# BALANSE NYC HAND SANITIZER- ethyl alcohol liquid YASHVIRE 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.

-----

#### **BALANSE NYC**

#### Active Ingredient

Ethyl Alcohol 70%

#### Purpose

Antiseptic

#### Uses

Hand sanitizer to help decrease bacteria on the skin. When water, soap and towel are not available. Recommended for repeated use

#### Warnings:

For external use only.
Flammable. Keep away from fire or flame
Do not apply around eyes. Do not use in ears & mouth
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

#### Keep out of reach of children.

Children must be supervised in use of this product

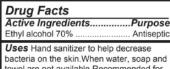
#### **Directions**

- Place enough product in your palm to spread on both hands.
- Rub your hands together thoroughly until dry.
- Children under 6 years of age should be supervised by an adult when using this product to avoid swallowing.

#### **Inactive ingredients**

Aqua, Glycerine, Carbomer, Triethanolamine, Fragrance, Tocopheryl Acetate

#### **Product Label**



bacteria on the skin. When water, soap and towel are not available. Recommended for repeated use

Warning For external use only

Flammable. Keep away from fire or flame

Do not apply around eyes. Do not use in ears & mouth

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

Keep out of reach of children. Children must be supervised in use of this product

Directions Pump as needed into your palms and thoroughly spread on both hands Rub into skin until dry.

Inactive ingredients Aqua, Glycerine, Carbon Triethanolamine, Fragrance, Tocopheryl Acetate

Kills 99.99% of Germs



Vitamin Enriched Hand Sanitizer



16.9 FL OZ (500ml)

- Kills more than 99.99% of germs\*
- Vitamin Enriched
- Contains Moisturizers

For external use only

Made in South Africa

Kills 99.99%

of Germs

Distributed in the USA by: Yashvire LLC 115 W 29th St, STE 808, New York, NY, 10001 www.BalanseNYC.com 646-969-2077



#### BALANSE NYC HAND SANITIZER

ethyl alcohol liquid

#### **Product Information**

HUMAN OTC DRUG NDC:74094-001 Product Type Item Code (Source)

**Route of Administration** TOPICAL

.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

**Active Ingredient/Active Moiety** 

**Basis of Strength Ingredient Name** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 70 mL in 100 mL

**Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX) CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) TROLAMINE (UNII: 903K93S3TK)

**Packaging Marketing Start Marketing End** Item Code **Package Description** Date Date 1 NDC:74094-001-01 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination 04/01/2020

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

## Labeler - YASHVIRE LLC (117396744)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
MARSHALLS TRADITIONAL HEALTHCARE CC		637662219	manufacture (74094-001)			

Revised: 4/2020 YASHVIRE LLC