

ELEMENT CONTROL RINSE FREE HAND SANITIZER SOOTHING- alcohol gel
Strategic Orient Sourcing Limited

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.

Element Control Rinse-Free Hand Sanitizer Soothing Gel

Drug Facts

Active ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Use

- 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 heat or flame.

Do not use

- in children less than 2 months of age or on open skin wounds.

When using this product

- keep out of eyes and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

- if irritation and redness develop

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- avoid freezing and excessive heat above 40°C (104°F)
- may discolor certain fabrics.

Inactive ingredients

Water, Glycerin, Aloe Barbadensis Extract, Aminomethyl Propanol, Propylene Glycol, Carbomer, Fragrance, Tocopherol.

Package Labeling:



ELEMENT CONTROL RINSE FREE HAND SANITIZER SOOTHING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79995-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

TOCOPHEROL (UNII: R0ZB2556P8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79995-027-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/25/2020	

Labeler - Strategic Orient Sourcing Limited (667569581)

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