

INSTANT HAND SANITIZER (GEL-TYPE)- instant hand sanitizer (gel-type) solution
Tranzonic Companies

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.

Instant Hand Sanitizer (Gel-Type)

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

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

For hand cleaning to decrease bacteria on skin that could cause disease. Recommended for repeated use.

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, contact a physician or poison center.

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.

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NED
NDA

INSTANT HAND SANITIZER (GEL-TYPE)

Kills 99.9% of common germs that can cause disease.
Formulated to sanitize hands in situations where water is not available.
Contains Aloe and Vitamin E.

Drug Facts

Active Ingredient

Ethyl Alcohol 62.5% w/v

Uses

For hand cleaning to decrease bacteria on skin that could cause disease.
Recommended for repeated use.

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, contact a physician or poison control center.

Directions

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

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

Inactive Ingredients

Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe (Barbados), Tocopheryl Acetate (Vitamin E), Aminomethyl Propanol.



Manufactured in the USA for:
HOSPECO
26301 Curtiss-Wright Pkwy
Cleveland, Ohio
www.hospeco.com



Open



Load refill and push nozzle back



Securely close

53341-056-27.jpg

INSTANT HAND SANITIZER (GEL-TYPE)

instant hand sanitizer (gel-type) solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53341-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53341-056-27	800 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/05/2013	

Labeler - Tranzonic Companies (007900020)**Establishment**

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(53341-056) , analysis(53341-056) , pack(53341-056)

Revised: 2/2014

Tranzonic Companies