

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

Drug Facts**Active Ingredients.....Purpose**
Ethyl alcohol 70% Antiseptic**Uses** Hand sanitizer to help decrease 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, Carbomer, Triethanolamine, Fragrance, Tocopheryl AcetateBALANSE
NYCVitamin Enriched
Hand Sanitizer

16.9 FL OZ (500ml)

Kills 99.99%
of GermsKills 99.99%
of Germs

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

For external use only

Made in South Africa

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74094-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74094-001-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	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	Business Operations
MARSHALLS TRADITIONAL HEALTHCARE CC		637662219	manufacture(74094-001)

Revised: 4/2020

YASHVIRE LLC