

KE-53PS HAND SANITIZER- ethanol gel
Kinzua Environmental 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.

KE-53PS Gel Hand Sanitizer

Drug Facts

Active Ingredient:

Ethanol (60% v/v)

Purpose:

Anti-Microbial Hand Sanitizer

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

- **For external use only**
- **Flammable, keep away from fire, heat, or flame**
- **Keep out of reach of children.**
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention
- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Use no water or towels
- Apply appropriate amount of product to palm of hand
- Rub until hands are completely covered
- Agitate lightly until dry
- Let air dry for 15 seconds
- Do not rinse or wipe with towel.

Other Information

- Store in a cool dry place below 104° F.

Inactive Ingredients

Water, Carbomer, Triethanolamine, PEG-75 Lanolin, Aloe Vera Gel, Fragrance.

Principal Display Panel

Principal Display Panel – Bottle Label

KE-53PS

Gel Hand Sanitizer

- Enhanced with Moisturizers
- Kills disease causing germs within seconds

- Effective against MRSA, VRE, E. coli (0157:H7) Staphylococcus, Streptococcus and other organisms
- Assists with OSHA Bloodborne Pathogen Standard Compliance

For Hospital and Professional Use Only
See Drug Facts panel for additional information

12-266-1362

Manufactured for:

KINZUA ENVIRONMENTAL, Inc.

1176 E. 38th. • CLEVELAND, OH 44114

1-800-233-5079

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S15-001-013-202B

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Net Contents: 4 Fl. Oz.

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S15-001-013-204F

KE-53PS HAND SANITIZER

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64121-515
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ethanol (UNII: 3K9958 V90 M) (ethanol - UNII:3K9958 V90 M)	ethanol	600 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
carbomer homopolymer type C (UNII: 4Q93RCW27E)	
aloe (UNII: V5VD430 YW9)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64121-515-27	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	05/21/2010	

Labeler - Kinzua Environmental Inc. (612966374)

Establishment

Name	Address	ID/FEI	Business Operations
Canberra Corporation		068080621	MANUFACTURE

Revised: 5/2010

Kinzua Environmental Inc.