

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.

alcohol lotion

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	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 HYDANTOIN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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	01/15/2014	

Labeler - TRIZ LABORATORIES LTD (421290822)

Establishment

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