

## **SUPERNOVA LAB PURE ORANGE- alcohol gel**

**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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### **Active Ingredient**

Ethyl Alcohol 70% v/v.

### **Purpose**

Antiseptic

### **Use(s)**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

### **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.

**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 a Poison Control Center right away.

### **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)

### **Inactive ingredients**

Carbomer, Distilled Water, Triethanolamine, Aloe Vera and Essential Oils.

### **Package Label - Principal Display Panel**

# HAND SANITIZER

PREMIUM



BY SUPERNOVA LAB

70% ETHYL ALCOHOL

16.9 Fl Oz (500ml)

## Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Hand sanitizer 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 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 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.	
<b>Other information</b> * Store between 15-30C (59-86F) * Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Carbomer, Distilled Water, Triethanolamine, Aloe Vera and Essential Oils.	

www.supernova-group.com

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

Av. Resurrección 18A, Puebla, México. CP 72228

Made in México

Questions? Phone +52-55-5980-22-60

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## SUPERNOVA LAB PURE ORANGE

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76726-002
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
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76726-002-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
2	NDC:76726-002-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
3	NDC:76726-002-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
4	NDC:76726-002-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
5	NDC:76726-002-05	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
6	NDC:76726-002-06	1000000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

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

Name	Address	ID/FEI	Business Operations
Supernova Coating, S.A. de C.V.		812888601	manufacture(76726-002)

Revised: 5/2020

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