

SOCAL FARMHOUSE GEL HAND SANITIZER- isopropyl alcohol gel

Blue Angel Hot Tubs

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.

SoCal Farmhouse Gel Hand Sanitizer 120 ML

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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.

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

glycerin, propylene glycol USP, TRIETHANOLAMINE, purified water USP, carbomer, fd&c red 3, yellow 5, blue 1

Package Label - Principal Display Panel

120 ml NDC: 77300-101-01

SoCal 
Farmhouse

Isopropyl Alcohol
Antiseptic
70%

Topical Solution

Hand Sanitizer

GEL

4 ounces – 120 ML
Non-Sterile Solution

Drug Facts

Active ingredient[s]	Purpose
Isopropyl alcohol 70% v/v.....	Antiseptic
Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame Do not use: <ul style="list-style-type: none">• on 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	

- on 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:

glycerin, propylene glycol USP, purified water USP, carbomer, triethanolamine, fragrance, fd&c: red 3, yellow 5, blue 1

FDA NDC Registration: 77300-101-01 120ML
Labeler Blue Angel Hot Tubs / Pensacola, FL

SOCAL FARMHOUSE GEL HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77300-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL	70 mL

UNII:ND2M416302)			ALCOHOL	in 100 mL
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			2 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			0.02 mL in 100 mL	
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)			3 mL in 100 mL	
CARBOMER 940 (UNII: 4Q93RCW27E)			0.3 mL in 100 mL	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			0.02 mL in 100 mL	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			0.05 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77300-101-01	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/15/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/14/2020	

Labeler - Blue Angel Hot Tubs (153641092)

Revised: 5/2020

Blue Angel Hot Tubs