

INSTACLEAN HAND SANITIZING- alcohol gel SHIELD LINE 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.

INSTACLEAN

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Keep out of reach of children.

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If swallowed, get medical help or contact a Poison Control Center right away. Children should be supervised by an adult when using this product.

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

Other Information

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

May discolor certain fabrics and surfaces.

Stop use and ask a doctor

if irritation and redness develop or if condition persists more than 72 hours.

Directions

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

Inactive Ingredients

Aloe Bardensis juice, Alpha Tocopherol, Carbopol 2020, FD&C Blue No.1, FD&C Yellow No. 5, Fragrance, PEG-18 Dimethicone, TEA, Water

AmeriDerm

InstaClean™
Instant Hand Sanitizer

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Warnings	
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Manufactured for Shield Line LLC
Hackensack, NJ 07601
www.ameriderm.com

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INSTACLEAN HAND SANITIZING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52410-8046
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)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52410-8046-2	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2018	
2	NDC:52410-8046-3	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2018	
3	NDC:52410-8046-4	800 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2018	
4	NDC:52410-8046-5	1000 mL in 1 BAG; 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	01/01/2015	

Labeler - SHIELD LINE LLC (078518916)