

**HAND SANITIZER- ethyl alcohol gel**  
**Tonic Bath & Body Products Shenzhen Ltd**

*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.*

-----

**Drug Facts**

**Active Ingredient(s)**

Ethyl Alcohol 65% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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**

- in 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 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.

Stop use and ask a doctor 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 this product to avoid swallowing.

**Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Water, Glycerin, Propylene Glycol, Carbomer, Fragrance, Tocopheryl Acetate, Isopropyl Alcohol,

Aminomethyl Propanol, Isopropyl Palmitate.

Package Label - Principal Display Panel



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 65% v/v.....	Antiseptic
<b>Use</b>	
<ul style="list-style-type: none"> <li>Hand sanitizer to help reduce bacteria on the skin.</li> </ul>	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>Flammable. Keep away from fire and flame.</b>	
<b>When using this product</b> avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation and redness develop.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Put enough on your palm to cover hands and rub hands together briskly until dry</li> <li>Children under 6 years of age should be supervised when using this product</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store at 20°C to 25°C (68°F to 77°F).</li> <li>May discolor some fabrics or surfaces.</li> </ul>	
<b>Inactive ingredients</b>	
Deionized Aqua (Water), Glycerin, Propylene Glycol, Carbomer, Fragrance (Parfum), Tocopheryl Acetate, Isopropyl Alcohol, Aminomethyl Propanol, Isopropyl Palmitate.	
<b>Questions?</b>	
1-888-942-2280 Monday – Friday 9 AM – 5 PM PST	
201106 DIST. BY SJ CREATIONS, INC. P.O. BOX 232428 LEUCADIA, CA 92023, U.S.A. WWW.SJCREATIONSINC.COM PRODUCT OF CHINA	

2236ml NDC: 43333-475-08

<b>HAND SANITIZER</b>			
ethyl alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43333-475
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43333-475-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/07/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Tonic Bath & Body Products Shenzhen Ltd (528197042)

## Establishment

Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528197042	manufacture(43333-475)

Revised: 5/2020

Tonic Bath & Body Products Shenzhen Ltd