ROADPRO HAND SANITIZER FOAMING- alcohol liquid Xiamen Wally Bath Manufacture Co., Ltd

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 70% 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, PEG-10 Dimethicone, purified water USP, Chlorhexidine digluconate, Fragrance (Parfum)

Package Label - Principal Display Panel

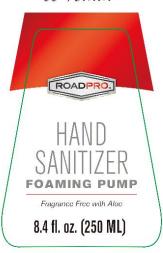
250 mL NDC: 78868-004-01

RPDF12

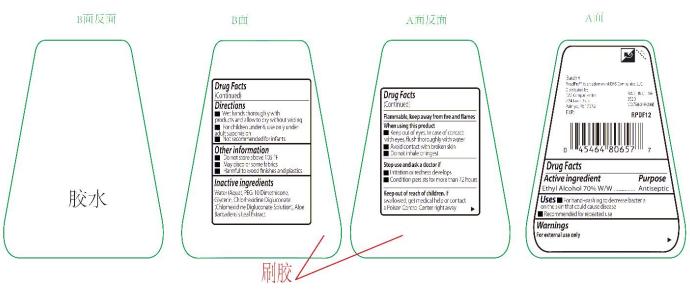


FOAMING PUMP Hand Sanitizer unscented 香型: 无香,加ALOE精华加批号/客人订单号PDQ材质同20107/20108液体无色 盖子实色白色

亮膜纸标 55*75MM



亮膜纸标 55*75MM



ROADPRO HAND SANITIZER FOAMING alcohol liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:78868-004 Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | |
|--|--------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL | |

| Inactive Ingredients | | |
|---|------------------|--|
| Ingredient Name | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) | 2.5 mL in 100 mL | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | 4 mL in 100 mL | |
| WATER (UNII: 059QF0KO0R) | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 | NDC:78868-004- 01 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |

| Marketing Information | | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 03/30/2020 | | |
| | | | | |

Labeler - Xiamen Wally Bath Manufacture Co., Ltd (548232606)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Xiamen Wally Bath Manufacture Co., Ltd | | 548232606 | manufacture(78868-004) | |

Revised: 1/2023 Xiamen Wally Bath Manufacture Co., Ltd