

CHEMISPHERE HAND SANITIZER- hand sanitizer gel

Chemisphere Corp

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.

Ethyl Alcohol 63%

Antimicrobial

Directions

Wet hands with enough product to cover hands. Rub hands together and allow to dry.

Children under 6 require adult supervision.

Warnings

For external use only.

Flammable. Keep away from heat and flame.

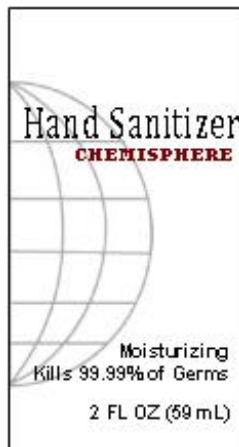
When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor is irritation or rash develops.

Water, Glycerin, Tocopheryl Acetate, T-Butyl Alcohol, Carbomer, Fragrance

Hand sanitizer to decrease bacterial on the skin.

Keep out of reach of children. If swallowed, get medical help of contact a Poison Control Center right away.



CHEMISPHERE HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61034-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYLAMINE (UNII: BR9JL140NO)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61034-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2016	

Labeler - Chemisphere Corp (071957146)**Establishment**

Name	Address	ID/FEI	Business Operations
Chemisphere Corp		071957146	manufacture(61034-001)

Revised: 5/2016

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