ANTIBACTERIAL HAND SANITIZER- alcohol hand sanitizer gel Accompany USA 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.

Accompany, Hand Sanitizer, Gel, Alcohol 75%; 237mL

Active Ingredient(s)

Ethyl alcohol 75% v/v. Purpose: Antimicrobial

Purpose

Antibacterial

Use

For handwashing to decrease bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame.

Do not use

For external use only.

When using this product avoid contact with eyes.

If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash develops and continues for 72 hours.

Keep Out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Take a palmful (5grams) of product in one hand.
- Spread on both hands and rub into skin until dry (approximately 1 to 2 minutes).

Other information

- Do not store above 860(300)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water, Carbomer, Glycerin, 2-Amino-2-methyl-1-propanol, Fragrance.

Package Label - Principal Display Panel

Drug Facts

Antibacterial Hand Sanitizer Gel

Active ingredient

Purpose

Ethyl alcohol 75%(V/V)......Antibacterial

Use For handwashing to decrease bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.

Keep Out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Take a palmful (5grams) of product in one hand.
- Spread on both hands and rub into skin until dry (approximately 1 to 2 minutes).

Other information

- Do not store above 86°F(30°C)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water ,Carbomer ,Glycerin ,2-Amino-2-methyl-1-propanol , Fragrance

8oz(237ml)

NDC:

ACH-237 - #200331 - EXP: 050822 Accompany USA Inc.

1135 Centre Drive Ste K & L, City of Industry, CA, 91789
Made In China

ANTIBACTERIAL HAND SANITIZER

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76816-115

TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	177.75 mL in 237 mL		

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
LEMON OIL (UNII: 19 GRO 8 2 4 L L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

ı	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:76816-115-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/27/2020		

Labeler - Accompany USA Inc (076052578)

Route of Administration

Registrant - A03 Lab of BTS (548009541)

Establishment					
Name	Address	ID/FEI	Business Operations		
Accompany USA Inc		076052578	label(76816-115)		

Establishment				
Name	Address	ID/FEI	Business Operations	
Shanghai Chuangshi Industry Group Co., Ltd		546872672	manufacture(76816-115)	

Revised: 5/2020 Accompany USA Inc