

SAFE AND CLEAN- hand sanitizer gel

SafeSupply 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.

SafeSupply-SNC Industria Sanitizer GEL

Active Ingredient(s)

Alcohol 75% 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

Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surfaces

Inactive ingredients

aloe vera extract, glycerin, hydrogen peroxide, carbomer, methylchloroisothiazolinone, trolamine, water, denatonium benzoate

Package Label - Principal Display Panel



Drug Facts	
Active Ingredient	Purpose
Alcohol 75% v/v	Antiseptic
Uses	
Hand sanitizer to help reduce bacteria on the skin 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"> in children less than 2 months of age on open skin wounds 	
When using this product do not use in or near the eyes. In case of contact, 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	
<ul style="list-style-type: none"> Put enough product on hands cover all surfaces. Rub hands together until dry. Children under 6 years of age should be supervised when using products. 	
Other Information	
<ul style="list-style-type: none"> Avoid freezing and excessive heat above 40C (104F). May discolor certain fabrics or surfaces. 	
Inactive ingredients Aloe Vera Extract, Distilled Water, Glycerine, Hydrogen Peroxide, Methylchloroisothiazolinone, Carbomer, Trolamine, Denatonium Benzoate.	

Distributed by:
SafeSupply LLC
806 Green Valley Rd, Suite 200
Greensboro NC 27408
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MADE IN BRAZIL

250 mL NDC: 79976-111-12

SAFE AND CLEAN			
hand sanitizer gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79976-111
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
METHYLCHLOROISOThIAZOLINONE (UNII: DEL7T5QRPN)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
TROLAMINE (UNII: 9O3K93S3TK)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79976-111-11	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
2	NDC:79976-111-12	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
3	NDC:79976-111-13	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
4	NDC:79976-111-14	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
5	NDC:79976-111-15	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/07/2020	

Labeler - SafeSupply LLC (117589082)

Establishment

Name	Address	ID/FEI	Business Operations
SNC Industria de Cosméticos Ltda		914610642	manufacture(79976-111)

Revised: 8/2020

SafeSupply LLC