TRITANIUM LABS HAND SANITIZER HAND SANITIZER- alcohol gel Tritanium Labs, USA 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.

Tritanium Labs Hand Sanitizer

Active Ingredients

Active ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial

Inactive Ingredients

Water (Aqua)

Aloe Barbadensis Leaf Juice (Stabilized* Aloe Vera Gel)

Isopropyl Alcohol

Glycerin

Tetrahydroxypropyl Ethylenediamine

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Tocopheryl Acetate Isopropyl Myristate.

Purpose Section

Uses

- Hand sanitizer to help decrease bacteria on the skin.
- When water, soap & towel are not available.
- Recommended for repeated use.

Warnings

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For external use only.

Flammable. Keep away from fire or flame.

Indications & Usage

When using this product, avoid contact with eyes.

In case of contact flush eyes with water.

Stop use and ask a doctor if

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• Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

Keep out of reach of children

Keep out of reach of children. Children must be supervised in use of this product.

Dosage & Administration Directions

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Other information

- store at 20 °C (68°F to 77°F)
- may discolor certain fabrics

Package Label Principal Display Panel





alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77757-121	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 g in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
EDETOL (UNII: Q4R969U9FR)				
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY81Z83H0 X)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				

ı	Pa	ckaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 N	IDC:77757-121-01	3780 g in 1 JUG; Type 0: Not a Combination Product	05/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - Tritanium Labs, USA LLC (080935552)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dhaliwal Pharmaceuticals Laboratories LLC		116933772	manufacture(77757-121)	

Revised: 5/2020 Tritanium Labs, USA LLC