

**HAND SANITIZER- alcohol gel**  
**Smart Solutions, Inc.**

*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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**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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**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**

Carbomer 940, Propylene Glycol USP, Isopryl Myristate, Imidurea, AMP-95, purified water USP

Smart Hand Sanitizer Gel is a hygienic handrub that is a fast-acting, quick-drying antibacterial skin cleanser that kills harmful bacteria/germs. For personal hand hygiene to help prevent the spread of bacteria.

**DIRECTIONS**

Adults and children over 2 years: Rub thoroughly into hands for at least 15 seconds. Allow to dry. Supervise children when they use this product. For occasional and personal domestic use.

Distributed by Smart Solutions Inc.  
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Newport Beach CA 92660  
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www.smartsolutions.net

Manufactured by Fluid USA Inc.



**Drug Facts**

Active ingredient	Purpose
Ethyl Alcohol (USP) 70% v/v	Antiseptic

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**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:90116-435
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68.77 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
IMIDUREA (UNII: M629807ATL)	0.1 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.13 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.15 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90116-435-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	08/10/2020	

2	NDC:90116-435-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
3	NDC:90116-435-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
4	NDC:90116-435-33	1249186 mL in 1 TANK; Type 0: Not a Combination Product	08/10/2020	
5	NDC:90116-435-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	08/10/2020	
6	NDC:90116-435-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	08/10/2020	
7	NDC:90116-435-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
8	NDC:90116-435-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	
9	NDC:90116-435-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2020	

**Labeler** - Smart Solutions, Inc. (017918057)

## Establishment

Name	Address	ID/FEI	Business Operations
Fluid USA, Inc		117508196	manufacture(90116-435)

Revised: 8/2020

Smart Solutions, Inc.