HAND SANITIZER- alcohol gel
HS HomeWorx 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.

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 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

to help reduce bacteria on skin

Warnings

Flammable. Keep away from fire, flame or high heat.

For external use only.

Do not use

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

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Avoid contact with broken skin. Do no inhale or ingest.

Stop use and ask a doctor if irritation or redness occurs.

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Directions

- Dispense into hands, rub thoroughly until dry.

Other information

- Do not store above 110F (43C)
- May discolor certain fabriocs or surfaces.

Inactive ingredients

water (aqua), glycerin, butylene glycol, fragrance (parfum), acrylates/C10-30 alkyl acrylate crosspolymer, triethanolamine, aloe barbadensis leaf extract, artemisia argyi leaf extract, cnidium monnieri fruit extract, sargassum fusiforme extract

Package Label - Principal Display Panel

236 mL NDC: 81282-044-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81282-044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	22 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81282-044-01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2021	

Labeler - HS HomeWorx LLC (080653110)

Establishment

Name	Address	ID/FEI	Business Operations
Cosbe Laboratory Inc		543033650	manufacture(81282-044)

Revised: 5/2021 HS HomeWorx LLC