

HAND SANITIZER- ethyl alcohol gel

Allure Labs 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.

DRUG FACTS

Active Ingredient(s)

Ethyl Alcohol 65% w/w.

Purpose

Antimicrobial

Use

- Hand Sanitizer to help reduce microorganisms on the skin.
- Recommended for repeat use.

Warnings

For external use only. Flammable. Keep away from fire or flame

When using this product do not use in or near the eyes. In case of contact, rise eyes thouroughly with water.

Stop use and ask a doctor if irritation or rash occurs and lasts.

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
- Allow to dry without wiping
- Not recommended for infants
- For children under 6, use only under adult supervision

Other information

- Store at room temperature
- Do not freeze
- May discolor certain fabrics or surfaces
- Do not store above 105 °F

Inactive ingredients

Water(aqua), Glycerin, Acrylates Copolymer, Sodium Hydroxide, Fragrance (parfum), Benzyl Benzoate, Citral, Geraniol, Hexyl Cinnamaldehyde, linalool

Package Label - Principal Display Panel

birdzeye | labs

Premium
HAND SANITIZER
Gel

1 gallon (128 fl oz) 3.78 L

Drug Facts

Active Ingredient Ethyl Alcohol 65% w/w	Purpose Antimicrobial
Uses ■ Hand sanitizer to help reduce microorganisms on the skin ■ Recommended for repeat use	
Warnings Flammable. Keep away from fire or flame.	
For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs and lasts.	
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 ■ Allow to dry without wiping ■ Not recommended for infants ■ For children under 6, use only under adult supervision.	
Other Information ■ Store at room temperature ■ Do not freeze ■ May discolor certain fabrics or surfaces ■ Do not store above 105°F	
Inactive Ingredients Water (Aqua), Glycerin, Acrylates Copolymer, Sodium Hydroxide, Fragrance (Parfum), Benzyl Benzoate, Citral, Geraniol, Hexyl Cinnamaldehyde, Linalool	
Meets Guidelines for Hand Hygiene in Healthcare Settings published by the CDC.	

HS3 - GAL - BB

Birdzeyelabs.com

Dist. and sold by Birdzeye Labs, LLC

San Mateo, CA USA

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4191
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL BENZOATE (UNII: N863NB338G)	
CITRAL (UNII: T7EU0O9VPP)	
GERANIOL (UNII: L837108USY)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:62742-4191-1	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		11/25/2020	

Labeler - Allure Labs Inc (926831603)

Registrant - Allure Labs Inc (926831603)

Establishment			
Name	Address	ID/FEI	Business Operations
Allure Labs Inc		926831603	manufacture(62742-4191)

Revised: 11/2020

Allure Labs Inc