# BODY LUXURIES TIHITIAN VANILLA ANTIBACTERIAL HAND SANITIZER - alcohol liquid

#### **ENCHANTE ACCESSORIES 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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# **Drug Fact**

# **Active Ingredient**

Ethyl Alcohol 63%

# Purpose

Antiseptic

#### Uses

To decrease bacteria on the skin that could cause diseases

## For external use only-hands

Flammable: Keep away from heat and flame

**When using this product: Keep out of eyes.** In case of contact with eyes, flush thoroughly with water. Avoid Contact with broken skin. Do not inhale or ingest.

# **Stop use and ask a doctor** if skin irritation develops

**Keep out of reach of children**. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately

#### **Directions**

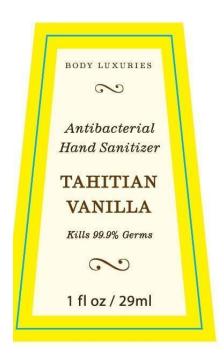
• Wet hands thoroughly with product and allow to dry without wiping

#### Other Information:

- Do not store above 105F
- May discolor some fabrics

### **Inactive Ingredient:**

Deionized Water, Triethanolamine, Carbomer, Fragrance, Disodium EDTA, may contain D and C Red No. 33, FD and C Red No. 40, FD and C Blue No. 1, FD and C Yellow No. 5, FD and C Yellow No. 6. lab





Drug Facts (continued)

WARNINGS
FOR EXTERNAL USE
ONLY-HANDS.
FLAMMABLE. KEEP AWAY FROM
HEAT AND FLAME. WHEN USING
THIS PRODUCT • KEEP OUT OF
EYES. IN CASE OF CONTACT
WITH EYES, FLUSH
THOROUGHLY WITH WATER. •
AVOID CONTACT WITH
BROKEN SKIN.
• DO NOT INHALE OR INGEST.
STOP USE AND ASK A
DOCTOR IF SKIN IRRITATION
DEVELOPS. IN CASE OF
ACCIDENTAL INGESTION,
SEEK PROFESSIONAL
ASSISTANCE OR CONTACT
A POISON CONTROL
CENTER IMMEDIATELY.
KEEP OUT OF REACH OF
CHILDREN EXCEPT
UNDER ADULT
SUPERVISION.

Directions

• Wet hands thoroughly with product and allow to dry without wiping.

Other information

• Do not store above 105°F.

• May discolor some fabrics.

Inactive Ingredients
Alcohol, Water, Carbomer,
Triethanolamine, Fragrance,
Disodium EDTA.
May Contain: Blue 1, Yellow 5,
Yellow 6, Red 33, Red 40.

Not tested on animals.
Designed in the USA. Made in China.
Formulated exclusively and distributed by:
Enchanté Accessories Inc. NY, NY 10016

1 2 3

# BODY LUXURIES TIHITIAN VANILLA ANTIBACTERIAL HAND SANITIZER

alcohol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50563-127

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	36.11 mL in 100 mL		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)			
TROLAMINE (UNII: 9O3K93S3TK)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50563-127-01	29 mL in 1 BOTTLE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	12/18/2012			

# Labeler - ENCHANTE ACCESSORIES INC. (186050696)

# Registrant - Zhejiang Aidi Cosmetics Co., Ltd. (530876820)

Establishment						
Name	Address	ID/FEI	Business Operations			
Zhejiang Aidi Cosmetics Co., Ltd.		530876820	manufacture(50563-127)			

Revised: 12/2012 ENCHANTE ACCESSORIES INC.