

PUREGEL ADVANCED SURFACE DISINFECTANT- ethyl alcohol liquid
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.

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 develops • 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.

Inactive ingredients

Purified water, glycerin, Hydrogen Peroxide, Vitamin E

Product label

80% ALCOHOL SURFACE DISINFECTANT

FDA RECOMMENDED 80%



- HELPS KILL GERMS
- QUICK & EFFECTIVE
- ANTIMICROBIAL FORMULA
- SANITIZES
- PHONES, TABLES, KEYBOARDS
- DOOR KNOBS & HANDLES
- FACE MASKS & PERSONAL PROTECTIVE EQUIPMENT (PPE)
- HANDBAGS, SHOES, & CLOTHING
- TOOLS
- DESKS, COUNTERS & WORK AREAS
- AND ALL OTHER SURFACES

30 SECOND CONTACT TIME



ADVANCED SURFACE DISINFECTANT

Drug Facts	
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FDA # 66284-003

NET CONTENT: 1 GALLON (3.785L)



ISSACO HOLDINGS INC. VERNON CA 90058



PUREGEL ADVANCED SURFACE DISINFECTANT

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75494-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N8 55PN Z1)	
WATER (UNII: 059QF0 KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060 AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75494-004-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
2	NDC:75494-004-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
3	NDC:75494-004-03	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
4	NDC:75494-004-04	1040990 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - Alchemy Nutra LLC (117481753)

Establishment

Name	Address	ID/FEI	Business Operations
Alchemy Nutra LLC		117481753	manufacture(75494-004)

Revised: 5/2020

Alchemy Nutra LLC