

LUXURY HAND SANITIZER ALOE- ethyl alcohol gel
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED Sirketi

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.

Luxury Hygiene Hand Sanitizer: Aloe

Active Ingredients

Ethyl Alcohol 75%

Purpose: Antiseptic

Purpose

Antiseptic

Uses

- helps reduce bacteria on the skin that could cause disease
- Recommended for repeated use

Directions

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Safety Instructions

Flammable, Keep away from fire and flame

Ask Doctor

Stop Use and Ask a doctor if irritation or redness develops

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact Poison Control right away

Other Information

Store below 110°F (43°C)

May discolor certain fabrics or surfaces.

Inactive Ingredients

water, glycerin, carbomer, aminomethyl propanol, fragrance, Aloe, Tocopheryl Acetate. Please review Label for further details





LUXURY
HYGIENE

HAND SANITIZER

- **Moisturizing Formula
with Vitamin E**



**KILLS UP TO 99.9 %
OF MOST GERMS**

8 FL.OZ.(236mL)



LUXURY **HAND
SANITIZER**
HYGIENE *advanced aloe vera*

Drug Facts

| Active ingredient | Purpose |
|------------------------|------------|
| Ethyl Alcohol 75%..... | Antiseptic |

Uses to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings For external use only. ■ flammable ■ keep away from source of heat or fire

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- put enough product in your palm to cover hands and rub hands together until dry.
- children under 6 years should be supervised when using this product.

Other information

- store at a temperature below 110°F (43°C).
- may discolor certain fabrics or surfaces.

Inactive Ingredients: Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum).

TSM Brands LLC

540 Equinox Ln
Manalapan, NJ 07726

www.tsmbrands.com

Made in TURKEY




**8 FL.OZ.
(236mL)**




LUXURY **HAND SANITIZER**
 HYGIENE *advanced aloe vera*

| Drug Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Ethyl Alcohol 75%..... | Antiseptic |
| Uses to help reduce bacteria on the skin. For use when soap and water are not available. | |
| Warnings For external use only. ■ flammable ■ keep away from source of heat or fire | |
| When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. | |
| Stop use and ask a doctor if irritation or redness develops and lasts. | |
| Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. | |
| Directions | |
| ■ put enough product in your palm to cover hands and rub hands together until dry. ■ children under 6 years should be supervised when using this product. | |
| Other information | |
| ■ store at a temperature below 110°F (43°C). ■ may discolor certain fabrics or surfaces. | |
| Inactive Ingredients: Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum). | |

TSM Brands LLC
 540 Equinox Ln
 Manalapan, NJ 07726
www.tsmbrands.com
 Made in TURKEY

2 FL.OZ.
(60mL)

LUXURY HAND SANITIZER ALOE

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76772-016 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.75 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | | |
|---|------------------|---|----------------------|--------------------|--|
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) | | | | | |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) | | | | | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | | | | | |
| | | | | | |
| Packaging | | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:76772-016-47 | 472 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/02/2020 | | |
| 2 | NDC:76772-016-23 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/02/2020 | | |
| 3 | NDC:76772-016-06 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/02/2020 | | |
| | | | | | |
| Marketing Information | | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | | part333E | 03/02/2020 | | |

Labeler - TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI(533120570)

Registrant - TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI(533120570)

| Establishment | | | | |
|--|--|---------|-----------|------------------------|
| Name | | Address | ID/FEI | Business Operations |
| TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI | | | 533120570 | manufacture(76772-016) |

Revised: 9/2020

TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI