BLUZEN - WINTER PINE, WINTERMINT, PEPPERMINT - KIT- ethyl alcohol Remcoda, Llc

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.

BLUZEN HAND SANITIZER KIT

BLUZEN HAND SANITIZER WINTER PINE

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on skin

Warnings

Flammable, keep away from fire/flame

For external use only

When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water

do not inhale or ingest

Stop use and ask a doctor if irritation and redness develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

■ Store below 104°F (40°C)

Inactive ingredients

water, aloe barbadensis leaf juice, glycerin, fragrance

Questions? 1-800-777-1603

MOISTURIZING FORMULA WITH ALOE VERA KILLS 99.9% OF GERMS

SULFATE FREE PARABEN FREE VEGAN, CRUELTY FREE MADE IN THE USA Distributed by: Remcoda, LLC, New York, NY, 10018 SHOPBLUZEN.COM

BLUZEN HAND SANITIZER PEPPERMINT

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic *Uses* ■ hand sanitizer to help reduce bacteria on skin

Warnings

Flammable, keep away from fire/flame

For external use only

When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water

do not inhale or ingest

Stop use and ask a doctor if irritation and redness develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

■ Store below 104°F (40°C)

Inactive ingredients

water, aloe barbadensis leaf juice, glycerin, fragrance

Questions? 1-800-777-1603

MOISTURIZING FORMULA WITH ALOE VERA KILLS 99.9% OF GERMS SULFATE FREE PARABEN FREE VEGAN, CRUELTY FREE

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BLUZEN HAND SANITIZER WINTERMINT

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on skin

Warnings

Flammable, keep away from fire/flame

For external use only

When using this product ■ do not get into eyes. In case of contact, rinse eyes thoroughly with water

do not inhale or ingest

Stop use and ask a doctor if irritation and redness develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

■ Store below 104°F (40°C)

Inactive ingredients

water, aloe barbadensis leaf juice, glycerin, fragrance

Questions? 1-800-777-1603

MOISTURIZING FORMULA WITH ALOE VERA KILLS 99.9% OF GERMS SULFATE FREE PARABEN FREE VEGAN, CRUELTY FREE MADE IN THE USA

Distributed by: Remcoda, LLC, New York, NY, 10018

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KIT LABEL



KIT COMPONENTS LABEL



| BUUZEN Inactive ingredients water, aloe barbadensis leaf juice, glycerin, fragrance Inactive ingredients Inactive ingredients KILLS 99.9% OF GERMS Other information usestions? 1-800-777-1603 Inactive ingredients Inactive ingredients | <section-header><text><text></text></text></section-header> | Drug Facts Active ingredient Purpose Etyl alcohol 70% v/vAntiseptic Uses = hand sanitizer to help Educe bacteria on skin Destination Destination For external use only Men using this product = do not get into eyes. In case of contact, rinse eyes thoroughly with water = do not inhale or ingest Stop use and ask a doctor if Initiation and redness develop? Destination Destination Destination < |
|---|---|--|
| | | age when using this product to avoid swallowing <i>Inactive ingredients</i> water, aloe barbadensis leaf juice, glycerin, fragrance <i>Other information</i> ■ Store below 104°F (40°C) <i>Questions</i> ? 1-800-777-1603 |



BLUZEN - WINTER PINE, WINTERMINT, PEPPERMINT - KIT

ethyl alcohol kit **Product Information Product** Type HUMAN OTC DRUG NDC:79200-705 Item Code (Source) Packaging Item Code # **Package Description Marketing Start Date Marketing End Date 1** NDC:79200-705-02 1 in 1 KIT; Type 0: Not a Combination Product 09/11/2020 **Quantity of Parts Total Product Quantity** Part # **Package Quantity** Part 1 1 BOTTLE, PUMP 60 mL Part 2 1 BOTTLE, PUMP 60 mL Part 3 1 BOTTLE, PUMP 60 mL

| _ | | | |
|--|--|-------------------------|-----------------------|
| Part 1 of 3 | | | |
| BLUZEN HAND | SANITIZER WINTER PINE | | |
| ethyl alcohol liquid | | | |
| | | | |
| | | | |
| Product Information | | | |
| Item Code (Source) | NDC:79200-605 | | |
| Route of Administration | TOPICAL | | |
| | | | |
| | | | |
| Active Ingredient/Ac | | Desite of Channel | C taur a still |
| | Ingredient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958 V | /90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |
| | | | |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |
| WATER (UNII: 059QF0KO0 | R) | | |
| ALOE VERA LEAF (UNII: Z | Y8 1Z8 3H0 X) | | |
| GLYCERIN (UNII: PDC6A30 | 200X) | | |
| | | | |
| | | | |
| Packaging | | | |
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:79200-605- 60 m 02 Produ | L in 1 BOTTLE, PUMP; Type 0: Not a Combination | | |
| | | | |
| | | | |
| Marketing Inform | nation | | |
| | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| Marketing Category | | Marketing Start Date | Marketing End Date |
| Marketing Category | Application Number or Monograph Citation | _ | Marketing End Date |
| Marketing Category | Application Number or Monograph Citation | _ | Marketing End Date |
| Marketing Category | Application Number or Monograph Citation | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 | Application Number or Monograph Citation | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 | Application Number or Monograph Citation part333A | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 BLUZEN HAND | Application Number or Monograph Citation part333A | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 BLUZEN HAND ethyl alcohol liquid | Application Number or Monograph Citation part333A | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 BLUZEN HAND | Application Number or Monograph Citation part333A | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 BLUZEN HAND ethyl alcohol liquid | Application Number or Monograph Citation part333A | _ | Marketing End Date |
| Marketing Category OTC monograph not final Part 2 of 3 BLUZEN HAND ethyl alcohol liquid Product Information | Application Number or Monograph Citation part333A SANITIZER PEPPERMINT | _ | Marketing End Date |

| Active Ingredient/Active Moi | etv | | |
|--|--------------------------------------|-------------------------|-----------------------|
| 0 | lient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALC | | ALCOHOL | 70 mL in 100 mL |
| | | | |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |
| WATER (UNII: 059QF0KO0R) | | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 | X) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | | | |
| Packaging | | | |
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:79200-606- 02 60 mL in 1 BOT Product | TLE, PUMP; Type 0: Not a Combination | | |
| | | | |
| Marketing Information | | | |
| | tion Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final part333A | | 09/11/2020 | |
| | | | |
| Part 3 of 3 | | | |
| BLUZEN HAND SANIT ethyl alcohol liquid | IZER WINTERMINT | | |
| | | | |
| Product Information | | | |
| Item Code (Source) | NDC:79200-607 | | |
| Route of Administration | TOPICAL | | |
| | | | |
| Active Ingredient/Active Moi | etv | | |
| | lient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALC | | ALCOHOL | 70 mL in 100 mL |
| | | | |
| Inactive Ingredients | | | |
| | Ingredient Name | | Strength |
| WATER (UNII: 059QF0KO0R) | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0 | X) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | | | |

| Pa | ackaging | | | |
|----|--------------------|--|--------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | 60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combinatio Product | n | |
| | | | | |
| M | larketing Inf | ormation | | |
| I | Marketing Catego | y Application Number or Monograph Citat | ion Marketing Start Date | Marketing End Date |
| 07 | C monograph not fi | al part333A | 09/11/2020 | |
| 01 | C monograph not m | ai panoora | 09/11/2020 | |
| 01 | e monograph not m | | 09/11/2020 | |
| | larketing Inf | | 09/11/2020 | |
| Μ | | ormation | | Marketing End Date |

Labeler - Remcoda, Llc (117130169)

Revised: 9/2020

Remcoda, Llc