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.

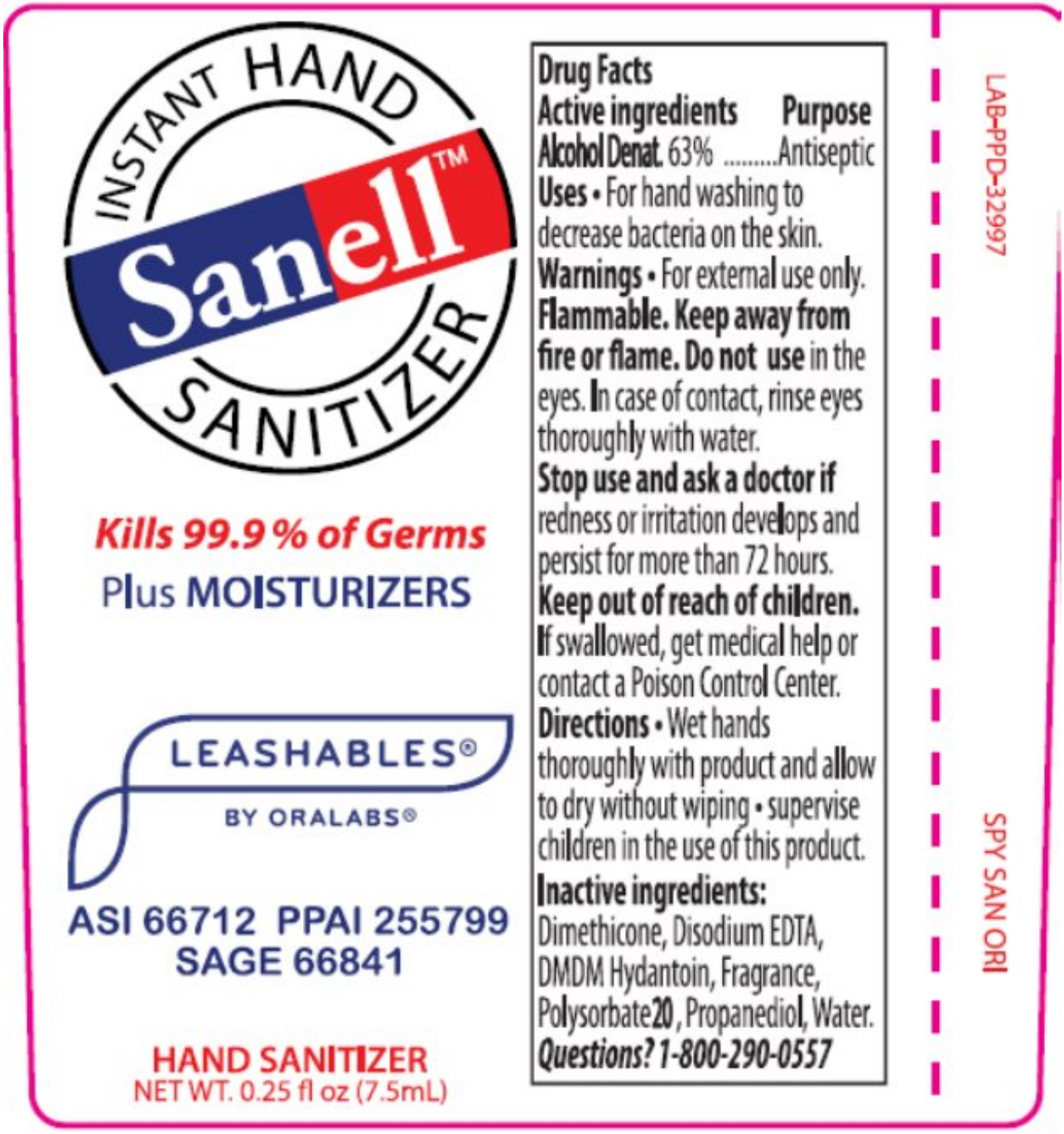
Directions

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:63645-167
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	0.043 mL in 1 mL
WATER (UNII: 059QF0KO0R)	56.205 mL in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63645-167-01	1 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(63645-167) , LABEL(63645-167)

Revised: 8/2019 OraLabs