

PURELL ADVANCED SKIN BALANCING HAND SANITIZER- alcohol gel
GOJO Industries, Inc.

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.

PURELL Advanced Skin Balancing Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110°F (43°C) • May discolor certain fabrics or surfaces

Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Glycerin, Bacillus Ferment, Caprylyl Glycol, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum)



PURELL ADVANCED SKIN BALANCING HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21749-480 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |

| Packaging | | | | |
|-------------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:21749-480-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2016 | |
| 2 | NDC:21749-480-02 | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2016 | |
| 3 | NDC:21749-480-08 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2016 | |
| 4 | NDC:21749-480-12 | 354 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/30/2016 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part333E | 12/30/2016 | |
| | | | | |

Labeler - GOJO Industries, Inc. (004162038)

| Establishment | | | |
|-----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| GOJO Industries, Inc. | | 036424534 | manufacture(21749-480) |