DERMOKIL- hand sanitizer gel gel
Halshe, LLC

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.

Active Ingredient(s)

Ethyl Alcohol 71.5% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

Do not use on damaged, inflamed or broken skin

When using this product

Avoid contact with eyes

In case of eye contact, rinse eyes thoroughly with water

Stop use

Stop use and ask a doctor if irritation or redness develops and lasts for more than 72 hours.

Keep out of reach of children

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
- allow to dry without wiping

Other information

Other information

- keep out of direct sunlight
- store in dry conditions

Inactive ingredients

glycerin, isopropyl alcohol, sodium hydroxide, purified water USP

Use

Use for hand sanitizing to decrease bacteria on the skin

Package Label - Principal Display Panel

500 ml NDC: 75004-786-55

DERMOKIL

hand sanitizer gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75004-786
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71.5 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75004-786-55	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Halshe, LLC (114395503)

Registrant - Halshe, LLC (114395503)

Establishment

Name	Address	ID/FEI	Business Operations
EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.S.		566224588	manufacture(75004-786)

Revised: 4/2020 Halshe, LLC