

MOJITO SUN - alcohol gel
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,

FD and C Yellow 5 CI 19140, 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.

FRONT LABELS



DOUBLE-S REMOVABLE



alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53057-013 |
| 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 YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:53057-013-01 | 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 | 05/13/2014 | |

Labeler - TRIZ LABORATORIES LTD (421290822)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|----------------|---------------|----------------------------|
| TRIZ LABORATORIES LTD | | 421290822 | manufacture(53057-013) |