

HAND SANITIZER- alcohol liquid
Maple River Distillery, 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.

hand sanitizer

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. Safflower Oil (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. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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.

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

- 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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

safflower oil, hydrogen peroxide, purified water USP

Germ Off
Hand Sanitizer

Directions
Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry.
For children under 6, use only under adult supervision. Not recommended for infants.

Contains: Ethanol 80%, Safflower Oil 1.45% and Hydrogen Peroxide 0.125%

128 oz. 03/31/20 Batch

Warnings
For external use only.
Flammable: Keep away from heat, fire, open flame, sparks and other ignitions sources. No smoking.
Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water.
Avoid contact with broken skin.
Do not inhale or ingest.
Keep out of reach of children

Other information
Do not store above 105 degrees F. May discolor some fabrics. Harmful to wood finishes and plastics. WHO-recommended handrub formulation

Germ Off LLC
1323 South 22nd Street
Bismarck, ND 58504
(701) 428-1705

World Health Organization recommended hand-rub formulation

Germ Off Hand Sanitizer

Directions

Shake before use.

Apply a palmful of alcohol-based handrub and cover all surfaces of the hands.

Rub hands until dry.

For children under 6, use only under adult supervision. Not recommended for infants.

Contains: Ethanol 80%
Safflower Oil 2.18%
Hydrogen Peroxide 0.125%

32oz, 946 ml D4/03/20 Batch A



Warning

For external use only.

Flammable: Keep away from heat, fire, open flame, sparks and other ignition sources. No smoking.

Avoid contact with eyes. In case of contact with eyes, flush thoroughly with water.

Avoid contact with broken skin.

Do not inhale or ingest.

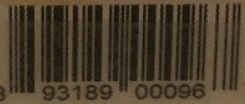
Keep out of reach of children

Other information

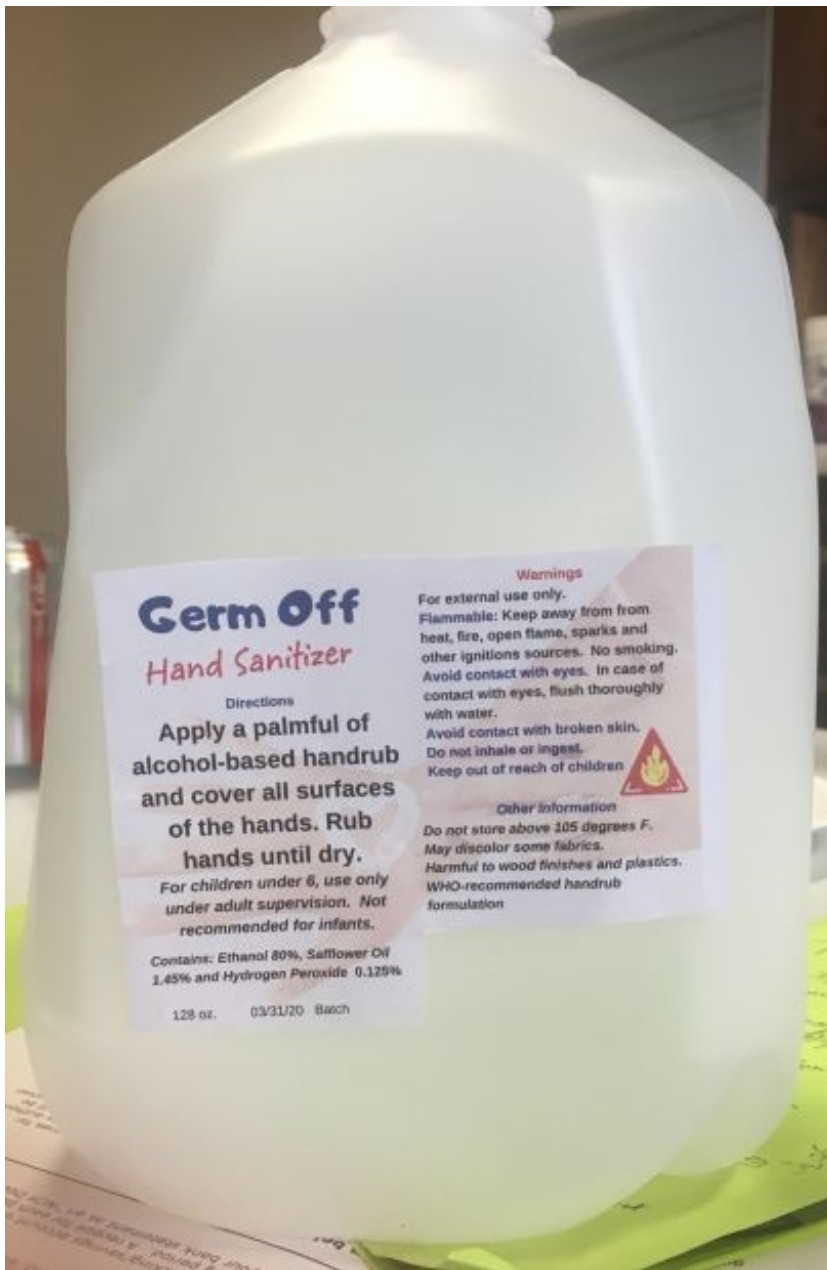
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May discolor some fabrics.

Harmful to wood finishes and plastics.



Germ Off LLC
PO Box 188
Casselton, ND 58012
(701) 428-1705



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74394-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SAFFLOWER OIL (UNII: 65UEH262IS)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74394-001-02	1900 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74394-001-05	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74394-001-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74394-001-09	475 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74394-001-01	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
6	NDC:74394-001-03	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
7	NDC:74394-001-04	17860 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
8	NDC:74394-001-07	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:74394-001-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Maple River Distillery, LLC (962531765)

Revised: 4/2020

Maple River Distillery, LLC