HAND SANITIZER- ethyl alcohol spray
Tonic Bath & 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 74% 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.

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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)

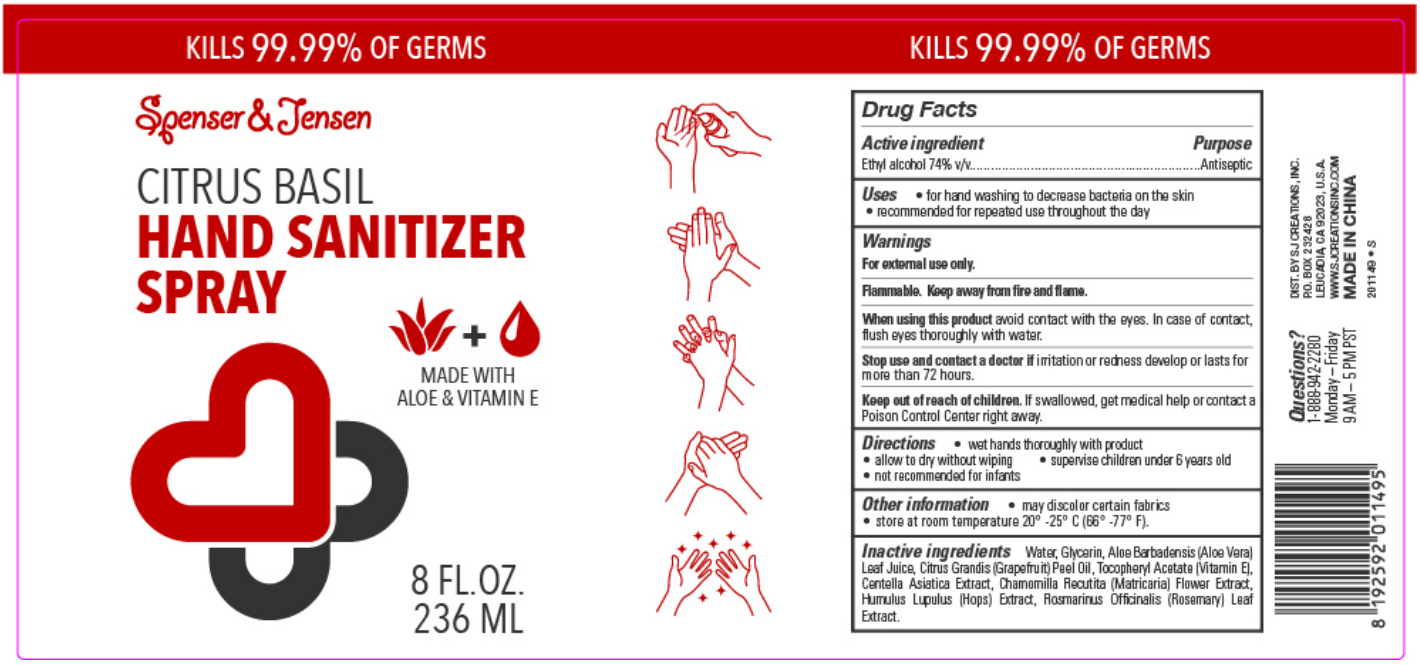
Inactive ingredients

Water, Glycerin, Aloe Barbadensis (Aloe Vera) leaf Juice, Citrus Grandis (Grapefruit) Peel Oil,

Tocopheryl Acetate (Vitamin E), Centella Asiatica Extract, Chamomilla Recutita (Matricaria) Flower Extract, Humulus Lupulus (Hops) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract.

Package Label - Principal Display Panel

201149
8oz Hand Sanitizer Spray
3 x 6.5in (165.1x76.2mm) - White/Glossy



236 ml NDC: 43333-484-08

HAND SANITIZER

ethyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43333-484
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	74 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
HUMULUS LUPULUS WHOLE (UNII: 912A6Q1N4A)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	

GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43333-484-08	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

Labeler - Tonic Bath & Products Shenzhen Ltd (528197042)

Establishment

Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528197042	manufacture(43333-484)

Revised: 5/2020 Tonic Bath & Products Shenzhen Ltd