# POWERFULX SSOK AIR SHOWER SANITIZER- alcohol liquid POWERFULX CO.,LTD

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.

-----

#### **Drug Facts**

Alcohol

Water, Glycerin, Propylene Glycol, Aloe Vera Gel, Camellia Sinensis Leaf Extract, Perfume

Antiseptic

KEEP OUT OF REACH OF THE CHILDREN

For the external use only

Do not use on the following body parts.

Around the eyes and ears, in the oral cavity, a wide range of body parts and damaged skin (may have irritating effects)

If the following symptoms appear, stop using them immediately and consult a doctor or pharmacist.

Symptoms of skin irritation

Other precautions

For external use only

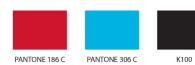
Be careful not to get into your eyes, and if so, rinse well with clean water and consult a doctor or pharmacist.

Be careful not to inhale vapor when using it extensively or for a long time. (If you drink ethanol vapor in large quantities or repeatedly, irritation to the mucous membrane, headache, etc. may occur). When repeated use on the same site, be careful as the skin may become rough due to degreasing. When used in sealed bandages, cast bandages, packs, etc., irritation symptoms may appear.

Do not use for any other purpose.

Wet hands thoroughly with spray, covering entire surface of hands, especially the fingernails and cuticles

rub hands together until dry







#### POWERFULX SSOK AIR SHOWER SANITIZER

alcohol liquid

| Product Information     |                |                    |                |  |
|-------------------------|----------------|--------------------|----------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:70042-0014 |  |
| Route of Administration | TOPICAL        |                    |                |  |

| Active Ingredient/Active Moiety                        |                   |                  |  |
|--|-------------------|------------------|--|
| Ingredient Name  | Basis of Strength | Strength         |  |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 310 mL in 500 mL |  |

| Inactive Ingredients                    |          |  |  |
|---|----------|--|--|
| Ingredient Name                         | Strength |  |  |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3) |          |  |  |
| WATER (UNII: 059QF0KO0R)                |          |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)       |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)             |          |  |  |
|   |          |  |  |

| # Item Code Package Description Marketing Start Date Marketing End Date  1 NDC:70042-0014- 500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 05/01/2020 | ] | Packaging       |                     |            |  |
|--|---|-----------------|---------------------|------------|--|
| 1 1 U 3/U 1/2 U 2 U  | # | # Item Code     | Package Description | <u> </u>   |  |
|  | 1 | NDC:70042-0014- |                     | 05/01/2020 |  |

| Marketing Inform        | mation                                   |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A                                 | 05/01/2020           |                    |
|                         |  |                      |                    |

### Labeler - POWERFULX CO.,LTD (689515038)

## Registrant - POWERFULX CO.,LTD (689515038)

| Establishment |         |           |                         |  |
|---------------|---------|-----------|-------------------------|--|
| Name          | Address | ID/FEI    | Business Operations     |  |
| SKINFARM      |         | 688594873 | manufacture(70042-0014) |  |

| Establishment     |         |           |                     |
|-------------------|---------|-----------|---------------------|
| Name              | Address | ID/FEI    | Business Operations |
| POWERFULX CO.,LTD |         | 689515038 | label(70042-0014)   |

Revised: 5/2020 POWERFULX CO.,LTD