## DERMACEN INSTANT HAND SANITIZER WITH ALOE- alcohol liquid Central Solutions Inc

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.

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## **Drug Facts**

Active Ingredients

Ethanol 64.5% (w/w)

Purpose

Hand Sanitizer

Uses

An antiseptic hand sanitizer for topical application

Prevents infection and cross contamination

Reduces transient microorganisms on intact skin

Keeps hands from drying out due to repeated uses

Warnings

For External Use Only

Flammable, keep away from fire or flame

When using this product

Avoid contact with eyes

In case of eye contact, flush with water for 15 minutes

Discontinue use and see a doctor if irritation occurs

Avoid contact with broken skin.

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.

Use no water or towels.

Other Information

DermaCen products are not tested on animals

**Inactive Ingredients** 

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, EDTA, Fragrance, Glycerin, Tetrahydroxypropyl Ethylenediamine, Tocopherol (Vitamin E), Water, Yellow 5, Blue 1

DermaCen

Instant

Hand Sanitizer

with Aloe

Contains

Vitamin E

For hand washing

to decrease bacteria

on the skin

Net Contents

2.5 ounces (74 ml)



alcohol liquid

Product Information				
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62654-143

Route of Administration TOPICAL

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	<b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	64.5 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
EDETIC ACID (UNII: 9G34HU7RV0)			
GLYCERIN (UNII: PDC6A3C0OX)			
EDETOL (UNII: Q4R969U9FR)			
TOCOPHEROL (UNII: R0ZB2556P8)			
WATER (UNII: 059QF0KO0R)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:62654-143- 19	74 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
2	NDC:62654-143- 12	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
3	NDC:62654-143- 06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
4	NDC:62654-143- 02	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
5	NDC:62654-143- 03	443 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
6	NDC:62654-143- 92	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/0 1/20 0 1		
7	NDC:62654-143- 37	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2001		
8	NDC:62654-143- 04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	0 1/0 1/20 0 1		

## Labeler - Central Solutions Inc (007118524)

Establishment				
Name	Address	ID/FEI	Business Operations	
Central Solutions Inc		007118524	manufacture(62654-143)	

Revised: 3/2020 Central Solutions Inc