POWERFULX SSOK HAND SANITIZER- alcohol gel
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.

POWERFULX - PowerfulX SSOK Hand Sanitizer

Alcohol

water, triethanolamine, etc

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

keep out of reach of the children

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.

For external use only. Flammable. Keep away from heat or flame.

Do not use

- in 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 thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

for external use only

Drug Facts

Active ingredient — **Purpose**
Ethyl Alcohol 62% — Antiseptic

Uses • Hand Sanitizer to help reduce bacteria on the skin that could cause disease • Recommended for repeated use

Warnings
For external use only: hands

Flammable. Keep away from heat or flame.

When using this product • keep out of eyes. In case of contact with eyes, flush thoroughly with water. • avoid contact with broken skin • do not inhale or ingest

Stop use and ask a doctor if skin irritation develops.

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

Directions • wet hands thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision • not recommended for infants

Inactive ingredients Green tea extract, Butylene Glycol, Aloe Ex, DL-Panthenol, Triethanolamine, Polysorbate20, Water, Fragrance

POWERFULX SSOK HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70042-0010
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**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70042-0010-1	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 - POWERFULX CO.,LTD (689515038)

Registrant - POWERFULX CO.,LTD (689515038)

Establishment

Name	Address	ID/FEI	Business Operations
POWERFULX CO.,LTD		689515038	manufacture(70042-0010) , label(70042-0010) , pack(70042-0010)

Revised: 4/2020 POWERFULX CO.,LTD