SPATHERAPY LAVENDER JASMINE - 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,

D and C Red 33 CI 17200, FD and C Blue 1 CI 42090

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.

Flammable, keep away from fire or flame

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.







SPATHERAPY LAVENDER JASMINE

alcohol lotion

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:53057-020

Route of Administration TOPICAL

Active Ingredient/Active Moiety

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

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)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6 Y9 FJJ2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Pacl	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:53057-020-01	30 mL in 1 BOTTLE			
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Marketing Information				
Marketing Category	Application Number or Monog	raph Citation	Marketing Start Dat	e Marketing End Date
OTC monograph not final	part333E		02/18/2015	

Labeler - TRIZ LABORATORIES LTD (421290822)

Establishment				
Name	Address	ID/FEI	Business Operations	
TRIZ LABORATORIES LTD		421290822	manufacture(53057-020)	

Revised: 2/2015 TRIZ LABORATORIES LTD