

**KE-53PS GEL HAND SANITIZER- ke-53ps gel hand sanitizer solution**  
**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.*

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**KE-53PS Gel Hand Sanitizer**

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

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

For hand cleaning to decrease bacteria on skin.

**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 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.

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NDC 64121-056-35

**≡ KE-53PS ≡**  
**Gel Hand Sanitizer**



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 62% v/v.....	Antibacterial Agent
<b>Uses</b>	
■ For hand cleaning to decrease bacteria on skin.	
<b>Warnings</b>	
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 doctor if irritation or rash appears and lasts.	
Keep out of reach of children. If swallowed, contact a physician or poison center.	
<b>Directions</b>	

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

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

Net Contents 119mL (4 fl. oz.)

Manufactured in the USA for:

**KINZUA ENVIRONMENTAL, Inc.**

1176 E. 38th. • CLEVELAND, OH 44114

1-800-233-5079

MG612KIN-1003

<p><b>DO NOT PRINT THIS BOX</b></p> <p>KUTOL INTERNAL</p> <p>Approved _____</p> <p>Date _____</p> <p>Changes:</p>	<p style="text-align: center;"><b>DO NOT PRINT THIS BOX</b></p> <hr/> <p>Label No.: MG612KIN</p> <p>Color: PMS 200 red</p> <p>Formula #: 056F</p> <p>Item #: KINZ5150627 Cust.Item #: KINZ-515#06-27</p> <p>Revised:</p> <hr/> <p style="text-align: center;"><b>DO NOT PRINT THIS BOX</b></p>
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64121-056-35.jpg

<b>KE-53PS GEL HAND SANITIZER</b>		
ke-53ps gel hand sanitizer solution		
<b>Product Information</b>		
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b> NDC:64121-056
<b>Route of Administration</b>	TOPICAL	
<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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:64121-056-35	119 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

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

**Labeler** - Kinzua Environmental, Inc. (612966374)

## Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(64121-056) , analysis(64121-056) , pack(64121-056)

Revised: 1/2014

Kinzua Environmental, Inc.