

## **CLEAN N FRESH- 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.*

-----

### **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. Methacrylic Acid - Ethyl Acrylate Copolymer (4500 MPA.S)
- 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.

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**

Methacrylic Acid - Ethylacrylate Copolymer, Water, Trolamine, Fragrance

**Package Label - Principal Display Panel**

<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>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use:</b>	
On children less than 2 months of age	
On open skin wounds	
<b>When using this product</b> keep out of eyes and mouth. In case of contact with eyes rinse thoroughly with water	
<b>Stop use and as 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>	
Methacrylic Acid - Ethyl Acrylate Copolymer, Trolamine, Polysorbate 20, Water.	
	L20050801



3785 ml (1 US Gal) NDC77411-001-01

<b>CLEAN N FRESH</b>			
hand sanitizer gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77411-001
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL
<b>Inactive Ingredients</b>			
Ingredient Name			Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)			1.1 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MP.A.S) (UNII: T967IEU43C)			3 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)			0.42 mL in 100 mL
WATER (UNII: 059QF0KO0R)			
<b>Product Characteristics</b>			
<b>Color</b>	white (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77411-001-01	3785 mL in 1 JUG; 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(77411-001)

Revised: 5/2020

SMC Technologies