

## **SUPERNOVA LAB- ethylic alcohol solution**

**Supernova Coating, S.A. de C.V.**

*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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### **Supernova Lab**

#### ***Active Ingredient***

Ethyl Alcohol

#### ***Purpose***

Antibacterial

#### **Uses**

Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.

#### ***Warnings***

**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

#### ***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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C(104F)

#### ***Keep out of reach of children***

If swallowed, get medical help or contact a poison control center right away.

#### ***Inactive Ingredient***

Triethanolamine, Distilled Water, Carbomer



Product Label

# HAND SANITIZER



**KILLS 99.99%  
OF GERMS**

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**70% ETHYL ALCOHOL**

4.39 Fl Oz (130ml)

Drug Fact	
<b>Active ingredient(s)</b>	Ethyl Alcohol 70% v/v .....
<b>Use(s)</b>	Health care personnel hand rub to help reduce bacteria that potentially can cause disease
<b>Warnings</b>	For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b>	- In children less than 2 months of age - On open skin wounds
<b>When using this product</b>	keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
<b>Stop use and ask a doctor</b>	if irritation or rash occurs. These may be signs of a serious condition.
<b>Keep out of reach of children.</b>	If swallowed, get medical help or contact a Poison Control Center right away
<b>Directions</b>	- Place enough product unhands to covet all surfaces. Rub hands together until dry. - Supervise children under 6years of age when using this product to avoid swallowing
<b>Other information.</b>	- Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)
<b>Inactive ingredients</b>	Carbomer, Distiled Water, Triethanolamine

SUPERNOVA LAB			
ethylic alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76726-001
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 940 (UNII: 4Q93RCW27E)			
WATER (UNII: 059QF0K00R)			



TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76726-001-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
2	NDC:76726-001-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
3	NDC:76726-001-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
4	NDC:76726-001-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
5	NDC:76726-001-05	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
6	NDC:76726-001-06	200000 mL in 1 DRUM; Type 0: Not a Combination Product	04/29/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final		part333A	04/29/2020	

**Labeler** - Supernova Coating, S.A. de C.V. (812888601)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Supernova Coating, S.A. de C.V.		812888601	manufacture(76726-001)

Revised: 4/2020

Supernova Coating, S.A. de C.V.