

**HAND SANITIZER- ethyl alcohol gel**  
**Landy International**

*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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**51706-914 Hand Sanitizer Ethyl Alcohol(62%)**

**Active Ingredient(s)**

Ethyl Alcohol 62%

**Purpose**

Antiseptic

**Use**

helps eliminate bacteria on hands

**Warnings**

For external use only.

Flammable, Keep away from heat or flame,

Do not use

On children less than 2 months of age. on open skin wounds

When using this product keep out of eyes, ear, and mouth.

In case of contact with eye, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash occurs,

These may be a sign of a serious condition.

Keep out of reach of children. except under adult supervision.

If swallowed, get medical help or contact a poison control center right away.

**Directions**

Place enough product on hands to cover all surfaces.

Rub hands together until dry.

Supervise children under 6 years of age When using this product to avoid swallowing.

**Inactive ingredients**

Acrylates(C10-30 acrylate crosspolymer, Ascorbyl palmitate, Blue 1 (CI42090), Cellulose, Fragrance (Parfum), Glycerin, Hydroxypropyl methylcellulose, Jojoba

Esters, latose, Red 33( CI17200), Tocopheryl actate, Triethanolamine, Ultramarines (CI77007), Water(Aqua).

## Package Label - Principal Display Panel

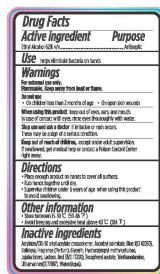
250ml (8.45oz) hand sanitizer wrap label / size:182\*70mm



Front

Back

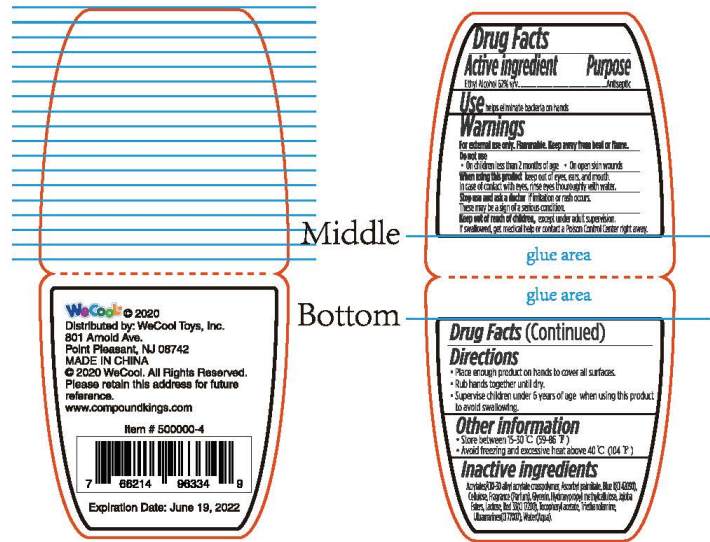
60ml (2.03oz) hand sanitizer front label  
size:32\*55mm



30ml (1 oz) hand sanitizer front label  
size:30\*32mm



30x32mm  
Base glue area



## HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51706-914
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TROLAMINE (UNII: 9O3K93S3TK)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

**ALPHA-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)

**ULTRAMARINE BLUE** (UNII: I39WR998BI)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-914-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:51706-914-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
3	NDC:51706-914-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

**Labeler** - Landy International (545291775)

**Registrant** - Landy International (545291775)

### Establishment

Name	Address	ID/FEI	Business Operations
Wecool Toys		080480202	label(51706-914)

### Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(51706-914)

Revised: 3/2022

Landy International