

## **CLEAN N FRESH 01- hand sanitizer gel**

### **SMC Technologies**

*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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### **Ingredients**

This hand sanitizer is manufactured using the following ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Carbomer Interpolymer Type A 55000 CPS
- c. Water.
- d. Trolamine
- e. Fragrance.

### **Active Ingredient(s)**

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.

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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

Methacrylic Acid - Ethylacrylate Copolymer, Water, Trolamine, Fragrance

### Package Label - Principal Display Panel

209.198L (55 US Gal) NDC77411-001-01

<b>Drug Facts</b>
<b>Active Ingredient[s]</b>
Alcohol 70% v/v.....
<b>Use[s]</b>
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
<b>Warnings</b>
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<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 15-30°C (59-86°F)
Avoid freezing and excessive heat above 40°C (104°F)
<b>Inactive ingredients</b>
Carbomer Interpolymer Type A 55000 cps, Trolamine, Polysorbate 20, Water.
L2005

# CLEAN & FRESH 01

An Easy Clean Product

## Hand Sanitizer Antiseptic Gel

Kills 99.99% of many harmful germs and bacteria in as little as 15 seconds



Alcohol 70%

Midwest City, Ok 73110 (405) 737-3740

Made in the U.S.A. 

208.198 L (55 US Gal) NDC 77411-002-55

## CLEAN N FRESH 01

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77411-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	67.38 kg in 100 kg

### Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.704 kg in 100 kg
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	0.618 kg in 100 kg
TROLAMINE (UNII: 9O3K93S3TK)	0.286 kg in 100 kg
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	white (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77411-004-55	859 kg in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - SMC Technologies (007188360)

**Registrant** - SMC Technologies (007188360)

## Establishment

Name	Address	ID/FEI	Business Operations
SMC Technologies		007188360	manufacture(77411-004)

Revised: 1/2022

SMC Technologies