

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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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, organic orange oil, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 77030-002-20

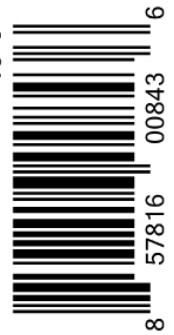


ORGANIC
Bath Co.™

ZESTY MORNING
HAND SANITIZER
2.0 FL. OZ. | 60 ml

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.	
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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 Orange Oil, Tangerine Oil	

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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:77030-002
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
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
ORANGE OIL (UNII: AKN3KSD11B)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77030-002-20	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(77030-002)

Revised: 6/2020

Organic Bath LLC