

ISSENGARD 24 HAND SANITIZER- 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.

DRUG FACTS

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ACTIVE INGREDIENTS

Benzalkonium Chloride, 0.18%

PURPOSE SECTION

Antimicrobial

WARNINGS

For external uses only

USES

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

WHEN USING SECTION

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 SECTION

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

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 CI 77947

PRINCIPAL DISPLAY PANEL - 473 mL

Issengard 24

Non-alcohol HAND SANITIZER

with Invisible Shield Technology

Kills > 99.99% of Germs

16 FL OZ / 473 mL

Made in USA

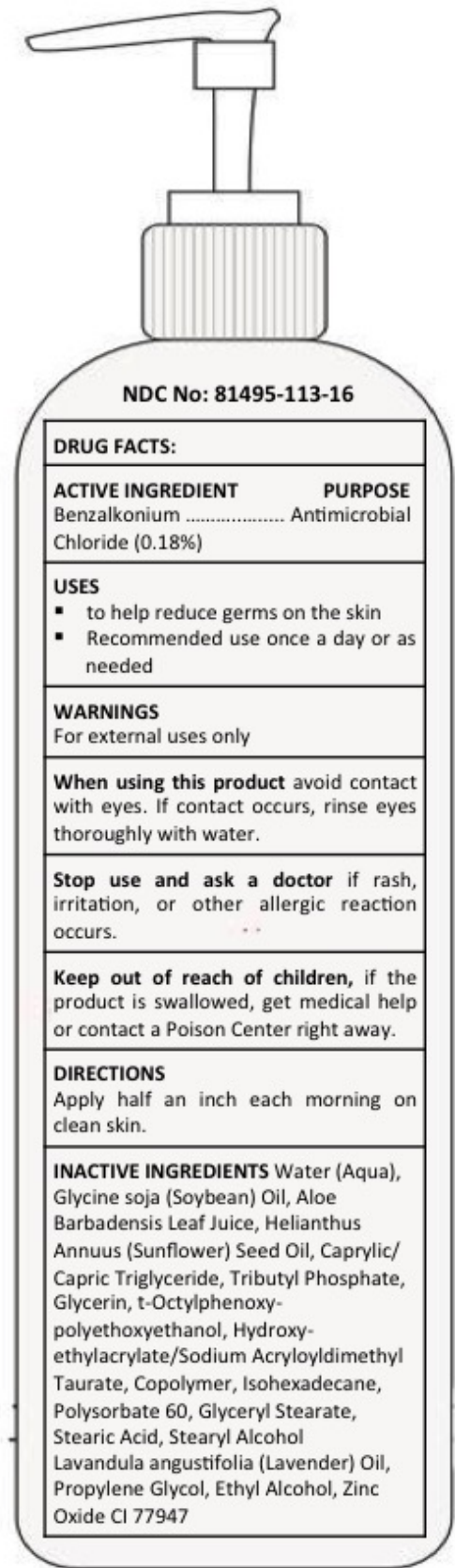
Product by: Clear Lake Research, LLC

www.issengard.com

10.25"



2.375"



ISSENGARD 24 HAND SANITIZER

benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81495-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.18 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TRI-N-BUTYL PHOSPHATE (UNII: 95UAS8YAF5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SOYBEAN OIL (UNII: 241ATL177A)	
OCTOXYNOL-1 (UNII: 20CAX7IO75)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81495-113-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/22/2021	

Labeler - Clear Lake Research, LLC (077493647)

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetic Manufacturing, Inc		068267863	manufacture(81495-113)

Establishment

Name	Address	ID/FEI	Business Operations
Clear Lake Research, LLC		077493647	label(81495-113)

Revised: 3/2021

Clear Lake Research, LLC