PURELL ADVANCED SOOTHING- 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 Hand Sanitizer Soothing Gel

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antimicrobial

Uses

- 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

- Put enough product in your palm to cover hands and rub hands together briskly until dry
- Children under 6 years of age should be supervised when using PURELL

Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum), Blue 1 (CI 42090), Yellow 5 (CI 19140)

Distributed by: GOJO Industries, Inc. Akron, OH 44309
Questions? Tel: 1-888-4-PURELL www.PURELL.com

PURELL ADVANCED SOOTHING

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21749-713
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)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21749-713-01	30 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:21749-713-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
3	NDC:21749-713-04	118 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
4	NDC:21749-713-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
5	NDC:21749-713-10	295 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
6	NDC:21749-713-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
7	NDC:21749-713-20	591 mL in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	11/01/2018	
8	NDC:21749-713-27	800 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
9	NDC:21749-713-28	826 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
10	NDC:21749-713-33	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
11	NDC:21749-713-40	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	
12	NDC:21749-713-67	2000 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/01/2018	

Labeler - GOJO Industries, Inc. (004162038)

Establishment

Name	Address	ID/FEI	Business Operations
GOJO Industries, Inc.		036424534	MANUFACTURE(21749-713)

Establishment

Name	Address	ID/FEI	Business Operations

GOJO Industries, Inc.		088312414	MANUFACTURE(21749-713) , label(21749-713) , pack(21749-713)