

PURELL ADVANCED HAND SANITIZER BE PEACEFUL- 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.

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antimicrobial

Use

Hand sanitizer to help reduce bacteria on the 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

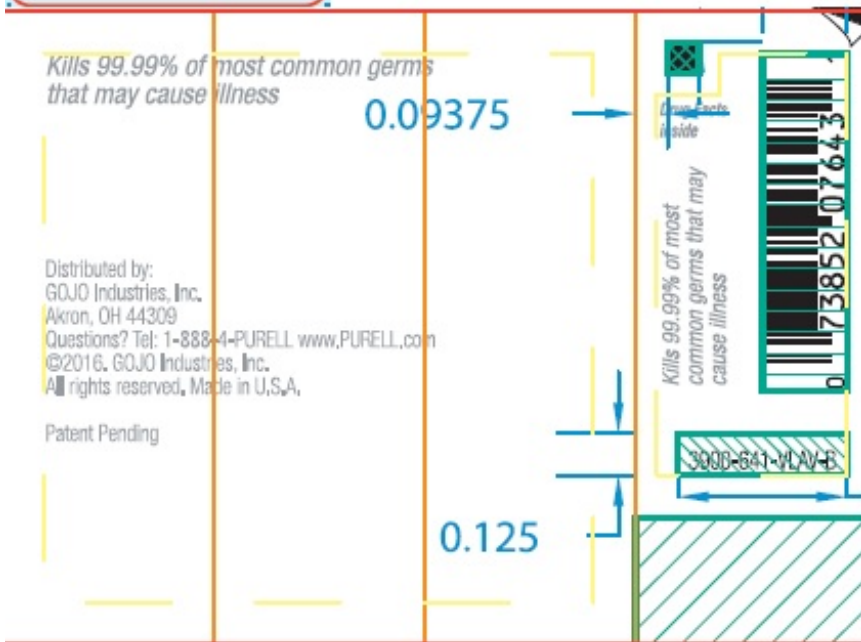
- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Caprylyl glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum), Blue 1 (CI 42090), Red 40 (CI 16035)



Drug Facts		Drug Facts (continued)	
Active ingredient	Purpose	Directions • Place enough product in your palm to thoroughly cover your hands	
Ethyl Alcohol 70% w/v	Antimicrobial	• Rub hands together briskly until dry	
Use • Hand sanitizer to help reduce bacteria on the skin		• Children under 6 years of age should be supervised when using this product	
Warnings		Other information	
Flammable. Keep away from fire or flame. For external use only.		• Store below 110°F (43°C)	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.		• May discolor certain fabrics or surfaces	
Stop use and ask a doctor if irritation or rash appears and lasts		Inactive ingredients	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Water (Aqua), Isopropyl Alcohol, Caprylyl glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum), Blue 1 (CI 42090) Red 40 (CI 16035)	



PURELL ADVANCED HAND SANITIZER BE PEACEFUL			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21749-027
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients			

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-027-01	30 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
2	NDC:21749-027-02	59 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
3	NDC:21749-027-04	118 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
4	NDC:21749-027-08	236 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
5	NDC:21749-027-10	295 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
6	NDC:21749-027-12	354 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
7	NDC:21749-027-45	450 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
8	NDC:21749-027-16	473 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	
9	NDC:21749-027-20	591 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/22/2016	

Labeler - GOJO Industries, Inc. (004162038)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	manufacture(21749-027)

Revised: 12/2016

GOJO Industries, Inc.