

**NUBAAL ALCOHOL ANTISEPTIC 80 TOPICAL ANTISEPTIC HAND RUB NON-STERILE-  
alcohol gel**

**Botanicals Internacional 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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**NUBAAL Alcohol Antiseptic 80% Topical Solution Antiseptic Hand Rub Non-sterile Solution**

***Drug Facts***

***Active ingredient (s)***

Organic Alcohol 80% v/v

***Purpose***

Antiseptic

***Use***

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**

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

***Inactive ingredients***

Glycerin, hydrogen pyroxide, purified water, Aloe vera extract, sweet orange essential oil, tocopherol

Package Labeling:

**alcohol  
antiseptic 80%  
topical solution  
hand sanitizer  
non-sterile solution**



**purehaven® body**

100% free of toxins

4 fl oz/118 ml

<b>Drug Facts</b>	
<b>Active Ingredient</b> Organic Alcohol (80%)v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> • Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<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 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> glycerin, hydrogen peroxide, purified water, sweet orange essential oil, tocopherol.	

distributed by  
Pure Haven, LLC, 1 Carding Lane, Johnston, RI 02919

[purehaven.com](http://purehaven.com)

**NUBAAL ALCOHOL ANTISEPTIC 80 TOPICAL ANTISEPTIC HAND RUB NON-STERILE**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51384-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
ORANGE OIL (UNII: AKN3KSD11B)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51384-001-01	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:51384-001-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

**Labeler** - Botanicals Internacional S.A. de C.V. (823968961)**Establishment**

Name	Address	ID/FEI	Business Operations
Botanicals Internacional S.A. de C.V.		823968961	manufacture(51384-001)

Revised: 6/2020

Botanicals Internacional S.A. de C.V.