

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.

Pumpkin Spice scented 70% 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. 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.

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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

236 mL NDC: 76865-014-01

PUMPKIN SPICE

HAND SANITIZER LIQUID FORM 70%

The mouth watering smell of a fresh baked
pumpkin pie. Store in a cool dark area.



8 oz

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

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- 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.

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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

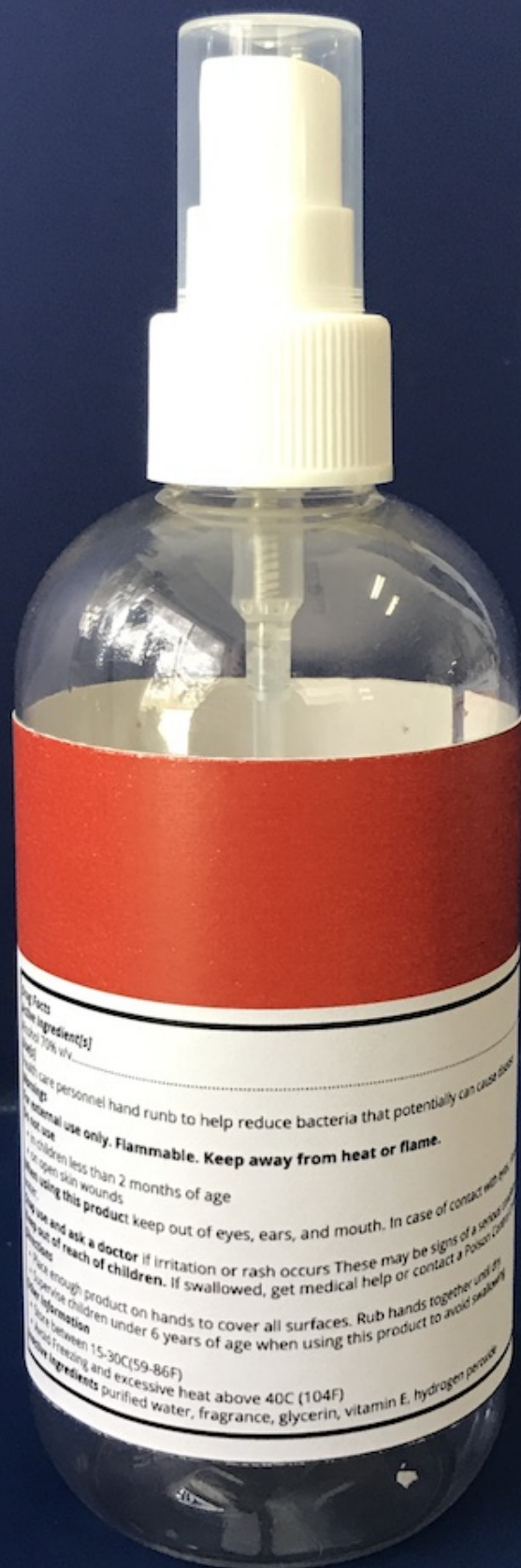
PUMPKIN SPICE

HAND SANITIZER
LIQUID FORM 70%

The mouth watering smell of a fresh baked
pumpkin pie. Store in a cool dark area.

 **Thomas Chemicals**
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8 oz



Use Facts
Active ingredient(s)
Contains 70% v/v
alcohol
For 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
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, wash with water.
If irritation or rash occurs. These may be signs of a sensitive reaction. Stop use and ask a doctor if irritation or rash occurs. If swallowed, get medical help or contact a Poison Control Center.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.
Store in a cool, dry place. Do not store in direct sunlight.
Keep 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.
For more information
Store between 15-30°C (59-86°F)
Do not freeze and excessive heat above 40°C (104°F)
Active ingredients: purified water, fragrance, glycerin, vitamin E, hydrogen peroxide

2 oz pumpkin spice

59mL NDC:76865-014-05





PUMPKIN SPICE

HAND SANITIZER

LIQUID FORM 70%

The mouth watering smell of a fresh baked pumpkin pie.

Store in a cool dark area.

2 oz

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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.
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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:76865-014
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:76865-014-01	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/24/2020	
2	NDC:76865-014-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2020	
3	NDC:76865-014-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2020	
4	NDC:76865-014-04	3785 mL in 1 JUG; Type 0: Not a Combination Product	07/24/2020	
5	NDC:76865-014-05	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/24/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/24/2020	

Labeler - Thomas Chemicals, LLC (117504978)

Registrant - Jessica Tutt (117504978)

Establishment			
Name	Address	ID/FEI	Business Operations
Thomas Chemicals, LLC		117504978	manufacture(76865-014)