

HAND SANITIZER- alcohol liquid

Thomas Chemicals, 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.

Liquid hand sanitizer with Apple Pie scent

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 70% 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.

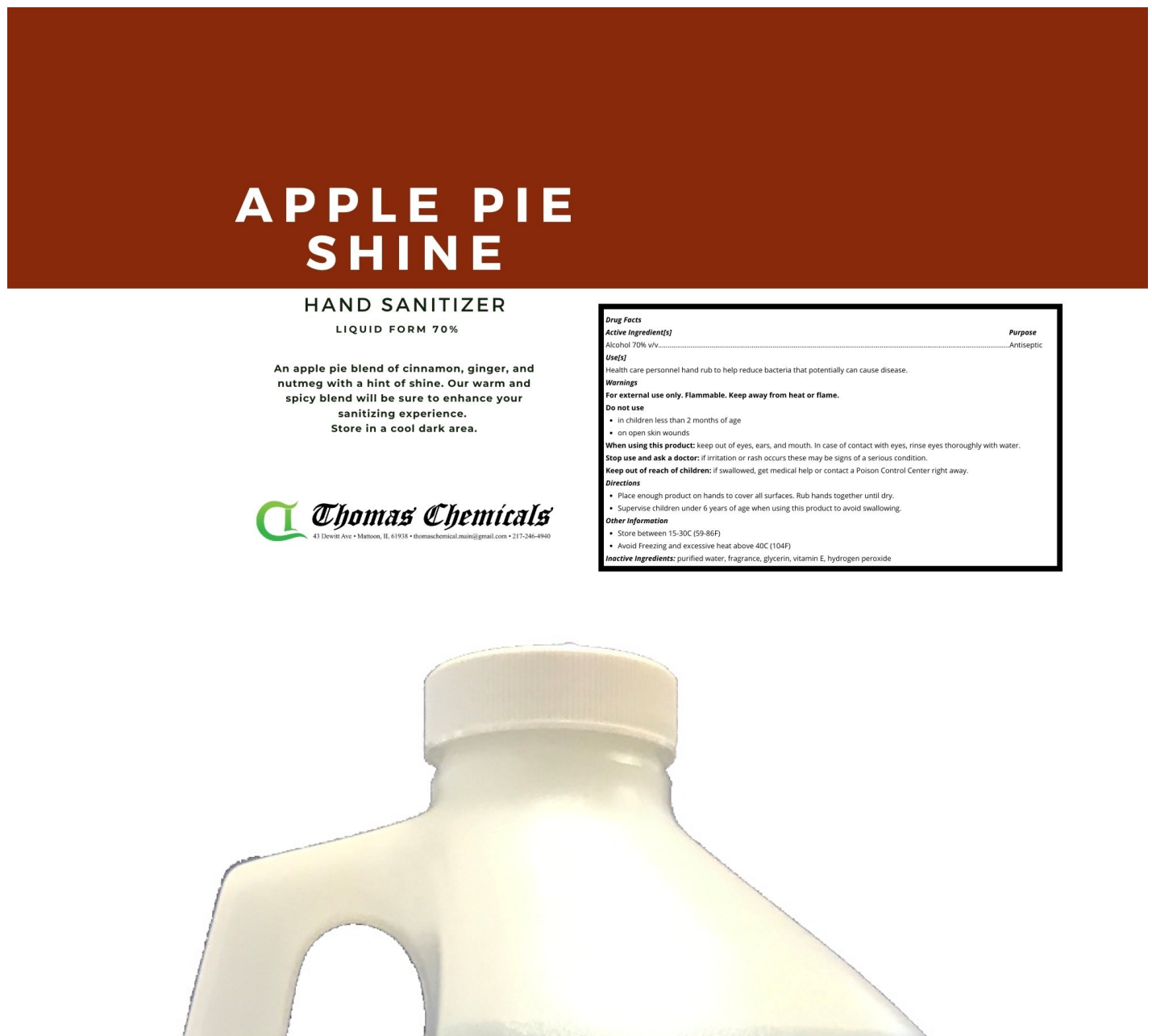
Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



APPLE PIE SHINE

HAND SANITIZER

LIQUID FORM 70%

An apple pie blend of cinnamon, ginger, and
nutmeg with a hint of shine. Our warm and
spicy blend will be sure to enhance your
sanitizing experience.

Store in a cool dark area.



Thomas Chemicals

43 Dewitt Ave • Mattoon, IL 61938 • thomaschemical.main@gmail.com • 217-246-4940

**Drug Facts****Active Ingredient(s)**

Alcohol 70% v/v

Purpose

Antiseptic

Use(s)

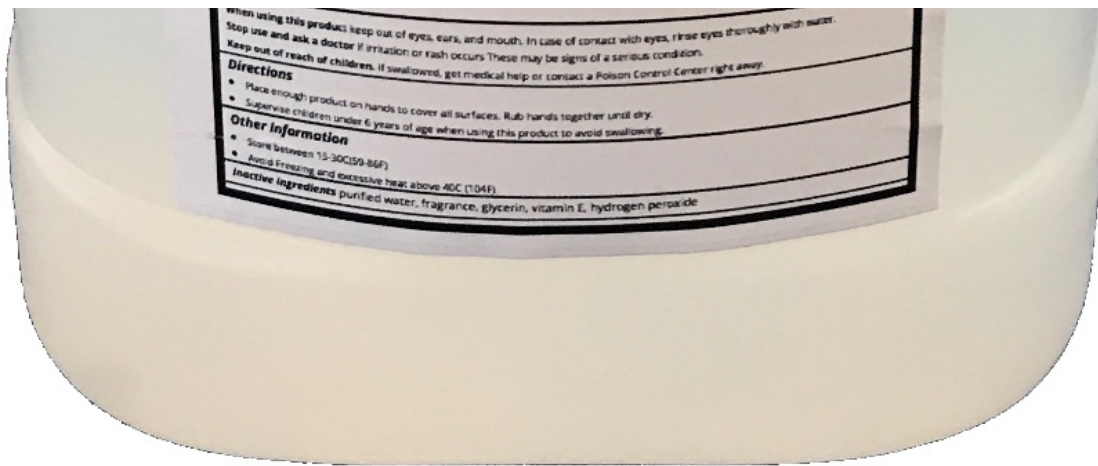
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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



3785 mL NDC: 76865-002-01

8 oz apple pie shine

APPLE PIE SHINE

HAND SANITIZER LIQUID FORM 70 %

An apple pie blend of cinnamon, ginger,
and nutmeg with a hint of shine. Our warm
and spicy blend will be sure to enhance
your sanitizing experience.
Store in a cool dark area.



8 oz

Drug Facts

Active Ingredient[s]

Alcohol 70% v/v.....Antiseptic

Purpose

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease

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.

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 purified water, Cedarwood essential oil, glycerin, vitamin E, hydrogen peroxide



Drug Facts

Active ingredient(s)

alcohol 70% v/v

Uses

Health care personnel hand rub to help reduce bacteria that potentially can cause infections.

Warnings

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

Do not use

• on 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, flush with water. If irritation or rash occurs, stop use and ask a doctor. These may be signs of an allergic reaction.

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

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.

Other information

• Store between 15-30C(59-86F)

• Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients purified water, Cedarwood essential oil, glycerin, stevia leaf extract.



236 mL NDC:76865-002-04

2 oz apple pie shine

59mL NDC: 76865-002-05



APPLE PIE S
HAND SANITIZER

LIQUID FORM 70%

blend of cinnamon, ginger, and nutmeg with a hint of vanilla to enhance your sanitizing experience.

2 oz
thomaschemical.maine@gmail.com

Helps reduce bacteria that potentially can cause illness.

Keep away from heat or flame.

For external use only. Avoid contact with eyes, ears, and mouth. In case of contact with eyes, flush with water. If irritation or rash occurs these may be signs of a sensitivity reaction. If you experience any of these symptoms, get medical help or contact a Poison Control Center.

Use on clean, dry hands. Rub hands together until completely dry. Cover all surfaces. Rub hands together until completely dry. Use on clean, dry hands. Rub hands together until completely dry.

Store at room temperature. Do not store above 40°C (104°F).

Ingredients: 70% Ethanol, Glycerin, Vitamin E, Hydrogen Peroxide.



APPLE PIE SHINE

HAND SANITIZER

LIQUID FORM 70 %

An apple pie blend of cinnamon, ginger, and nutmeg with a hint of shine. Our warm and spicy blend will be sure to enhance your sanitizing experience. Store in a cool dark area.
2 oz

43 Dewitt Ave • Mattoon, IL 61938 • thomaschemical.main@gmail.com • 217-246-4940 • cornvalley.us

Drug Facts

Active Ingredient[s]

Alcohol 70% v/v.....Antiseptic

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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: purified water, fragrance, glycerin, vitamin E, hydrogen peroxide

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76865-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.2 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76865-002-01	3765 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
2	NDC:76865-002-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
3	NDC:76865-002-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	
4	NDC:76865-002-04	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/25/2020	
5	NDC:76865-002-05	59 mL in 1 BOTTLE, SPRAY; 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		part333A	06/25/2020	

Labeler - Thomas Chemicals, LLC (117504978)

Registrant - Jessica Tutt (117504978)

Establishment			
Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-002)