SPATHERAPY LEMON POMEGRANATE - 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,

Denat Alcohol, FD and C Yellow 5 (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.

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 LEMON POMEGRANATE

alcohol lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53057-021
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 HYDANTO IN (UNII: BYR0546 TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6 Y9 FJJ2)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:53057-021-01	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	02/18/2015	

Labeler - Triz Laboratories Ltd (421290822)

Establishment				
Name	Address	ID/FEI	Business Operations	
TRIZ LABORATORIES LTD		421290822	manufacture(53057-021)	

Revised: 2/2015 TRIZ LABORATORIES LTD