# ISSENGARD 24 HAND SANITIZER 3 OZ- benzalkonium chloride cream CLEAR LAKE RESEARCH, LLC

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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#### **Active Ingredient**

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Benzalkonium Chloride 0.18%

#### **Purpose section**

**Antimicrobial** 

#### Warnings

For external uses only

#### **Drug Facts**

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## When using this product

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

## Stop use and ask a doctor

Stop use and ask a doctor if rash, irritation, or other allergic reaction occurs

## **Keep Out of Reach of Children**

**Keep out of reach of children**, if the product is swallowed, get medical help or contact a Poison Center right away.

#### Uses

- to help reduce germs on the skin
- Recommended use once a day or as needed

#### **Directions**

Apply half an inch each morning on clean skin.

#### **Inactive Ingredients**

Water (Aqua), Glycine soja (Soybean) Oil, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Caprylic/Capric Triglyceride, Tributyl Phosphate, Glycerin, t-Octylphenoxy-polyethoxyethanol, Hydroxy-ethylacrylate/Sodium Acryloyldimethyl Taurate, Copolymer, Isohexadecane, Polysorbate 60, Glyceryl Stearate, Stearic Acid, Stearyl Alcohol, Lavandula angustifolia (Lavender) Oil, Propylene Glycol, Ethyl Alcohol, Zinc Oxide Cl 77947

#### Principal Display Panel - 30 mL

**ISSENGARD** 

Hand Cream Protectant

Kills > 99.99% of Germs

Non-alcohol HAND SANITIZER

1 FL OZ / 30 mL

Made in USA

<u> </u>	DRUG FACTS:	,
Research,	ACTIVE INGREDIENT PURPOSE Benzalkonium Antimicrobial Chloride (0.18%)	DC No: 8
Product by: Clear Lake Research, LLC www.clearlakeresearch.com	USES  to help reduce germs on the skin  Recommended use once a day or as needed	NDC No: 81495-112-01
www	WARNINGS For external uses only	
	When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.	
	Stop use and ask a doctor if rash, irritation, or other allergic reaction occurs.	
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n	DIRECTIONS Apply half an inch each morning on clean skin.	
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## **ISSENGARD 24 HAND SANITIZER 3 OZ**

benzalkonium chloride cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:81495-112

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.18 mg in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
POLYSORBATE 60 (UNII: CAL22UVI4M)			
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)			
ISOHEXADECANE (UNII: 918X1OUF1E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)			
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)			
ZINC OXIDE (UNII: SOI2LOH54Z)			
GLYCERIN (UNII: PDC6A3C0OX)			
OCTOXYNOL-1 (UNII: 20CAX7IO75)			
ALCOHOL (UNII: 3K9958V90M)			
SOYBEAN OIL (UNII: 241ATL177A)			
LAVENDER OIL (UNII: ZBP1YXW0H8)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
TRI-N-BUTYL PHOSPHATE (UNII: 95UAS8YAF5)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81495-112- 01	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/31/2022	

Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date

OTC monograph not final	part333E	01/03/2022	

# Labeler - CLEAR LAKE RESEARCH, LLC (077493647)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Clear Lake Research, LLC		077493647	label(81495-112)

Revised: 12/2022 CLEAR LAKE RESEARCH, LLC