AUTOSPRITZ- alcohol solution ORIGYN 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.

ACTIVE INGREDIENTS

Alcohol 80% v/v

INACTIVE INGREDIENTS

Glycerin, hydrogen peroxide, purified water USP

PURPOSE

Antiseptic

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.

INDICATIONS & USAGE

- Hand sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available

WARNINGS

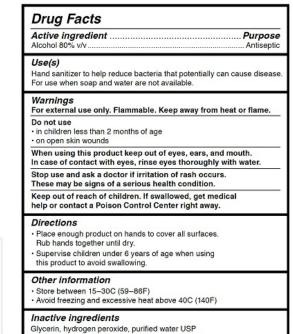
- For external use only. Flammable. Keep away from heat or flame.
- Do not use
 - for children less than 2 months of age
 - on open skin wounds
- When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation of rash occurs. These may be signs of a serious health condition.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Refill Bottle 33.8 fl oz (1L)





Auto Dispenser Bottle 12 fl oz (355ml)



AUTOSPRITZ alcohol solution Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79281-010 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 L in 100 L |

| Inactive Ingredients | | | | |
|--|-------------------|--|--|--|
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | 1.45 L in 100 L | | | |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 L in 100 L | | | |
| WATER (UNII: 059QF0KO0R) | 18.425 L in 100 L | | | |

| l | Packaging | | | |
|---|------------------------|---|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 NDC:79281-010- 01 | 1 L in 1 BOTTLE; Type 0: Not a Combination Product | 07/02/2020 | |
| l | 2 NDC:79281-010- 02 | $0.355\ L$ in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 07/02/2020 | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 07/02/2020 | | |
| | | | | |

Labeler - ORIGYN LLC (117542954)

| Establishment | | | | |
|--------------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Guangzhou Shiruoni Cosmetics Co. Ltd | | 551125378 | manufacture(79281-010) | |

Revised: 7/2020 ORIGYN LLC