

**ADVANCED FIRST HAND SANITIZER- hand sanitizer gel
SYNERGYPLANETS 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.

Active Ingredient

Alcohol 70% v/v

Purpose

Antiseptic

Use

- Hand sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of serious condition.

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

Directions

- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Supervise children when using this product to avoid swallowing.

Other Information

- Avoid freezing and excessive heat above 104°F(40°C).
- May discolor certain fabrics or surface.

Inactive Ingredients

Water, Glycerin, Carbomer, Trolamine, L-Menthol, Green Tea Leaf, Aloe Vera Leaf

Questions?

1.310.635.7007

Package Label - Principal Display Panel



ADVANCED FIRST HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75484-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL
LEVOMENTHOL (UNII: BZ1R15MTK7)	0.02 mL in 100 mL
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	0.001 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 mL in 100 mL
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.6 mL in 100 mL

WATER (UNII: 059QF0KO0R)	20.120 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75484-002-10	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

Labeler - SYNERGYPLANET S INC. (695720324)

Registrant - SYNERGYPLANET S INC. (695720324)

Establishment

Name	Address	ID/FEI	Business Operations
ICOMAX Co., Ltd.		694834031	manufacture(75484-002)

Revised: 4/2020

SYNERGYPLANET S INC.