### 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.

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# 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**

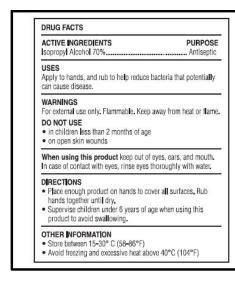
- Place enough product on hands to cover all surtaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### 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)









GREDIENTS: BOPROPYL ALCOHOL, WATER (ADUA), GLYCERIN, CARBOMER, TREYHANDLAMINE, FRAGRANCE (PARFUM)

ORIENTAL PLUM

16.9 FL OZ / 500 ML

DRUG FACTS	
ACTIVE INGREDIENTS Repropyl Alcohol 70%	PURPOSE Antiseptio
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OTHER IMPORMATION  • Store between 15-80" C (58-86"F)  • Avoid freezing and expessive heat ab	ova 40°C (104°F)
Stop use and ask a doctor if initiation be signs of a serious condition.	ar rish eccurs, These may
Keep out of reach of children. It swall contact Poison Control Center right away	
MACTIVE INGREDIENTS Water (Aqua), Glycerin, Carbonier, Triethe (Perkun)	en <b>de</b> mine, Freguesco
OBSTREEUTED BY Alexander Sprekenhas AS Munkedamow Made in USA	ien 67, 0270 Delo, Narwe

## **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		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				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333A	10/15/2020			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

## **Labeler -** Alexander Sprekenhus AS (548540280)

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

Revised: 4/2021 Alexander Sprekenhus AS