

HAND SANITIZER- alcohol gel
Super Dope Laboratories LLC

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.

Super Dope Coconut Banana

Active Ingredient(s)

Ethyl 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

Water, Carbomer 940, Glycerin, Hydrogen Peroxide, Trolamine, Fragrance

Package Label - Principal Display Panel

SÜPR
HAND SANITIZER

SANITIZING GEL
+ Coconut Banana
Instant Gel

4 FL OZ.
(120 mL)

Drug Facts

Active Ingredient(s)
Ethyl Alcohol 70% w/v

Uses
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soiled.

Warnings
For external use only. Flammable. Keep away from heat or flame.

Do not use
* 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, wash.

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.

Directions * Place enough product on hands to cover all surfaces. Rub hands together until 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: Water, Carbomer 940, Glycerin, Hydrogen Peroxide, Trolamine, Fragrance

Questions? Call (786) 504-1212.

Distributed by Super Dope Laboratories 508 NE 189 St

120 mL NDC: 74220-009-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74220-009
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
GLYCERIN (UNII: PDC6A3C0OX)	
.GAMMA.-NONALACTONE (UNII: I1XGH66S8P)	
VANILLIN (UNII: CH1530446X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:74220-009-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		09/01/2020	

Labeler - Super Dope Laboratories LLC (055650002)

Establishment			
Name	Address	ID/FEI	Business Operations
Super Dope Laboratories LLC		055650002	manufacture(74220-009) , label(74220-009)

Revised: 9/2020

Super Dope Laboratories LLC