

PURESAN HAND SANITIZING- alcohol gel
Avro Enterprises LLC

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.

Puresan Hand Sanitizing Gel

Drug Facts

Active ingredient

Alcohol 70% v/v

Purpose

Antiseptic

Uses

- To decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

For external use only. Flammable, keep away from fire or flame.

When using this product keep out of eyes. In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours.

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

Directions

- Apply liberally to hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under 6 years old.
- Not recommended for infants.

Inactive ingredients Water, Isopropyl Alcohol, PEG/PPG-18/18 Dimethicone, Acrylates/C 10/30 Alkyl Acrylate Crosspolymer, Fragrance, Triethanolamine, Alpha-tocopherol Acetate (Vitamin E), Aloe Barbadosensis Leaf Juice, FD&C Yellow 5, FD&C Blue 1.

Distributed By: Puresan

24 Ames Blvd., Hamburg, NJ 07419

855.500.8080 • puresanusa.com

Instant **Hand Sanitizing gel**

70% Alcohol • Kills 99.9% Germs

With Aloe Vera & Vitamin E

33.8 fl. oz. (1000 mL) Refill Bag GEL

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Other information May discolor certain fabrics and surfaces.	
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Item# HS1000
AVRO-HS1000 Rev. 1.02

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PURESAN HAND SANITIZING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73062-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII:	

132584PQMO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73062-135-01	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/20/2021	07/11/2024
2	NDC:73062-135-18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/06/2021	11/11/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/20/2021	07/11/2024

Labeler - Avro Enterprises LLC (804030166)

Revised: 1/2023

Avro Enterprises LLC