

DERMAGEL HAND SANITIZING- 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.

DermaGel 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 more than 72 hours.

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

Directions

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

Other information

- Store between 15 - 30°C (59-86°F)
- May discolor certain fabrics and surfaces.

Inactive ingredients Water, Isopropyl Alcohol, PEG/PPG-18/18 Dimethicone, Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Triethanolamine, Alpha-tocopheryl Acetate (Vitamin E), Aloe Barbadosensis Leaf Juice, FD&C Yellow 5, FD&C Blue 1.

Inopak LTD.

Ringwood, NJ 07456


1-800-762-7725 • www.inopak.com

DermaGel®

HAND SANITIZING GEL with moisturizers

70% Alcohol with **ALOE VERA & VITAMIN E**

33.8 fl. oz. (1000 mL)

<p style="font-size: 24px; margin: 0;">DermaGel®</p> <p style="font-size: 18px; margin: 0;">HAND SANITIZING GEL with moisturizers</p> <p style="font-size: 16px; margin: 0;">70% Alcohol with ALOE VERA & VITAMIN E</p> <p style="font-size: 16px; margin: 0;">KILLS 99.99% OF GERMS!</p>	<p>33.8 fl. oz. (1000 mL)</p>
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 <div style="display: inline-block; vertical-align: middle; margin-left: 10px;"> <p>Inopak, LTD. Ringwood, NJ 07456 1-800-762-7725 • www.inopak.com</p> </div> <div style="display: inline-block; vertical-align: middle; margin-left: 100px;"> <p>5025-L1000 5025-L Rev.1.02</p> </div>	

DERMAGEL HAND SANITIZING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58575-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-130-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/1990	
2	NDC:58575-130-04	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/1990	
3	NDC:58575-130-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/1990	
4	NDC:58575-130-18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/1990	
5	NDC:58575-130-37	3785 mL in 1 JUG; Type 0: Not a Combination Product	09/01/1990	
6	NDC:58575-130-65	650 mL in 1 BAG; Type 0: Not a Combination Product	09/01/1990	
7	NDC:58575-130-80	800 mL in 1 BAG; Type 0: Not a Combination Product	09/01/1990	02/01/2020
8	NDC:58575-130-10	1000 mL in 1 BAG; Type 0: Not a Combination Product	09/01/1990	02/01/2020
9	NDC:58575-130-81	800 mL in 1 POUCH; Type 0: Not a Combination Product	09/01/1990	
10	NDC:58575-130-82	1000 mL in 1 POUCH; Type 0: Not a Combination Product	09/01/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/01/1990	

Labeler - Inopak. Ltd (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak. Ltd		194718243	manufacture(58575-130)

Revised: 5/2021

Inopak. Ltd