

REGAL CARE- alcohol gel
SERVICE TOOL COMPANY, L.L.C.

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 72% v/v

Purpose

Antiseptic

Use

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

- on 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.

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.

Other information

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

Inactive ingredients

water, glycerin, acrylates/vinyl isodecanoate crosspolymer, aminomethylpropanol, fragrance, panthenol, aloe barbadensis leaf juice, tocopherol acetate.

Package Label - Principal Display Panel

NDC 78710-072-03

REGAL-CARE™

20050

Disinfection and Sterilization

HAND SANITIZER 72% ALCOHOL GEL

Contains Aloe!

Quick-Drying!

- Rub On
- Dries Fast
- Non-Sticky
- Bacteria Sterilization for Hand Protection

3.38oz/100ml

REGAL-CARE™

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Drug Facts	
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Warnings For external use only. Flammable. Keep away from heat or flame.	
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Service Tool Co., LLC
337-365-1704

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#20050
Made in China

REGAL CARE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78710-072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78710-072-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/06/2020	

Labeler - SERVICE TOOL COMPANY, L.L.C. (055024855)

Registrant - SERVICE TOOL COMPANY, L.L.C. (055024855)

Establishment

Name	Address	ID/FEI	Business Operations
ZheJiang Ushas Cosmetics Co., Ltd		544910474	manufacture(78710-072)

Revised: 7/2020

SERVICE TOOL COMPANY, L.L.C.