CINNAMON BARK SANITIZER- alcohol spray
CINNAMON BARK HAND SANITIZER- hand sanitizer gel
Morning Star Aesthetics

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.

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 FDA recommendations: Classification of OTC Consumer Antiseptic Rub Active Ingredients in the 1994 TFM and in the 2016 Proposed Rule. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (60-90%), volume/volume (v/v)) in an aqueous solution denatured

Active Ingredient(s)

Alcohol 75%(Gel) - 80% (Spray) 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)

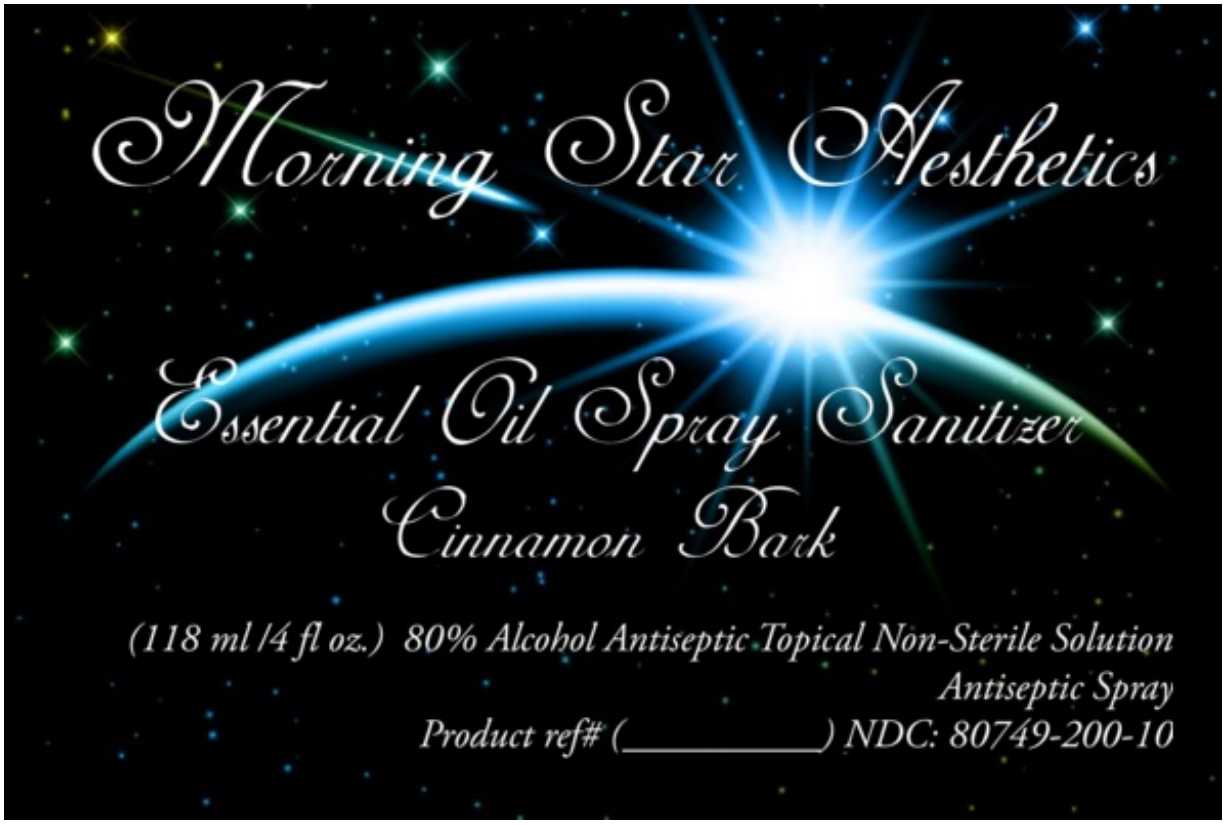
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, Cinnamon Bark Essential Oil

Package Labels - Front and Rear

Essential Oil Sanitizer Spray Cinnamon Bark 4oz

(118 ml /4 fl oz) NDC: 80749-200-10



Essential Oil Hand Sanitizer Cinnamon Bark 1oz

(29.5 ml /1 fl oz.) NDC: 80749-200-20

Essential Oil Hand Sanitizer Cinnamon Bark 16oz

(473ml / 16 fl oz.) NDC: 80749-200-21

Sanitizer Rear Label

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 FDA recommendations: Classification of OTC Consumer Antiseptic Rub Active Ingredients in the 1994 TFM and in the 2016 Proposed Rule. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (60-90%), volume/volume (v/v)) in an aqueous solution denatured
ACTIVE INGREDIENT: ehtyl alcohol 75%(gel) - 80% (spray) v/v. Purpose: antisepetic
Antiseptic, Hand Sanitizer
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
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.
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.
Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
INACTIVE INGREDIENTS: glycerin, hydrogen peroxide, purified water USP, cinnamon bark essential oil.(gel only: HydroxyEthyl Cellulose, aloe vera, vitamin E oil)

CINNAMON BARK SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80749-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	23.66 mL in 29.57 mL

Inactive Ingredients

Ingredient Name	Strength
CINNAMON OIL (UNII: E5GY4I6YCZ)	0.09 mL in 29.57 mL
WATER (UNII: 059QF0KO0R)	5.36 mL in 29.57 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.43 mL in 29.57 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.04 mL in 29.57 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:80749-100-10	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/19/2020	

CINNAMON BARK HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80749-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	22.2 mL in 29.57 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.04 mL in 29.57 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	0.31 mL in 29.57 mL
CINNAMON OIL (UNII: E5GY4I6YCZ)	0.09 mL in 29.57 mL
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	0.96 mL in 29.57 mL
WATER (UNII: 059QF0KO0R)	5.4 mL in 29.57 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.4 mL in 29.57 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.15 mL in 29.57 mL

Product Characteristics

Color	white (Mainly Clear Gel)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80749-200-20	29.57 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/19/2020	
2	NDC:80749-200-21	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/19/2020	

Labeler - Morning Star Aesthetics (117675328)

Registrant - Thomas D Smith (117675328)

Establishment

Name	Address	ID/FEI	Business Operations
Morning Star Aesthetics		117675328	pack(80749-100, 80749-200) , relabel(80749-100, 80749-200) , repack(80749-100, 80749-200) , label(80749-100, 80749-200) , manufacture(80749-100, 80749-200)

Revised: 10/2020 Morning Star Aesthetics