

HAND SANITIZER- alcohol gel
Oxygen Development 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.

Oxygen Health Wellness Hand Sanitizer infused with Aloe Vera 70% Alcohol

Active Ingredient(s)

Ethyl Alcohol 70%

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

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

When using

When using this product do not use in or near the eyes, rinse eyes thoroughly with water.

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

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

Stop use

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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Put enough product in your palm to cover hands and rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110F (43C)
- May discolor certain fabric surfaces.

Inactive ingredients

Water / aqua, Glycerin, Carbomer, Aminomethyl Propanol, Aloe Barbadosis Leaf Juice.

Package Label - Principal Display Panel



Customer: Oxygen	Color Guide:	<p>PRECISION LABEL CORPORATION</p> <p>50 Marcus Blvd. Hauppauge, NY 11788 tel 631.293.4200 fax 631.293.4203</p> <p>IMPORTANT: Please review proof for typographical errors, format, style and color breaks. This is a representation of the desired color. Please reference PANTONE® color guide for a more accurate color.</p> <p>PLEASE NOTE: Before proceeding, all proofs and revised proofs MUST be signed and returned.</p> <p><input type="checkbox"/> Approved <input type="checkbox"/> Not Approved</p>
Folder: Oxygen•artwork	<input type="checkbox"/> outline does not print <input type="checkbox"/> deco area does not print <input type="checkbox"/> Gloss Varnish	
File: OXYGEN LABEL_PetClearBottleAltira925mL_050-LBL-WRP-149.ai	<input type="checkbox"/> PMS 318 <input type="checkbox"/> PMS 7487 <input type="checkbox"/> PMS 288 <input type="checkbox"/> black	
ITEM#: 050-LBL-WRP-149 PRECISION#: 60664		
SIZE: 5" x 9.35" w/.125" cr		
JOB#: 14046		
UNWIND: 4		
SUBSTRATE: White BOPP 76999	PREPARED BY: JR	
DATE: 6/29/2020	PROOF #: 1	

HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61354-045

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70.47 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	GLYCERIN (UNII: PDC6A3C0OX)	1.49 mL in 100 mL		
	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.5 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)	27.44 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-045-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/11/2022		

Labeler - Oxygen Development LLC (137098492)

Establishment			
Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-045)

Revised: 1/2022

Oxygen Development LLC