITAMIN B5
TO MOISTURIZE

OCEAN

3.4 FL OZ / 100mL

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HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62516-001
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		
Water (UNII: 059QF0KO0R)				
Glycerin (UNII: PDC6A3C0OX)				
Propanediol (UNII: 5965N8W85T)				
Panthenol (UNII: WV9CM0O67Z)				
Aminomethylpropanol (UNII: LU49E6626Q)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
Safflower Oil (UNII: 65UEH262IS)				
Cucumber (UNII: YY7C30VXJT)				
Aloe Vera Leaf (UNII: ZY81Z83H0X)				
Phenoxyethanol (UNII: HIE492ZZ3T)				
Hyaluronate Sodium (UNII: YSE9PPT4TH)				
D&C Green No. 5 (UNII: 8J6RDU8L9X)				
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62516-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333A	06/19/2020		

Labeler - Weckerle Cosmetics LLC (152060273)

Establishment

Name	Address	ID/FEI	Business Operations
Weckerle Cosmetics LLC		152060273	LABEL(62516-001) , MANUFACTURE(62516-001)

Revised: 7/2020

Weckerle Cosmetics LLC