CANDO ULTRA HAND SANITIZER- alcohol gel Fabrication Enterprises

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.

CANDO Ultra Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

USES

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 flame.

DO NOT USE

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

WHEN USING THE 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 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

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

OTHER INFORMATION

- •Store below 104°F (40°C)
- Avoid freezing and excessive heat above 104°F (40°C)
- May discolor certain fabrics or surfaces

INACTIVE INGREDIENTS

Aloe Vera, Carbomer Interpolymer (type B), Glycerin, Lemon oil, Triethanolamine, Water (Aqua)

Package Label - Principal Display Panel



Enhanced with moisturizers (including Aloe Vera) for soft hands

> Kills 99% of most common germs

Net Wt. 8 FL. OZ. (236ml)

Drug Facts	NDC XXXXX-XXXX-X
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Manufactured for: Fabrication	
250 Clearbrook Road, Suite 2 tel: +1-914-345-9300 / 800-4 fax: +1-914-345-9800 / 800-6 FabEnt.com	31-2830
250 Clearbrook Road, Suite 2 tel: +1-914-345-9300 / 300-43 fax: +1-914-345-9800 / 800-6	31-2830 194-5370
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CANDO ULTRA HAND SANITIZER

alcohol gel

Prod	uct Ii	nform	ation
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Product Type HUMAN OTC DRUG NDC:51452-108 Item Code (Source)

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	
TROLAMINE (UNII: 9O3K93S3TK)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
LEMON OIL (UNII: 19 GRO 8 2 4 L L)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:51452-108- 01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/29/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/29/2020	

Labeler - Fabrication Enterprises (070577218)

Revised: 9/2020 Fabrication Enterprises