

HAND SANITIZER- alcohol gel
Bell Food & Beverage Inc.

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.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use[s]

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

Aloe Barbadosis Leaf Juice, Caprylyl Glycol, CI-42090, Ethyl Macadamiate, Eucalyptus Globulus Leaf Oil, Glycerin, Menthol, Polysorbate 80, Propylene Glycol, Safflower Glyceride, Tocopheryl Acetate, Water, 1,2-Hexanediol

Package Label - Principal Display Panel



The Ultimate In Hand Sanitizer

- 75% Ethyl Alcohol
- Refreshing Scent
- Anti-Bacterial
- Quick Drying
- Effective Protection
- Aloe Enhanced
- Gentle on Skin




Alkame[®]

Premium Gel Hand Sanitizer



with Aloe Vera

500 ml 16.9 fl. oz.

KILLS 99.9% OF MOST GERMS

NDC: 73806-0004-1

Drug Facts

Active ingredient(s)	Purpose
Alcohol 75 % v/v	Antiseptic
Use(s)	
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 the 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	
Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Cit-2008, Ethyl Macadamiate, Escalypus Globulus Leaf Oil, Citronellol, Menthyl Polysiloxane-80, Propylene Glycol, Sulfonium Glycolate, Tocopheryl Acetate, Water, 1,2-Hexanediol	




Manufactured By Bell Food & Beverage Inc.
3213 Waconda Road, Gervais, OR. 97026





500 mL NDC: 73806-0004-1

1892 mL NDC: 73806-0004-2



The Ultimate In Hand Sanitizer

- 75% Ethyl Alcohol
- Refreshing Scent
- Anti-Bacterial
- Quick Drying
- Effective Protection
- Aloe Enhanced
- Gentle on Skin




Alkame[®]

Premium Gel Hand Sanitizer



with Aloe Vera

64 fl. Oz. 1892 ml

KILLS 99.9% OF MOST GERMS

NDC: 73806-0004-2

Drug Facts

Active ingredient(s)	Purpose
Alcohol 75 % v/v	Antiseptic
Use(s)	
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 the 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	
Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Cit-2008, Ethyl Macadamiate, Escalypus Globulus Leaf Oil, Citronellol, Menthyl Polysiloxane-80, Propylene Glycol, Sulfonium Glycolate, Tocopheryl Acetate, Water, 1,2-Hexanediol	




Manufactured By Bell Food & Beverage Inc.
3213 Waconda Road, Gervais, OR. 97026





3785mL NDC: 73806-0004-3



- 75% Ethyl Alcohol
- Refreshing Scent
- Anti-Bacterial
- Quick Drying
- Effective Protection
- Aloe Enhanced
- Gentle on Skin

Alkame[®] Premium Gel Hand Sanitizer



128 fl. Oz. 3785ml

KILLS 99.9% OF MOST GERMS



NDC: 73806-0004-3

Drug Facts	
Active ingredient(s) Alcohol 75% v/v	Purpose Antiseptic
[Uses] 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 the 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 sensitive 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 Aloe Barbados Leaf Juice, Caprylyl Glycol, G-420M, Ethyl Macadamiate, Escalates Globulus Leaf Oil, Glycerin, Menthol, Polysorbate 80, Propylene Glycol, Safflower Glyceride, Tocopheryl Acetate, Water, 1,2-Hexanediol	



Manufactured By Bell Food & Beverage Inc.
3213 Waconda Road, Gervais, OR. 97026



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73806-0004
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
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73806-0004-1	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
2	NDC:73806-0004-2	1892 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2020	
3	NDC:73806-0004-3	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/20/2020	

Labeler - Bell Food & Beverage Inc. (081550987)

Establishment

Name	Address	ID/FEI	Business Operations
Bell Food & Beverage Inc.		081550987	manufacture(73806-0004)

Revised: 11/2020

Bell Food & Beverage Inc.