

SANIDERM ADVANCED HAND SANITIZER- ethyl alcohol gel

Spa de Soleil

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.

Saniderm Advanced Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70.0 %

Purpose

Antimicrobial

Warnings

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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.

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Directions

Place enough product in the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

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Inactive Ingredients:

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Aqua, Glycerin, *CO Glycerin, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Limon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract, Xanthan Gum

Saniderm Advanced Hand Sanitizer 70.jpg



ADVANCED

HAND SANITIZER

**70% ALCOHOL
CONTENT**

Kills 99.9% of all germs

8FL OZ (236mL)

Drug Fact:

Active Ingredient	Purpose
Ethyl Alcohol 70.00%.....	Antimicrobial

Uses: Helps reduce bacteria on the skin that could cause diseases.





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Drug Fact (continued):

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Manufactured For And Distributed By:
Polarized, LLC
www.sanidermproducts.com

Made in USA

SANIDERM ADVANCED HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-2281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	166 mL in 236 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LEMON PEEL (UNII: 72O054U628)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-2281-1	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	04/07/2020	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-2281)

Revised: 4/2020

Spa de Soleil