

**SANTI-GEL INSTANT HAND SANITIZER- s anti-gel instant hand sanitizer solution  
Kutol Products Company, 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.*

-----

**Santi-Gel Instant Hand Sanitizer**

**Flammable. Keep away from heat or flame.**

**For external use only.**

**Do not use** in the eyes. In case of contact, immediately flush with water.

**Stop use and ask a doctor if** irritation or rash appears and lasts.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Ethyl Alcohol 62% v/v.....Antibacterial Agent

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis leaf, Tocopheryl Acetate (Vitamin E), Carbomer, Aminomethyl Propanol

To decrease bacteria on skin, apply a small amount to palm. Briskly rub, covering hands with product until dry.

Children under 6 years of age should be supervised when using this product.

Hand Sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

Hand Sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

Do not use in the eyes. In case of contact, immediately flush with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



50865-056-65.jpg

## SANTI-GEL INSTANT HAND SANITIZER

santi-gel instant hand sanitizer solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50865-056
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62.5 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)

.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50865-056-07	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/22/2013	
2	NDC:50865-056-12	1200 mL in 1 BAG; Type 0: Not a Combination Product	05/22/2013	05/10/2017
3	NDC:50865-056-19	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	
4	NDC:50865-056-30	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	
5	NDC:50865-056-34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	
6	NDC:50865-056-35	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	
7	NDC:50865-056-65	800 mL in 1 BAG; Type 0: Not a Combination Product	05/22/2013	05/10/2017
8	NDC:50865-056-79	1892 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/22/2013	
9	NDC:50865-056-82	800 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2013	07/17/2016
10	NDC:50865-056-86	800 mL in 1 BAG; Type 0: Not a Combination Product	05/22/2013	07/19/2016
11	NDC:50865-056-93	1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	05/10/2017
12	NDC:50865-056-67	2000 mL in 1 BAG; Type 0: Not a Combination Product	05/22/2013	
13	NDC:50865-056-36	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2013	
14	NDC:50865-056-66	800 mL in 1 BAG; Type 0: Not a Combination Product	05/10/2017	
15	NDC:50865-056-03	208175 mL in 1 DRUM; Type 0: Not a Combination Product	05/15/2015	
16	NDC:50865-056-38	800 mL in 1 BAG; Type 0: Not a Combination Product	05/10/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2013	

**Labeler** - Kutol Products Company, Inc. (004236139)

**Registrant** - Kutol Products Company, Inc. (004236139)

### Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company,		004236139	manufacture(50865-056) , analysis(50865-056) , label(50865-056) , pack(50865-

