SANELL HAND SANITIZER- alcohol spray
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. Do not use in the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor: if irritation and redness develop and persists for more than 72 hours.

Directions

Wet hands thoroughly with product and allow to dry without wiping. Supervise children in the use of this product.

Inactive Ingredients

Dimethicone, Disodium EDTA, DMDM Hydantoin, Fragrance, Polysorbate 20, Propanediol, Water.

Package/Label Principal Display Panel

SANELL HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63645-174
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	6.3 mL in 10.0 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	0.004 mL in 10.0 mL
WATER (UNII: 059QF0KO0R)	3.581 mL in 10.0 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-174-02	10.0 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/12/2019	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-174) , LABEL(63645-174)

Revised: 1/2022 OraLabs