

## **SIMPLY SAFER HAND SANITIZER- alcohol gel**

### **Simply Safer Products Llc**

*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.*

-----

### **75% alcohol hand sanitizer (no water)**

#### **Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### **Use(s)**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### **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, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

#### **Stop use and ask a doctor if**

if irritation or rash occurs. These may be signs of a 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 hands to cover all surfaces. Rub hands together until dry
- Supervise children under 6 years of age when using product to avoid swallowing

#### **Other information**

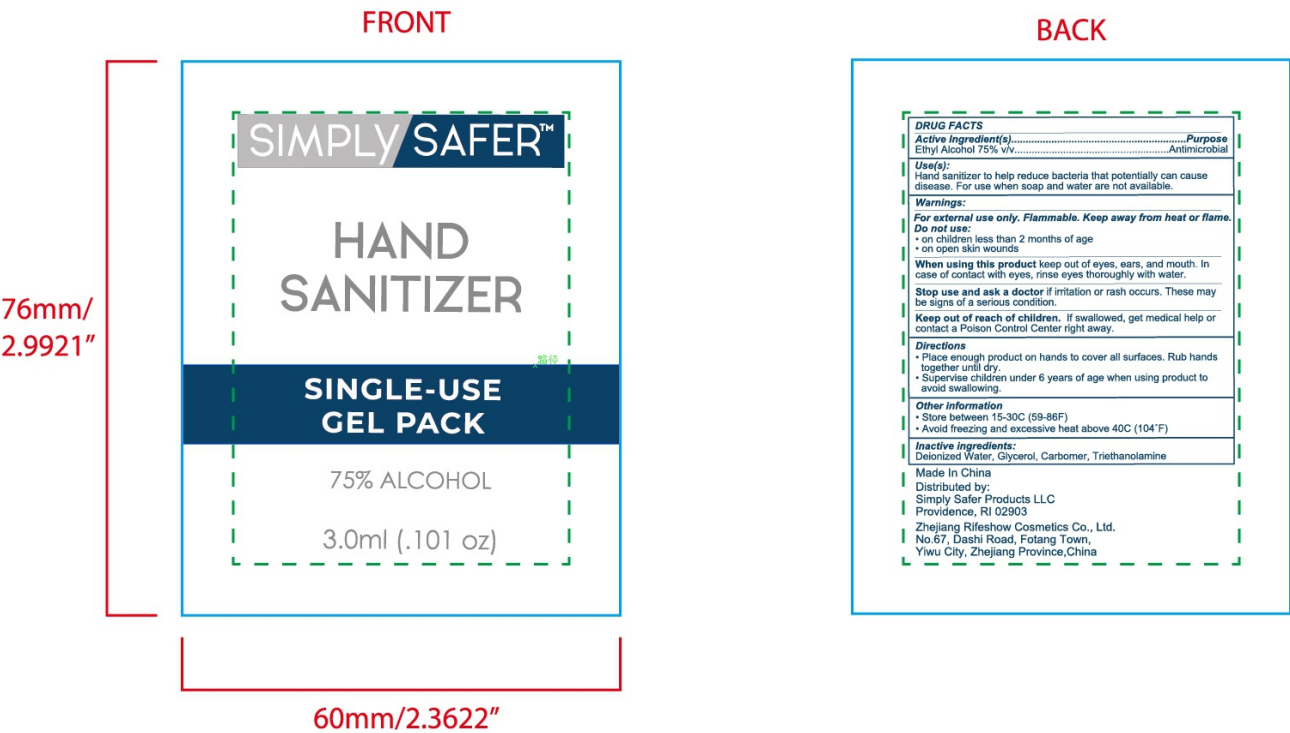
- Store between 15-30C (59-84F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

Deionized Water, Glycerol, Carbomer, Triethanolamine

Package Label - Principal Display Panel

3 mL NDC: 79754-001-01



SIMPLY SAFER HAND SANITZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79754-001(NDC:56084-021)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
GLYCERIN (UNII: PDC6A3C0OX)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79754-001-01	3 mL in 1 BAG; Type 0: Not a Combination Product	07/23/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/23/2020	

**Labeler** - Simply Safer Products Llc (117579462)

Revised: 7/2020

Simply Safer Products Llc