

**SOHO FRESH HAND SANITIZER- alcohol gel**  
**ESSAAR INC.**

*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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**Soho Fresh Hand Sanitizer**

**DRUG FACTS**

**Active Ingredients**

Ethyl alcohol 70%

**Purpose**

Antiseptic

**Use**

To decrease bacteria on the skin that could cause disease. Recommended for repeated use.

**Warnings**

For external use only: hands. Flammable, Keep away from fire or flame.

**When using this product**

Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

**Stop use and ask a doctor if**

Irritation or redness develops. Condition persists for more than 72 hours.

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Thoroughly cover your hands with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product. Not recommended for infants.

**Other information**

Store below 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.

**Inactive ingredients**

Water, propylene glycol, carbomer, triethanolamine.

**Package Labeling: 60ml**

DRUG FACTS	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl alcohol 70%.....	Antiseptic
Alcohol	
<b>Use</b> To decrease bacteria on the skin that could cause disease. Recommended for repeated use.	
<b>Warnings</b> For external use only: hands. Flammable, Keep away from fire or flame.	
<b>When using this product</b> Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.	
<b>Stop use and ask a doctor if</b> Irritation or redness develops. Condition persist for more than 72 hours.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Thoroughly cover your hands with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product. Not recommended for infants.	
<b>Other information</b> Store below 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.	
<b>Inactive ingredients</b> Water, propylene glycol, carbomer, triethanolamine.	



Net Cont. 2 fl. Oz. (60ml)

Made in Mexico, Distributed By  
SOHO Fresh, New Jersey



307171510423

# SoHo Fresh™

## Hand Sanitizer

Gel Antibacterial

Maximum  
Moisturizing  
Formula

Kills  
99.9%  
of germs

Net Cont. 2 fl. Oz.  
(60 ml)

Package Labeling: 250ml

DRUG FACTS	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl alcohol 70%.....	Antiseptic Alcohol
<b>Use</b> To decrease bacteria on the skin that could cause disease. Recommended for repeated use.	
<b>Warnings</b> For external use only: hands. Flammable, Keep away from fire of flame.	
<b>When using this product</b> Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.	
<b>Stop use and ask a doctor if</b> Irritation or redness develops. Condition persist for more than 72 hours.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Thoroughly cover your hands with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product. Not recommended for infants.	
<b>Other information</b> Store below 105°F. May discolor some fabrics. Harmful to wood finishes and plastics.	
<b>Inactive ingredients</b> Water, propylene glycol, carbomer, triethanolamine.	



Net Cont. 8.4 fl. Oz. (250ml)

Made in Mexico, Distributed By  
SOHO Fresh, New Jersey



# Soho Fresh™

## Hand Sanitizer

Gel Antibacterial

Maximum  
Moisturizing  
Formula

Kills  
99.9%  
of germs

Net Cont. 8.4 fl. Oz.  
(250 ml)

Package Labeling: 500ml

DRUG FACTS

Active Ingredients

Ethyl alcohol 70%.....

Purpose

Antiseptic Alcohol

Use

To decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

For external use only: hands. Flammable, Keep away from fire of flame.

When using this product

Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if

Irritation or redness develops. Condition persist for more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Thoroughly cover your hands with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product. Not recommended for infants.

Other information

Store below 105°F. May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

Water, propylene glycol, carbomer, triethanolamine.

Soho Fresh™

Hand Sanitizer

Gel Antibacterial

Maximum Moisturizing Formula

Kills 99.9% of germs

Net Cont. 16.9 fl. Oz. (500 ml)

sf

Made in Mexico  
Distributed By  
SOHO Fresh  
New Jersey

307171510426

Package Labeling: 1000ml

DRUG FACTS

Active Ingredients

Ethyl alcohol 70%.....

Purpose

Antiseptic Alcohol

Use

To decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

For external use only: hands. Flammable, Keep away from fire of flame.

When using this product

Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if

Irritation or redness develops. Condition persist for more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Thoroughly cover your hands with product and allow to dry without wiping. Children under 6 years of age should be supervised when using this product. Not recommended for infants.

Other information

Store below 105°F. May discolor some fabrics. Harmful to wood finishes and plastics

Inactive ingredients

Water, propylene glycol, carbomer, triethanolamine.

Soho Fresh™

Hand Sanitizer

Gel Antibacterial

Maximum Moisturizing Formula

Kills 99.9% of germs

Net Cont. 33.81 fl. Oz. (1 L)

sf

Made in Mexico  
Distributed By SOHO Fresh  
New Jersey

7502268987367

SOHO FRESH HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78533-000
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.7 in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
TROLAMINE (UNII: 9O3K93S3TK)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78533-000-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:78533-000-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:78533-000-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
4	NDC:78533-000-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - ESSAAR INC. (627007441)