

ANTIBACTERIAL HAND SANITIZER- alcohol hand sanitizer gel

Accompany USA I 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%

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 86° (30°)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, Carbomer, 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, Glycerin, Carbomer, Fragrance

2oz(60ml)

NDC

ACH-60 - #200331 - EXP: 050822

Accompany USA I Inc.

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

Made In China

Drug Facts

Antibacterial Hand Sanitizer Gel

Active ingredient

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

Purpose**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.**

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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

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- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, Carbomer, Fragrance

3.4oz(100ml)

NDC

ACH-100 - #200311 - EXP: 050822

Accompany USA I Inc.

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

Made In China

ANTIBACTERIAL HAND SANITIZER

alcohol hand sanitizer gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76816-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|------------------------------------------------------------|------------------------------------------|------------------------------------------------------|----------------------|--------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 45 mL in 60 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | | | |
| CLOVE (UNII: K48IKT5321) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:76816-101-01 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 04/30/2020 | | |

ANTIBACTERIAL HAND SANITIZER

alcohol hand sanitizer gel

| Product Information | | | | |
|------------------------------------------------------------|----------------|---------------------|----------------------|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76816-102 | |
| 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 | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | | | |
| CLOVE (UNII: K48IKT5321) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| | | | | |
|------------------------------|-------------------------------------------------|-------------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:76816-102-01 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | | 04/30/2020 | |

Labeler - Accompany USA I Inc (076052578)

Registrant - A03 Lab of BTS (548009541)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|-----------------------------|
| Accompany USA I Inc | | 076052578 | label(76816-101, 76816-102) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------------------|---------|-----------|-----------------------------------|
| Shanghai Chuangshi Industry Group Co., Ltd | | 546872672 | manufacture(76816-101, 76816-102) |

Revised: 4/2020

Accompany USA I Inc