HIGEEN ANTISEPTIC HANDS AND THINGS SANITIZER MARACUJA- ethyl alcohol spray SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)

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.

HiGeen® ANTISEPTIC HANDS & THINGS SANITIZER SPRAY MARACUJA

Drug Facts

Active ingredient

Ethyl alcohol 70% V/V

Purpose

Antiseptic

Uses

- for hand washing to decrease bacteria on the skin.
- recommended for repeated use.

Warnings

Flammable, keep away from fire or flame. For external use only.

When using this product

• do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation and redness develops.
- condition persist for more than 72 hours.

Keep out of reach of children.

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

Directions

• Spray on clean, dry hands and nails, Wet hands thoroughly with product and allow to dry without wiping.

Other information

- store at 20° to 25°C (68° to 77°F).
- may discolor certain fabrics.

Inactive ingredients

triethanolamine, carbomer, acrylates /C10-C30 alkyl acrylate crosspolymer, glycerin, glyceryl stearate, aloe barbadensis, panthenol, water (aqua), fragrance.

Questions or comments?

call **+1-419-322-4731**

available from Monday to Friday (8 am - 4 pm). You may report serious side effects to this phone number.

NO WATER NO SOAP

Hands Face Masks WC Mobiles Laptops

Spray with Moisturizer

Manufactured by:

Sukhtian Households and Toiletries Manufacturing Co. Ltd.

Al Hizam street

Abu Alanda, Amman, Jordan 11118

P.O.BOX: 1027

Made in Jordan

Packaging









HIGEEN ANTISEPTIC HANDS AND THINGS SANITIZER MARACUJA

ethyl alcohol spray

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71490-046 |
|-------------------------|----------------|--------------------|---------------|
| 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 | |
| TROLAMINE (UNII: 903K93S3TK) | | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | |
| PANTHENOL (UNII: WV9CM0O67Z) | | |
| WATER (UNII: 059QF0KO0R) | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:71490- 046-13 | 10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 11/05/2021 | | |
| 2 | NDC:71490- 046-09 | 100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 11/05/2021 | | |
| 3 | NDC:71490- 046-08 | 250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 11/05/2021 | | |

| Marketing Information | | | | |
|---|---|---|--|--|
| Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| part333A | 11/05/2021 | | | |
| | Application Number or Monograph Citation | Application Number or Monograph Marketing Start Citation Date | | |

Labeler - SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO) (557666494)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO) | | 557666494 | manufacture(71490-046) | |

Revised: 10/2021 SUKHTIAN-HTM (HOUSEHOLDS & TOILETRIES MFG.CO)