BODY PRESCRIPTIONS REFRESHING HAND SANITIZER UNSCENTED- ethyl alcohol gel ENCHANTE ACCESSORIES 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.

Active Ingredient

Alcohol Denat. 75%

Purpose

Antiseptic

Use

To decrease bacteria on the skin that could cause disease
Recommended for repeated use

WARNINGS

For external use only, Hands

Flammable. Keep away from heat and flame

When using this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water

Avoid contact with broken skin

Do not inhale or ingest

Stop Use

Stop use and ask a doctor if skin irritation develops

keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

Directions

Wet hands thoroughly with product and allow to dry without wiping For children under 6, use only under adult supervision Not recommended for infants

Other information

Do not store above 105F May discolor some fabrics Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, PEG-40 Hydrogenated castor oil, Carbomer, Triethanolamine, Blue 1, Red 33



BODY PRESCRIPTIONS REFRESHING HAND SANITIZER UNSCENTED ethyl alcohol gel

Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-197
Route of Administration	TOPICAL		
Active Ingredient/Ac	tive Moiety		
	Ingredient Name	Basis of Streng	th Strength
ALCOHOL (UNII: 3K9958)	V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
WATER (UNII: 059QF0KOC	DR)		
GLYCERIN (UNII: PDC6A3	C0OX)		
FD&C BLUE NO. 1 (UNII: H	BR47K3TBD)		
TROLAMINE (UNII: 903K9)3S3TK)		
CARBOMER 934 (UNII: Z1	35WT9208)		
D&C RED NO. 33 (UNII: 91	DBA0SBB0L)		
Packaging			
# Item Code	Package Description	Marketing Start Da	te Marketing End Date

1 NDC:50563-197-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
Marketing In	formation		

Marketing motimation					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	06/01/2020			

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment Name Address ID/FEI Business Operations

INdille	Auuress	ID/FLI	Dusiness Operations
Xiamen Chengda Industrial Co.,Ltd		540042034	manufacture(50563-197)

Revised: 6/2020

ENCHANTE ACCESSORIES INC.