

HAND SANITIZER- alcohol spray
Organic Bath 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.

Active Ingredient(s)

Alcohol 63% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For handwashing to decrease bacteria on skin.

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.

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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, lavender essential oil, purified water USP

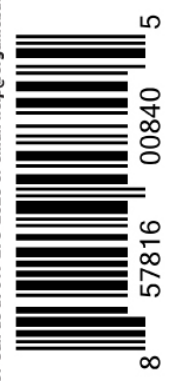
Package Label - Principal Display Panel

60 mL NDC: 77030-001-20



| Drug Facts | |
|--|----------------|
| Active Ingredient | Purpose |
| Ethyl Alcohol 63%..... | Antiseptic |
| Uses: For handwashing to decrease bacteria on skin | |
| Warnings For external use only. Flammable, keep away from fire 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. | |
| 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: Purified Water USP, Glycerin, Organic Lavender | |

Made in USA by Organic Bath LLC | www.organicbath.co
Questions? Call us at 617 273-2523 or email help@organicbath.co



| HAND SANITIZER | | | | |
|--|------------------|---|-----------------------------|---------------------------|
| alcohol spray | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77030-001 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 63 mL in 100 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | | 1.45 mL in 100 mL | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 5 mL in 100 mL | | |
| WATER (UNII: 059QF0K00R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:77030-001-20 | 60 mL in 1 BOTTLE, SPRAY; 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 - Organic Bath LLC (117491676)

Registrant - Organic Bath LLC (117491676)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Organic Bath LLC | | 117491676 | manufacture(77030-001) |

Revised: 4/2020

Organic Bath LLC