SANELL HAND SANITIZER- alcohol gel
OraLabs

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.

Drug Facts

Active ingredient

Ethyl Alcohol 63.00%

Purpose

Antiseptic

Keep Out of Reach of Children

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

Uses

For handwashing to decrease bacteria on the skin.

Warnings

For external use only: Hands. Flammable. Keep away from fire or flame. When using this product: keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest. Stop use and ask a doctor: if irritation and redness develop. Condition persists for more than 72 hours.

Directions

Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

Inactive Ingredients

Carbomer, DMDM Hydantoin, Fragrance, Isopropanol, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Package/Label Principal Display Panel

SANELL HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63645-166
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58.10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.010 mg in 1 g
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	.310 mg in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	.500 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-166-01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	03/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/07/2018	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-166) , LABEL(63645-166)

Revised: 11/2022 OraLabs