HAND SANITIZER- alcohol gel DVRYL International Limited

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

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use.

Warnings

Flammable, keep away from fire or flame

For external use only.

Do not use

in the eyes.

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Wet hands thoroughly with product and allow to dry without wiping.

Other information

Store at 15° to 25°C (59° to 77°F)

Inactive ingredients

Carbomer, propylene glycol, purified water, titanium dioxide

TO REPOT ADVERSE EVENT, CONTACT +1(727)441-3222

Package Labeling:





HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78894-000

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) ALCOHOL 0.7 mL in 1 mL

Strength

Ingredient Name

 $\textbf{CARBO\,MER\,HO\,MO\,PO\,L\,YMER,\,UNSPECIFIED\,TYPE}~(UNII:\,0\,A5MM30\,7FC)$

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

Inactive Ingredients

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:78894-000-06	1 in 1 BOX	05/10/2020	

1 2	00 mL in 1 BOTTLE; Type 0: Not a Combination Produc	t				
Marketing Info	Aarketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333E	05/10/2020				

Labeler - DVRYL International Limited (664206198)

Revised: 7/2020 DVRYL International Limited