

HAND SANITIZER- hand sanitizer gel
GUANGZHOU XUELEI COSMETIC 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.

HAND SANITIZER

Active Ingredient

Alcohol 75% v/v

Purpose

Antiseptic

Uses

help decrease bacteria on the hands

Warnings

For external use only.

Flammable. Keep away from fire or flame. Do not store in car.

Avoid contact with eyes, in case of contact, rinse eyes thoroughly with water immediately

Keep out of reach of children except under adult supervision. If swallowed, get medical help or contact a poison control center right away.

If irritation develops, discontinue use and consult a doctor.

Keep out of reach of children except under adult supervision. If swallowed, get medical help or contact a poison control center right away.

Directions

Wet hands thoroughly with product and rub lightly until dry. Do not wipe off or rinse.

Other Information

May discolor fabrics or surfaces. Store below 95 °F (35 ° C).

Inactive ingredients

Carbomer, Denatonium Benzoate, Purified Water USP, Tert-butyl Alcohol, Triethanolamine.

50ml NDC: 74658-010-01



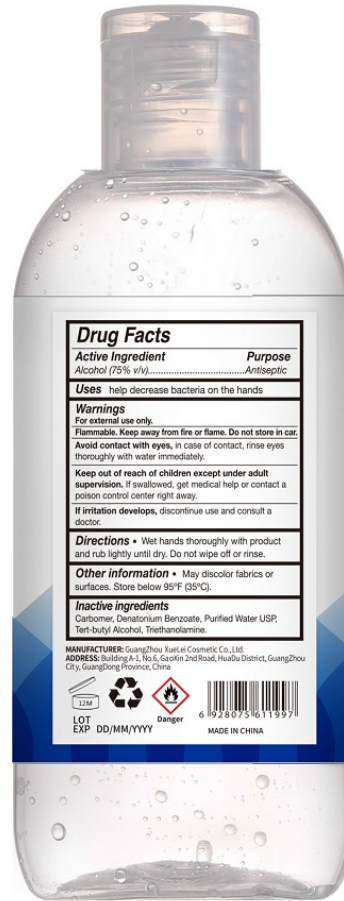
50ML

60ml NDC: 74658-010-02



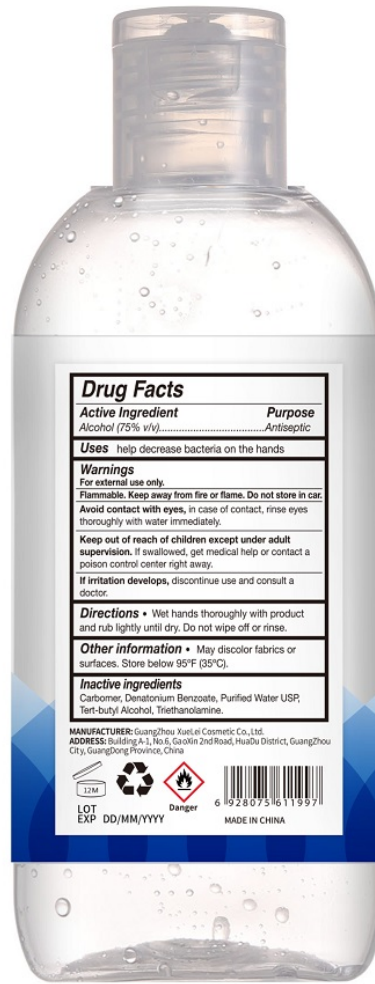
60ML

236ml NDC: 74658-010-03



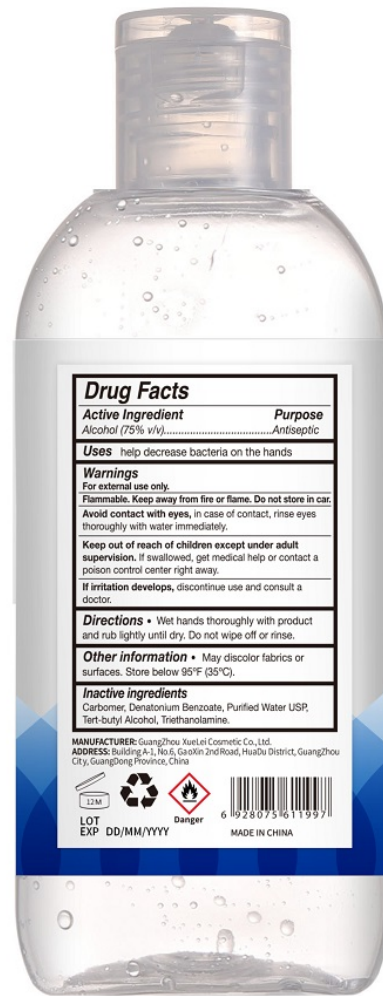
236ml

250ml NDC: 74658-010-04



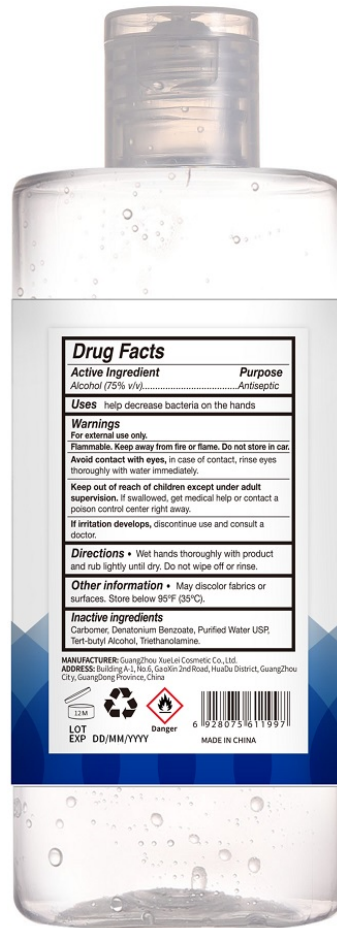
250ml

260ml NDC: 74658-010-05



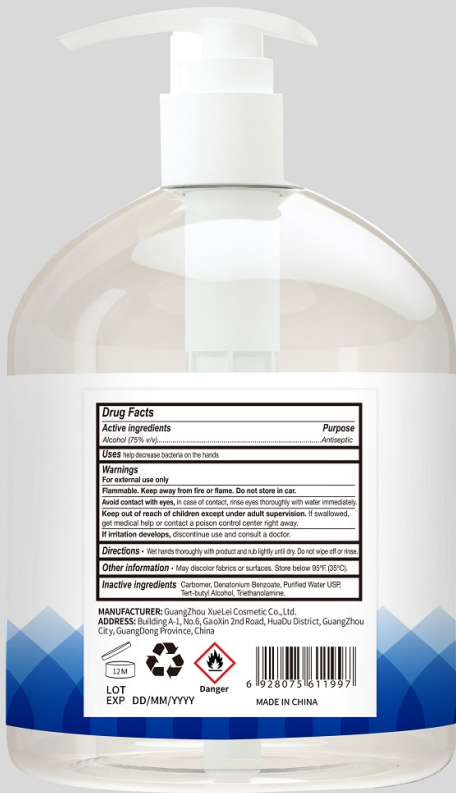
260ml

300ml NDC: 74658-010-06



300ml

500ml NDC: 74658-010-07



1000ml NDC: 74658-010-08



5000ml NDC: 74658-010-09



5000ml

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74658-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	22.1937 g in 100 mL
TEPT BUTYL ALCOHOL (UNII: MDD3EE05O)	0.0809 g

TERI-BOTTLE ALCOHOL (UNII: MD655FE959)	in 100 mL
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.4 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.22 g in 100 mL
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	0.0004 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74658-010-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
2	NDC:74658-010-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
3	NDC:74658-010-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
4	NDC:74658-010-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
5	NDC:74658-010-05	260 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
6	NDC:74658-010-06	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	
7	NDC:74658-010-07	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/02/2020	
8	NDC:74658-010-08	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/02/2020	
9	NDC:74658-010-09	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/02/2020	

Labeler - GUANGZHOU XUELEI COSMETIC CO.,LTD. (526885026)

Registrant - GUANGZHOU XUELEI COSMETIC CO.,LTD. (526885026)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU XUELEI COSMETIC CO.,LTD.		526885026	manufacture(74658-010) , pack(74658-010) , label(74658-010)

Revised: 11/2021

GUANGZHOU XUELEI COSMETIC CO.,LTD.