

CLEAN XPRESS ALCOHOL GEL INSTANT SKIN SANITIZER- clean xpress alcohol gel instant skin sanitizer liquid

Spartan Chemical 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.

Clean Xpress Alcohol Gel Instant Skin Sanitizer

Ethyl Alcohol 62% v/v

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 decrease bacteria on the skin that can cause disease.

Use between regular handwashings.

Recommended for repeated usage.

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Stop use and ask a doctor if irritation or rash appears and lasts. If swallowed get medical help or contact a Poison Control Center right away. Keep out of reach of children.

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For external use only.

Flammable. Keep away from heat or flame.

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.

5627

Instant Hand Sanitizer boxless bag -
label can be any PMS ink color

CLEAN Xpress Spartan **Alcohol Gel**
Instant Skin Sanitizer

Drug Facts Active Ingredient Ethyl Alcohol 62%w/v.....Antibacterial Agent Purpose Antibacterial Agent	1
Uses ■ Hand sanitizer to help decrease bacteria on the skin that can cause disease. ■ Use between regular hand washings. ■ Recommended for repeated usage.	2
Warnings For external use only. Flammable. Keep away from heat or flame. 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.	3
Directions ■ 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.	
Inactive Ingredients Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf, Tocopheryl Acetate (Vitamin E), Carbomer, Aminomethyl Propanol.	

LA707Y-0813 MADE IN USA
FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY
Manufactured for:
Spartan Chemical Company, Inc.,
1110 Spartan Drive, Maumee, OH 43537 USA, 1-800-537-8990
Medical Emergency: 888-314-6171
www.spartanchemical.com ©SCC 7/13 #312007
Net Contents 1000mL (33.8 Fl. oz.)

Customer approval for art file,
please sign/initial:
Approved *M. Williams*
Date 8/8/2013

KUTOL Hand Hygiene Specialists 513-527-5500 513-527-5506 fax blevenson@kutol.com	Label No. <u>LA707Y</u>
	Size _____ Unwind _____
KUTOL INTERNAL Approved _____ Date _____ Changes:	Colors <u>PMS 206 red</u>
	Printed on <u>white polyp.</u>
	Formula <u>056F</u> <small>Printer - please put our formula number on your proof.</small>
	Item No. (Kutol use only) <u>312007</u>
	Revisions:

CLEAN XPRESS ALCOHOL GEL INSTANT SKIN SANITIZER

clean xpress alcohol gel instant skin sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64009-056
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64009-056-34	1000 mL in 1 BAG		

Marketing Information

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

Labeler - Spartan Chemical Company, Inc. (005036728)

Registrant - Kutol Products Company, Inc (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(64009-056) , analysis(64009-056) , pack(64009-056)