

# **INSTANT HAND SANITIZER KE-53SAN- instant hand sanitizer ke-53san liquid Kinzua Environmental**

*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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## **Hand Sanitizer PLD template II**

### **Active Ingredient**

Ethyl Alcohol 60%.....Antiseptic

### **purpose**

Antiseptic

### **Uses**

- Handwash to help decrease bacterial on the skin.
- Recommended for repeated use.

### **Warnings**

- Flammable. Keep away from fire or flame.
- For external use only.

### **do not use**

- In the eyes

### **When Using**

- Do not use in or near the eyes.
- If contact occurs, flush eyes with water for 15 minutes. Consult physician if irritation persists.
- If swallowed, seek medical assistance or consult a poison control center immediately.

### **Stop Use**

- Stop use and ask a doctor if: Irritation develops. If condition persists for more than 72 hours consult a doctor.
- Keep out of reach of children.
- Keep out of reach of children.

### **Directions for Use**

- Place a palmful ( 5 grams) of product in one hand,.
- Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes).
- Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds).
- Will air dry in 15 seconds.
- Store below 95 ° F.
- Close spout to avoid evaporation.

Water, triethanolamine, fragrance, acrylic polymer

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 60%	Antiseptic
<b>Uses</b>	
• Handwash to help decrease bacteria on the skin. • Recommended for repeated use.	
<b>Warnings</b> • <b>Flammable. Keep away from fire or flame.</b> • <b>For external use only.</b>	
<b>Do not use</b> • In the eyes.	
<b>When using this product</b> • Do not use in or near the eyes. If contact occurs, flush eyes with water for 15 minutes. Consult physician if irritation persists. • If swallowed, seek medical assistance or consult a poison control center immediately.	
<b>Stop use and ask a doctor if</b> • Irritation develops. If condition persists for more than 72 hours consult a doctor. <b>Keep out of reach of children.</b>	
<b>Directions</b>	
Place a 'palmful' (5 grams) of product in one hand. • Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes). • Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds). • Will air dry in 15 seconds.	
<b>Other information</b> Store below 95°F. • Close spout to avoid evaporation.	
<b>Inactive ingredients</b> Water, Triethanolamine, Fragrance, Acrylic Polymer.	

<b>Datos Médicos</b>	
<b>Ingrediente Activo</b>	<b>Propósito</b>
Alcohol etílico 60%	Antiséptico
<b>Usos</b>	
• Lave con las manos para disminuir la bacteria en la piel • Recomendado para uso repetitivo	
<b>Advertencia</b> • <b>Inflamable. Mantenga alejado del fuego.</b> • <b>Para uso externo solamente.</b>	
<b>No use</b> • En los ojos	
<b>Cuando usando este producto</b> • No use cerca los ojos. Si contacto ocurre, lave los ojos con agua por 15 minutos. Consulte con un medico si persiste la irritación. • Si se ingiere, busque asistencia médica o consulte con el control venenos inmediatamente.	
<b>Pare el uso y pregúntele a un doctor</b> • Si la irritación se desarrolla. Si la condición persiste por más de 72 horas, consulta con un doctor. • <b>Mantenga lejos de los niños.</b>	
<b>Direcciones</b>	
Coloque 5 gramos del producto en la palma de una mano. • Difundir en ambas manos y frotar dentro de la piel hasta que se seque. • Coloque una cantidad mas pequeña (2.5 gramos) en una mano, difundir sobre las dos manos hasta la muñeca, y frote en la piel hasta que se seque (aproximadamente 30 segundos). • Se seca con el aire en 15 segundos.	
<b>Otra Información</b> Almacene bajo de 95°F. • Cierre el pico para evitar evaporación.	
<b>Ingredientes inactivo</b> Agua, Trietanolamina, Fragancia, Acrílico Polímero.	

Made in USA

NDC 64121-693-02

600008166



## INSTANT HAND SANITIZER KE-53SAN

instant hand sanitizer ke-53san liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64121-693
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	67 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64121-693-02	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/23/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/23/2022	

**Labeler** - Kinzua Environmental (612966374)

### Establishment

Name	Address	ID/FEI	Business Operations
QuestSpecialty Corporation		103840377	manufacture(64121-693)

Revised: 3/2022

Kinzua Environmental