# PRIMAL BLENDS ADVANCED MOISTURIZING GEL SANITIZER- alcohol solution Alchemy Nutra 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.

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#### **Active Ingredient**

Ethyl Alcohol 80% v/v.

#### Purpose

Antiseptic

#### Uses

- to decrease bacteria on the skin that could cause disease.
- recommended for repeated use

#### Warnings

For external use only: hands

Flammable. Keep away from fire or flame

#### When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin.
- do not inhale or ingest.

#### Stop using and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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.
- for children under 6, use only under adult supervision.
- not recommended for infants.

#### **Other Information**

- do not store above 105°F.
- may discolor some fabrics.
- not recommended for infants.

#### **Inactive ingredients**

Purified water, Glycerin, Hydroxypropyl Cellulose, Vitamin E

#### Package Label - Principal Display Panel

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118 mL

	ctive Ingredient hyl Alcohol 80% v/v	Purpose Antiseptic
th	ses • to decrease bacteria at could cause disease. • re r repeated use.	
	arnings r external use only: hands	
Flo	ammable, keep away from	fire or flame.
ey th	then using this product • ke res. In case of contact with oroughly with water. • avoi oken skin • do not inhale o	eyes, flush id contact with
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ge	eep out of reach of childrer et medical help or contact o ontrol Center right away.	
pi cł	irections • wet hands thou roduct and allow to dry wit sildren under 6, use only u spervision • not recommend	thout wiping • for nder adult
10	ther Information • do n 05°F • may discolor some to pt recommended for infants	fabrics •
P	nactive Ingredients urified water, Glycerin, Hyd ellulose, Vitamin E	droxypropyl



D	rug Facts	
	ctive Ingredient Purpose thyl Alcohol 80% v/v Antiseptic	
th	Ises • to decrease bacteria on the skin at could cause disease. • recommended or repeated use.	
Warnings For external use only: hands		
Fl	ammable, keep away from fire or flame.	
When using this product • keep out of eyes. In case of contact with eyes, flush thoroughly with water. • avoid contact with broken skin • do not inhale or ingest.		
a	top using and ask a doctor if • irritation nd redness develop • condition persists or more than 72 hours.	
g	eep out of reach of children. If swallowed, et medical help or contact a Poison ontrol Center right away.	
P	Directions • wet hands thoroughly with oroduct and allow to dry without wiping • for hildren under 6, use only under adult upervision • not recommended for infants.	
1	Other Information • do not store above 05°F • may discolor some fabrics • or recommended for infants.	

**Inactive Ingredients** 

Purified water, Glycerin, Hydroxypropyl Cellulose, Vitamin E

3785 mL



**Drug Facts** Active Ingredient Purpose Ethyl Alcohol 80% v/v ..... Antiseptic Uses · to decrease bacteria on the skin that could cause disease. • recommended for repeated use. Warnings For external use only: hands Flammable, keep away from fire or flame. When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water. • avoid contact with broken skin • do not inhale or ingest. Stop using and ask a doctor if • irritation and redness develop · condition persists for more than 72 hours. 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 • for children under 6, use only under adult supervision • not recommended for infants. Other Information · do not store above 105°F · may discolor some fabrics · not recommended for infants. Inactive Ingredients Purified water, Glycerin, Hydroxypropyl Cellulose, Vitamin E

1 gal. US 3.78 L

## PRIMAL BLENDS ADVANCED MOISTURIZING GEL SANITIZER

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	tem Code (Source)	NDC:75494-006
Route of Administration	TOPICAL		
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Active Ingredient/Act	ive where		
Active Ingredient/Act	Ingredient Name	Basis of Streng	th Strength
Active Ingredient/Act ALCOHOL (UNII: 3K9958V		Basis of Streng ALCOHOL	th Strength 80 mL in 100 mL
ALCOHOL (UNII: 3K9958VS	Ingredient Name		
ALCOHOL (UNII: 3K9958VS	Ingredient Name		
	Ingredient Name 90M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name		80 mL in 100 mL
ALCOHOL (UNII: 3K9958 V Inactive Ingredients	Ingredient Name 90M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name 00X)		80 mL in 100 mL
ALCOHOL (UNII: 3K9958V9 Inactive Ingredients GLYCERIN (UNII: PDC6A3C	Ingredient Name 90M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name 0OX) JNII: H4N855PNZ1)		80 mL in 100 mL

Packaging					
#	Item Code		Package Description	Marketing Start Date	Marketing End Date
1	NDC:75494-006- 01	59 m Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination act	05/25/2020	
2	NDC:75494-006- 02	118 m Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination act	05/25/2020	
3	NDC:75494-006- 03	3785 Pro du	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	0 5/25/20 20	
Marketing Information					
	Marketing Categ	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat
OTC monograph not final		c· 1	part333A	05/25/2020	

### Labeler - Alchemy Nutra LLC (117481753)

Establishment			
Name	Address	ID/FEI	Business Operations
Alchemy Nutra LLC		117481753	manufacture(75494-006)

Revised: 5/2020

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Alchemy Nutra LLC