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.

51706-912 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 eve, rinse eyes thouroughly 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), Celluulose, Fagrance (Parfum), Glycein, Hydroxypropvl methylcellulose, Jojoba

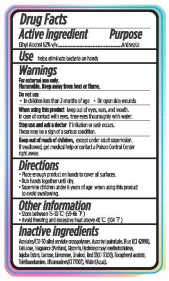
Esters, latose, Limonene, Linalool, Red 33(CI17200), Tocopheryl actate, Triethanolamine, Ultramarines (CI77007), Water(Aqua).

Package Label - Principal Display Panel

250ml (8.45oz) hand sanitizer wrap label / size:182*70mm 白色PE+光油

Front Back

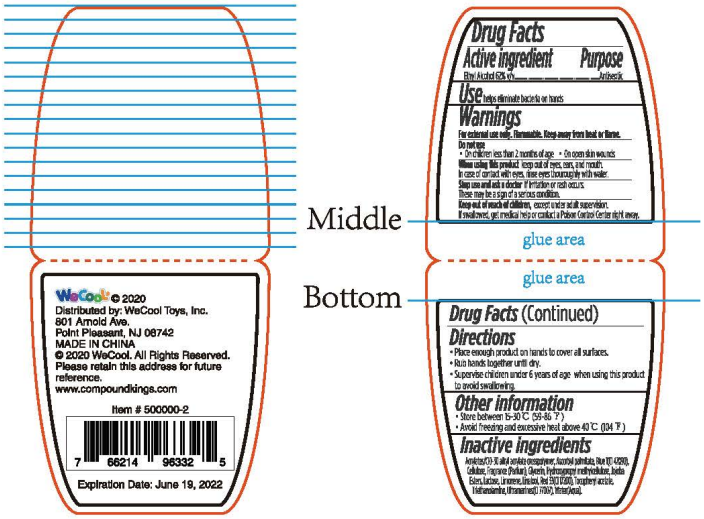
60ml (2.03oz) hand sanitizer front label
size:32*55mm



50X50MM,hand tag

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

30x32mm
Base glue area



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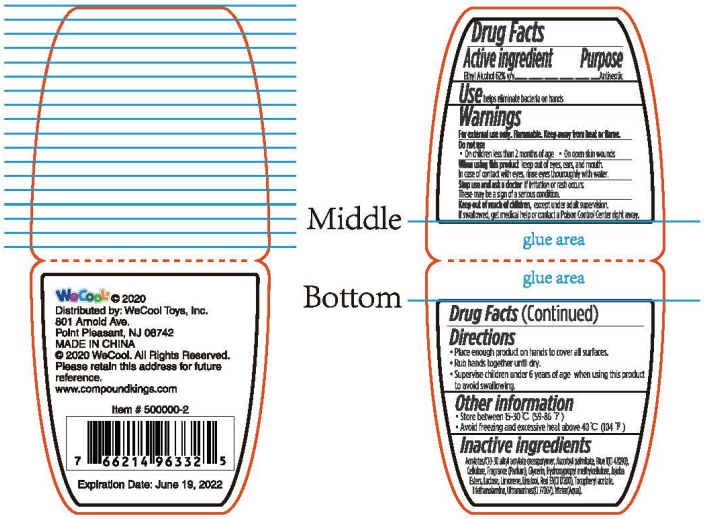

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51706-912
Route of Administration	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)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
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:51706-912-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:51706-912-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
3	NDC:51706-912-03	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(51706-912)

Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(51706-912)

Revised: 3/2022

Landy International