

MISSHA OH MY CLEAN THE PURE SANITIZER- alcohol gel
Able C&C 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.

ACTIVE INGREDIENT

Alcohol 62%

INACTIVE INGREDIENT

Water, Carbomer, Triethanolamine, Glycerin, Tocopheryl Acetate, Salvia Officinalis (Sage) Extract, Hedera Helix (Ivy) Extract

PURPOSE

Antiseptic

WARNINGS

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 eyes 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.

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

Directions

- 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.
- Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.)
- This product is intended only for hand sanitizing.
- To prevent contents from drying out and contaminants from entering, close lid completely after use.
- Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.
- Do not use over bandages, castings, etc. as irritation may occur.

Other information

- Store between 15-30 °C (59-86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MISSHA OH MY CLEAN THE PURE SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13733-451
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	86.8 mL in 140 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
Glycerin (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SALVIA OFFICINALIS ROOT (UNII: 236QY0A1BL)	
HEDERA HELIX LEAF (UNII: ZP9XFG71A7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13733-451-01	140 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - Able C&C Co., Ltd. (689540284)**Registrant** - Able C&C Co., Ltd. (689540284)**Establishment**

Name	Address	ID/FEI	Business Operations
SISKINKOREA CO.,LTD.		695625974	manufacture(13733-451)

Revised: 5/2020

Able C&C Co., Ltd.