

HAND SANITIZER- alcohol gel
Orlandi Inc.

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.

50x80

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Reduces bacteria on skin

Warnings

Flammable. Keep away from fire or flame. For external use only. Do not use in or near the eyes. In case of contact rinse with water.

Do not use

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

For external use only. Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and consult a doctor if irritation occurs. Keep out of reach of children, If swallowed, get medical help or contact a Poison Control Center immediately.

Stop use and ask a doctor if irritation occurs.

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

Directions

- Place enough product in your palm to thoroughly cover your hands and rub together until dry.
- Children under 6 years should be supervised when using this product.

Other information

Store at temperature below 110F (43C)

May discolor certain fabrics or surfaces.

Inactive ingredients

water, glycerin, carbomer, triethanolamine

Package Label - Principal Display Panel

.05 fl oz (1.5 ml) NDC 68320-234



V-Shapes Design Layout

50 x 80 mm

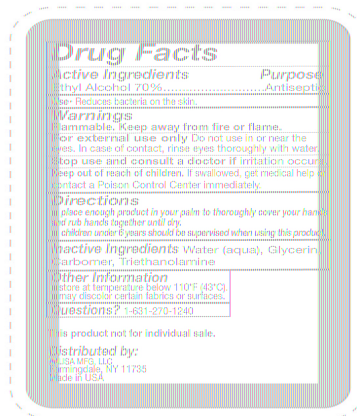
TOP LAYOUT

- Die cut
- Heat Seal



BOTTOM LAYOUT

- Die cut
- Heat Seal



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68320-234
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)	0.02 mL in 100 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.7 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68320-234-05	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	05/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

Labeler - Orlandi Inc. (079801467)

Registrant - orlandi inc (079801467)

Establishment

Name	Address	ID/FEI	Business Operations
Orlandi Inc		079801467	manufacture(68320-234) , pack(68320-234) , label(68320-234)

Revised: 5/2020

Orlandi Inc.