# HAND SANITIZER- alcohol gel MCRL Overseas Printing 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.

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# **Active Ingredient**

Ethyl Alcohol 70% v/v

# **Purpose**

Sanitizer

#### Use

- to decrease bacterias on the skin that could cause diseases.
- recommended for repeated use

# **Warnings**

IFor external use only-hands. Use only as directed. Excessive use or prolonged exposure may cause irritation to skin. Discontinue use if rash, redness or itching appears. Flammable. Keep away from heat or flame.

# When using this product

- keep out of eyes. In case of contact with eyes, immediately flush with water and call a doctor.
- avoid contact with broken skin.

**Stop use and ask a doctor if** irritation or redness develops.

**Keep out of reach of children.** In case of accidental ingestion seek professional assistance or contact a poison control center immediatly.

## **Directions**

Put a thumb size amount in your palm and rub hands together briskly until dry.

#### Other information:

- do not store in temperature over 118F.
- children under the 6 years of age should be supervised while using this product.
- may discolor certain fabrics.

# **Inactive ingredients**

Water, glycerin, propylene Glycol, carbomer, sodium hydroxide

# Package Label - Principal Display Panel

Label 1



# HAND SANITIZER

TUE **99.9%** OF GERMS DES GERMES WITHOUT WATER/SANS EAU

# DÉSINFECTANT **POURLES MAINS**

60 ml / 2U.S. fl.oz.

### Drug Facts

Active ingredient Ethyl Alcohol 70 %......Sanitizer

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#### Flammable, Keep away from heat and flame,

When using this product

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Stop use and ask a doctor if irritation or redness develops,

#### Keep out of reach of children.

In case of accidental ingestion, seek professional assi-stance or contact a Poison Control Center immediately

#### Directions

put a thumb size amount in your palm and rub hands together briskly until dry.

#### Other information

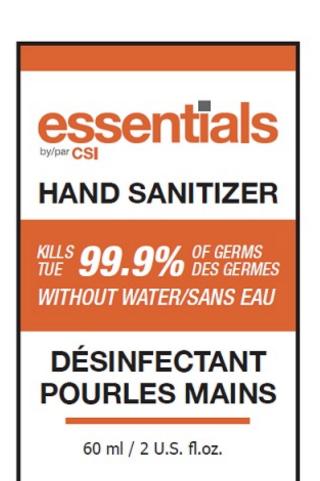
do not store in temperatures over 118° F.
children under 6 years of age should be supervised while using this product, may discolor certain fabrics.

#### Inactive ingredients

Water, glycerin, propylene glycol, carbomer, sodium hydroxide



Label 2



# **Drug Facts**

Active ingredient Ethyl Alcohol 70%...

Purpose .Sanitizer

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Water, glycerin, propylene glycol, carbomer, sodium hydroxide



### HAND SANITIZER

alcohol gel

### **Product Information**

NDC:76626-002 Product Type HUMAN OTC DRUG Item Code (Source)

TOPICAL **Route of Administration** 

### 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 WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) SODIUM HYDRO XIDE (UNII: 55X04QC32I)

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76626-002- 01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
2	NDC:76626-002- 02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
3	NDC:76626-002- 03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
4	NDC:76626-002- 04	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
5	NDC:76626-002- 05	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
6	NDC:76626-002- 06	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		
7	NDC:76626-002- 07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	04/17/2020				

# **Labeler -** MCRL Overseas Printing Inc (257078621)

Establishment							
Name	Address	ID/FEI	Business Operations				
Huizhou Bliss Commodity Co. Ltd		417467331	manufacture(76626-002)				

Revised: 4/2020 MCRL Overseas Printing Inc