

## **HAND SANITIZER- 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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### **Active Ingredient(s)**

Alcohol denat 62%

### **Purpose**

Antiseptic

### **Use**

for handwashing to decrease bacteria on the skin

### **Warnings**

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

### **Do not use**

dose not contain grain alcohol,do not drink,if taken internally will produce serious gastric disturbances.

When using this product

avoid contact with eyes,if contact occurs,flush eyes with water

avoid contact with broken skin

Stop use and ask a doctor if condition worsens

redness or irritation develops

condition persists for more than 3 days

Keep out of reach of children.

in case of accidental ingestion ,seek professional assistance or contact a Poison Control Center immediately.

### **Directions**

- rub dime sized amount between hands until dry.
- supervise children in the use of this product.
- in the case of eye contact ,rinse eyes thoroughly with water.

- wet hands with product and allow to dry without wiping.

## Other information

Store at 68° to 77F(20° to 25°c).  
Do not store above 105°.  
May discolor some fabrics.  
Not recommended for infants.  
Harmful to wood finishes and plastics.

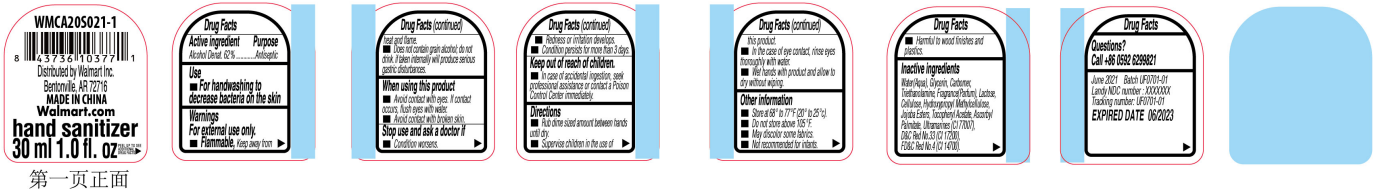
## Inactive ingredients

Water(Aqua), Glycerin, Carbome,Triethanolamine, Fragrance(Parfum),Lactose, Cellulose, Hydroxypropyl Methylcellulose,Jojoba Estes, Iocopheryl Acetate, Ascorbyl,Palmitate, Ultramarines(CI 77007), D&C Red NO.33(CI 17200),FD&C YVellow No.5(CI 19140).

## Package Label - Principal Display Panel

30 mL WMCA20S021-1 NDC: 51706-964-01

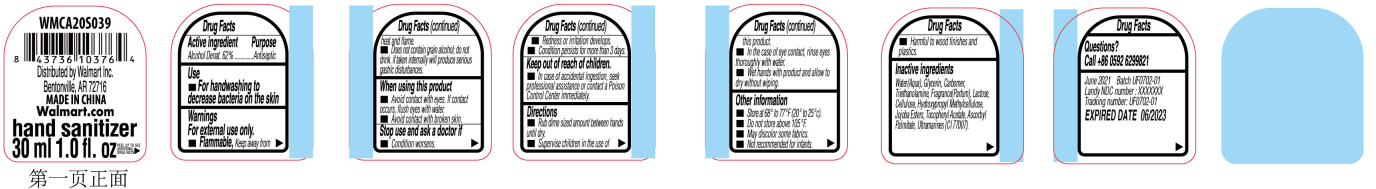
WMCA20S021-1



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30 mL WMCA20S039 NDC: 51706-964-02

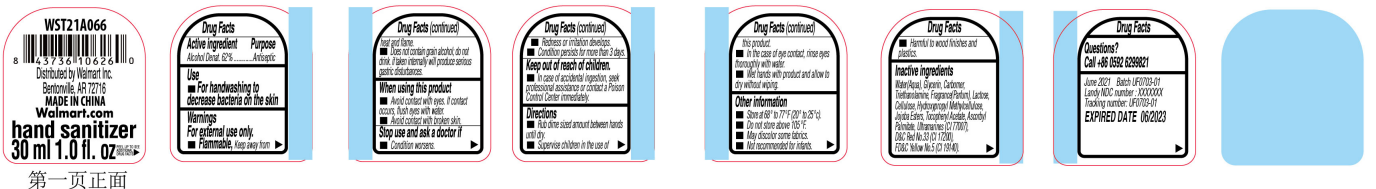
WMCA20S039



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30 mL WST21A066 NDC: 51706-964-03

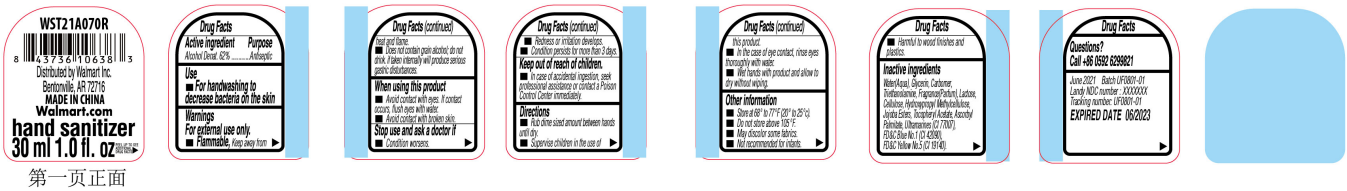
WST21A066



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30 mL WST21A070R NDC: 51706-964-04

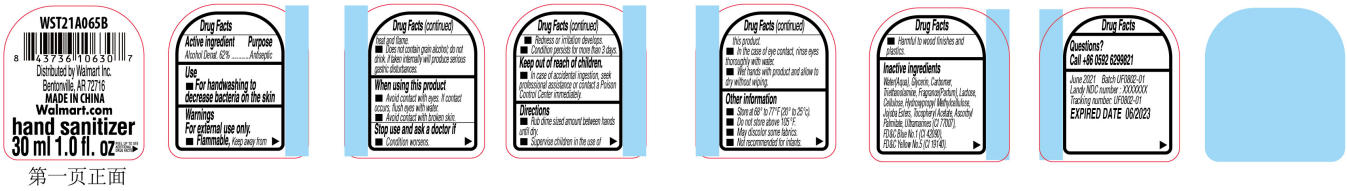
WST21A070R



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30 mL WST21A065B NDC: 51706-964-05

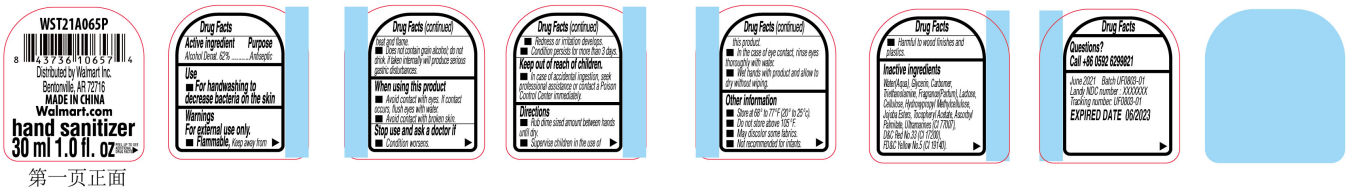
WST21A065B



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30 mL WST21A065P NDC: 51706-964-06

WST21A065P



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## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51706-964
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
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 903K93S3TK)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51706-964-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
2	NDC:51706-964-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
3	NDC:51706-964-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
4	NDC:51706-964-04	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
5	NDC:51706-964-05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
6	NDC:51706-964-06	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

**Labeler** - Landy International (545291775)

## Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(51706-964)

Revised: 5/2021

Landy International