LUIANTT HAND SANITIZER GEL- alcohol gel DERMACOS KOREA

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)

Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.
- Not recommended for infants.

Other information

- Store at room temperature (33.8oF-86oF, 1oC-30oC) and avoid cold or dry place.
- May discolor certain fabrics or surfaces.
- Harmful to wood finishes and plastics.

Inactive ingredients

Aloe Vera Gel, Carbomer, Fragrance (Lemon), Glycerin, Green Tea Extract, Purified Water, Sodium Hyaluronate, Triethanolamine.

Package Label - Principal Display Panel



Product Info	rmation				
Product Type		HUMAN OTC DRUG Item Co		(Source)	NDC:77637-100
Route of Admin	istration	TOPICAL			
Active Ingre	lient/Active Moi	ety			
	Ingred		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL	70 mL in 100 mL
Inactive Ingr	edients				
		Ingredient Name			Strength
GREEN TEA LEA	F (UNII: W2ZU1RY8B	0)			
ALOE VERA LEA	AF (UNII: ZY81Z83H02	X)			
GLYCERIN (UNI					
WATER (UNII: 05	9QF0KO0R)				
	NII: 903K93S3TK)				
	SODIUM (UNII: YSES	9PPT4TH) PECIFIED TYPE (UNII: 0A5MM30)			
	acteristics	Score			
Color	racteristics	Score			
Color Shape	racteristics	Size			
Color Shape Flavor	acteristics				
Color Shape Flavor	racteristics	Size			
Color Shape Flavor Contains	acteristics	Size			
Color Shape Flavor Contains Packaging		Size Imprint Code		Marketing Start	Marketing End
Color Shape Flavor Contains Packaging		Size		Marketing Start Date	Marketing End Date
Color Shape Flavor Contains Packaging # Item Code	2	Size Imprint Code		_	_
Color Shape Flavor Contains Conta	2. 500 mL in 1 BOT Product D- 300 mL in 1 BOT Product	Image: Size Image: Size Image: Size Image: Size Image: Size Image: Size	natio n	Date	_
Color Shape Shape Flavor Contains Item Code 1 NDC:77637-10 2 NDC:77637-10 3 NDC:77637-10	 500 mL in 1 BOT 500 mL in 1 BOT Product 300 mL in 1 BOT Product 100 mL in 1 TUB 	Imprint Code Package Description TLE, PUMP; Type 0: Not a Combin	natio n natio n	Date 05/13/2020	_
Color Shape Flavor Contains Cont	 500 mL in 1 BOT 500 mL in 1 BOT Product 300 mL in 1 BOT Product 100 mL in 1 TUB 	Imprint Code Imprint Code	natio n natio n	Date 0 5/13/20 20 0 5/13/20 20	_
C → I → F S → J → F S → J → F F → T → T → T → T → T → T → T → T → T →	 Soo mL in 1 BOT Product Soo mL in 1 BOT Product 300 mL in 1 BOT Product 100 mL in 1 TUB 1 in 1 BOX 2 mL in 1 PACKE 	Imprint Code Imprint Code	lation lation	Date 0 5/13/20 20 0 5/13/20 20 0 5/13/20 20	Date
S → pe F → vor C → ntains B → ckaging # Item Code 1 NDC:77637-10 2 NDC:77637-10 3 NDC:77637-10 4 NDC:77637-10	 Soo mL in 1 BOT Product Soo mL in 1 BOT Product Soo mL in 1 BOT Product 100 mL in 1 TUB 1 in 1 BOX 2 mL in 1 PACKE 0 in 1 BOX 	Imprint Code Package Description TLE, PUMP; Type 0: Not a Combination Prod E; Type 0: Not a Combination Prod	lation lation luct luct	Date 0 5/13/20 20 0 5/13/20 20 0 5/13/20 20	Date



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - DERMACOS KOREA (695625857)

Registrant - DERMACOS KOREA (695625857)

Establishment

Name	Address	ID/FEI	Business Operations
DERMACOS KOREA		695625857	manufacture(77637-100)

Revised: 5/2020

DERMACOS KOREA