

HAND SANITIZER- isopropyl alcohol gel

Alexander Sprekenhus AS

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.

ALEXANDER SPREKENHAUS - HAND SANITIZER GEL - 70% ISOPROPYL ALCOHOL

ACTIVE INGREDIENT

ISOPROPYL ALCOHOL 70%

PURPOSE

ANTISEPTIC

USES

Apply to hands, and rub to help reduce bacteria that potentially can cause disease.

WARNING

For external use only. Flammable, Keep away from heat or flame.

DO NOT USE

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

OTHER INFORMATION

- Store between 15-30° C {58-86° F}
- Avoid freezing and excessive heat above 40° C (104° F)

INACTIVE INGREDIENTS

WATER (AQUA), CARBOMER, GLYCERIN, TRIETHANOLAMINE, FRAGRANCE (PARFUM)

DRUG FACTS

ACTIVE INGREDIENTS

Isopropyl Alcohol 70%.....

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SPREKENHUS

OSLO

HAND
SANITIZER

INGREDIENTS: ISOPROPYL ALCOHOL,
WATER (AQUA), GLYCERIN, CARBOMER,
TRIETHANOLAMINE, FRAGRANCE
(PARFUM)

ORIENTAL PLUM

1.69 FL OZ / 50 ML

DRUG FACTS (continued)

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

INACTIVE INGREDIENTS

Water (Aqua), Glycerin, Carbomer, Triethanolamine, Fragrance (Parfum)

DISTRIBUTED BY

Alexander Sprekenhus AS, Munkedamsveien 67, 0270 Oslo, Norway
Made in USA

EN: Hand hygiene without soap or water. Flammable.

DE: Händehygiene ohne wasser oder seife. Brennbar.

FR: Hygiène des mains sans savon ni eau. Inflammable.

NO: Håndhygiene uten såpe eller vann. Brannfarlig.


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EN: HAND HYGIENE WITHOUT SOAP OR WATER. FLAMMABLE.
DE: HÄNDEHYGIENE OHNE WASSER ODER SEIFE. BRENNBAR.
FR: HYGIÈNE DES MAINS SANS SAVON NI EAU. INFLAMMABLE.
NO: HÅNDEHYGIENE UTEN SÅPE ELLER VANN. BRANNFARLIG.

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MANUFACTURED IN USA



7 090031 697402

SPREKENHUS

OSLO

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HAND SANITIZER

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80574-101
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			

GLYCERIN (UNII: PDC6A3C0OX)

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

TROLAMINE (UNII: 903K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80574-101-11	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	
2	NDC:80574-101-12	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/15/2020	

Labeler - Alexander Sprekenhus AS (548540280)

Establishment

Name	Address	ID/FEI	Business Operations
BotanicaLabs, Inc.		038497536	manufacture(80574-101)

Revised: 4/2021

Alexander Sprekenhus AS