

HAND SANITIZER- ethanol liquid
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)

Ethanol 75% v/v. Purpose, Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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.

Other Information

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

Inactive ingredients

Ceraphyl 31(cetyl lactate, lauryl lactate, myristyl lactate), distilled water, glycerin, hydrogen peroxide, Hydroxypropyl cellulose

Principal Display Label



AFFEX Care Hand Hygiene is a 75% Alcohol, No-Rinse Hand Sanitizer.

AFFEX Care Hand Hygiene helps reduce microbes and bacteria on skin when used as directed. AFFEX Care Hand Hygiene will not leave skin chapped or feeling rough. No added colors or fragrances.

Ideal for use in office buildings, hotels, schools, factories, restaurants and anywhere hand sanitizing is suggested.

Manufactured For:
AFFEX
1400 AFFEX Drive,
Tuscaloosa, AL 35406
(888) 388-2308

NDC 73806-0003-3



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AFFEX CARE
HAND HYGIENE

**75% ETHYL ALCOHOL
HAND SANITIZER**
Desinfectante con alcohol para manos

AC01-04

1 US gal (3785.4)

DRUG FACTS:	
ACTIVE INGREDIENTS	PURPOSE:
ETHYL ALCOHOL 75%	ANTISEPTIC
USES:	
Wash surfaces help reduce microbes and bacteria on skin when used as directed.	
WARNINGS:	
FLAMMABLE:	
Keep away from heat or flame.	
FOR EXTERNAL USE ONLY	
DI NOT USE:	
If children is less than two months of age.	
Do not use near flames.	
PRECAUTIONS: THIS PRODUCT	
Keep out of eyes, ears, and mouth. In case of contact, flush thoroughly with water.	
STOP USE AND ASK DOCTOR IF:	
Irritation or rash on face, and if it:	
IF EYE IRRITATION PERSISTS:	
Seek medical attention.	
KEEP OUT REACH OF CHILDREN	
DIRECTIONS:	
Place enough product in palm to cover hands.	
Wash hands to palms, wrists, up to mid forearm.	
1. Apply to palms, backs of hands, wrists, fingers, and thumbs.	
2. Rub hands together for 20 seconds.	
3. Rinse hands with water.	
4. Dry hands with a clean towel.	
CONTAINS ETHYL ALCOHOL	
NON-STERILE SOLUTION	

KEEP OUT OF REACH OF CHILDREN
For more information, see package insert.
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QUESTIONS? Call: (800) 395-2206 Between 8:00AM-5:00PM Monday-Friday (CST)

3785mL: 73806-0003-3

HAND SANITIZER

ethanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73806-0003
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
LAURYL LACTATE (UNII: G5SU0BFK7O)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL LACTATE (UNII: A7EVH2RK4O)	
MYRISTYL LACTATE (UNII: 1D822OC34X)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73806-0003-3	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

Labeler - Bell Food & Beverage Inc (081550987)

Establishment

Name	Address	ID/FEI	Business Operations
Bell Food & Beverage Inc		081550987	manufacture(73806-0003)

Revised: 5/2020

Bell Food & Beverage Inc