MEDIFECT HAND SANITIZER- alcohol liquid
Medical Chemical Corporation

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.

MediFect Spray

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Hydrogen peroxide, 0.13% w/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Uses: Intended for use as a hand sanitizer spray.

Warnings

Danger: Highly flammable liquid and vapor. Keep away from heat, sparks, open flames, and hot surfaces. No smoking. Keep container tightly closed. Use only non-sparking tools. Take precautions against static discharge. Wear protective clothes and eye protection. In case of fire, use fire extinguishers approved for alcohol fires. In case of ingestion, contact a poison control center. Discontinue use if irritation or redness develops. Keep out of reach of children.

Warnings

Keep out of reach of children.

Directions

Spray about 5 g (1 tsp.) on to one hand and spread over both hands to the wrist. Rub into the skin until dry. Repeat.

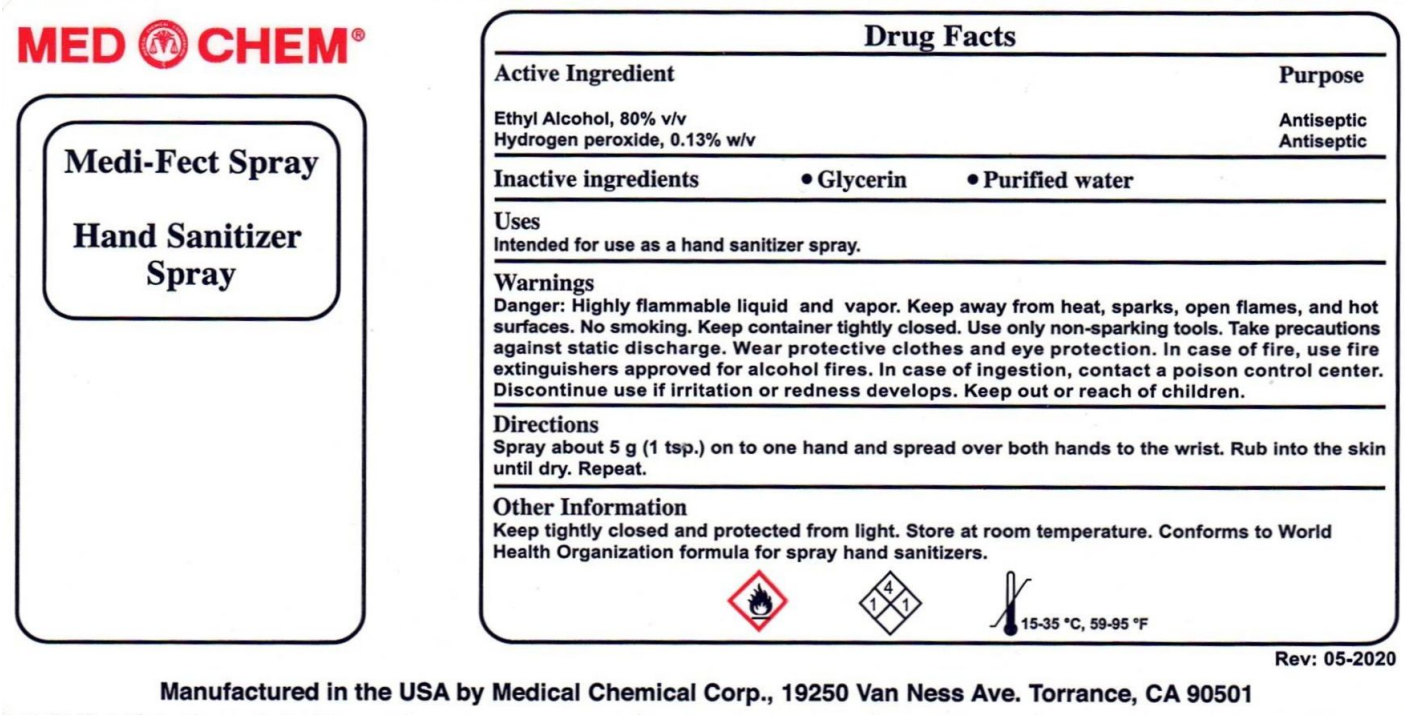
Other information

Keep tightly closed and protected from light. Store at room temperature. Conforms to World Health Organization formula for spary hand sanitizers.

Inactive ingredients

glycerin, purified water

Package Label - Principal Display Panel



MEDIFECT HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12745-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	4.17 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12745-901-01	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2020	
2	NDC:12745-901-02	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2020	
3	NDC:12745-901-03	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Medical Chemical Corporation (008496861)

Registrant - Medical Chemical Corporation (008496861)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Chemical Corporation		008496861	manufacture(12745-901)

Revised: 1/2022 Medical Chemical Corporation