SPATHERAPY - alcohol lotion TRIZ LABORATORIES LTD

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.

Drug Facts

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Acrylates/C10-30

Alkyl Acrylate Crosspolymer, DMDM Hydantoin, Parfum,

Sodium Hydroxide, Tocopherol Acetate,

Simmondsia, Chinensis

(Jojoba) Seed Wax,

CI 42090, CI 19140

Active Ingredient

Alcohol Denat 60 % w/w

Purpose Antibacterial

Use - To decrease bacteria

on the skin and clean hands - Recommended

for repeated use

Warnings

For external use only

Keep Out of Reach of Children. If accidentally

swallowed, get medical help or contact a

Poison Control Center right away.

Do not get into eye. If contact

occurs, rinse thoroughly with water.

Discontinue use if irritation or redness

develops. If irritation persists for more than

72 hours, consult a doctor.

Directions - Apply to hands

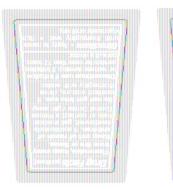
until thoroughly wet. Rub

vigorously until dry.

Bubble Gum 310C







alcohol lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53057-010
Poute of Administration	TOPICAL.		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	18 mL in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6 Y9 FJJ2)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53057-010-01	30 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 1/15/20 14		

Labeler - TRIZ LABORATORIES LTD (421290822)

Establishment				
Name	Address	ID/FEI	Business Operations	
TRIZ LABORATORIES LTD		421290822	manufacture(53057-010)	

Revised: 2/2014 TRIZ LABORATORIES LTD