PURESAN HAND SANTIZING GEL- alcohol gel
Inopak. 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.

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puresan Hand Sanitizing Gel 135

Active Ingedient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Children reach

- Keep out of eyes, ears or mouth. In case of eye contact, flush eyes with water.

Uses

- To decrease bacteria on the skin that potentially can cause disease
- Recommended for repeated use

Warnings

- Flammable, keep away from heat or flame.
- For external use only.
- Keep out of eyes, ears or mouth. In case of eye contact, flush 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 right away. Children should be supervised by an adult when using this product.

Stop Use

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

Directions

- Apply sufficient amount of product to your palm to cover both hands.
- Rub until dry.

Inactive Ingredient

Acrylates/C 10/30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, D&C Blue 1, FD&C Yellow 5, Fragrance, Isopropyl Alcohol, PEG/PPG-18/18 Dimethicone, Triethanolamine, Vitamin E, Water

puresan individual lable

Instant Waterless

Hand Kills 99.99% of Germs

Santizing Gel

With Aloe Vera & Vitamin E

1000 mL

Refill Bag GEL

Item# Hs1000 puresan

Cleaning innovations

MADE

IN THE USA

Drug Facts **Active Ingredient** **Purpose** Ethyl Alcohol 70% v/v …….. Antiseptic **Uses** • To decrease bacteria on the skin that potentially can cause disease • Recommended for repeated use **Warnings** • Flammable, keep away from heat or flame. • For external use only. • Keep out of eyes, ears or mouth. In case of eye contact, flush 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 right away. Children should be supervised by an adult when using this product.	**Directions** • Apply sufficient amount of product to your palm to cover both hands. • Rub until dry. **Other Information** May discolor certain fabrics and surfaces. **Inactive Ingredients** Acrylates/C 10/30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, D&C Blue 1, FD&C Yellow 5, Fragrance, Isopropyl Alcohol, PEG/PPG-18/18 Dimethicone, Triethanolamine, Vitamin E, Water

Rev. 1.01

PO Box 170 Sparta NJ 077871

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puresan case label

puresan puresanusa.com

cleaning innovations (855) 800-8080

ITEM # HS1000GOB-D-C8

PURESAN 1000ml Instant Hand Sanitizer

Disc Refill pouch case of I

QTY 8

1000ml refills per case 94026 39611

puresanusa.com

(855) 500-8080

ITEM # HS1000GOB-D-C8

PURESAN 1000ml Instant Hand Sanitizer
Disc refill pouch case of 8

QTY 8
1000ml refills per case

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PURESAN HAND SANTIZING GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58575-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PERFLUOROALKYLETHYL ACRYLATES (C6-C14) (UNII: TKA54G588X)	
ALOE (UNII: V5VD430YW9)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-135-01	1000 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2018	02/01/2020
2	NDC:58575-135-02	8000 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:58575-135-03	1000 mL in 1 POUCH; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

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

Labeler - Inopak. Ltd (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak. Ltd		194718243	manufacture(58575-135)

Revised: 2/2020 Inopak. Ltd