OPLUS ANTISEPTIC INSTANT HAND SANITIZER- alcohol gel
TDC USA Inc

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.

OPLUS Antiseptic Instant Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 75%

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin

Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use

in the eyes

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

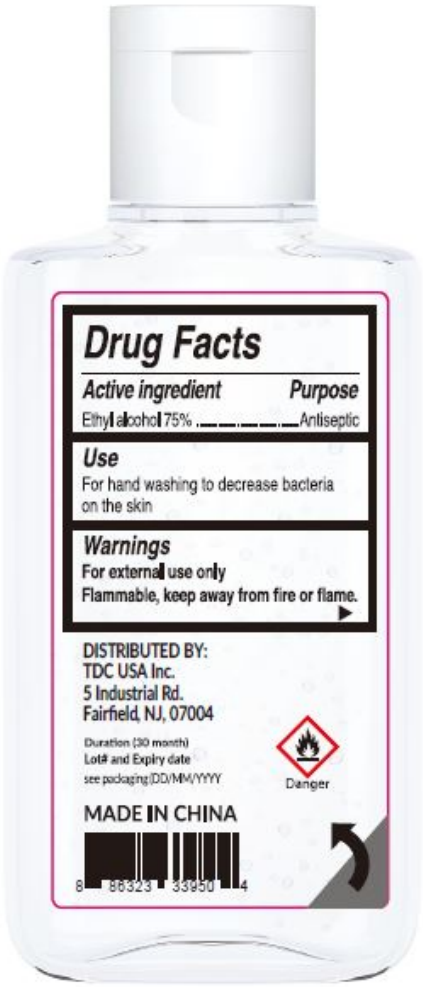
Other information

- do not store above 105°F (41°C)
- may discolor certain fabrics
- harmful to wood finishes and plastics

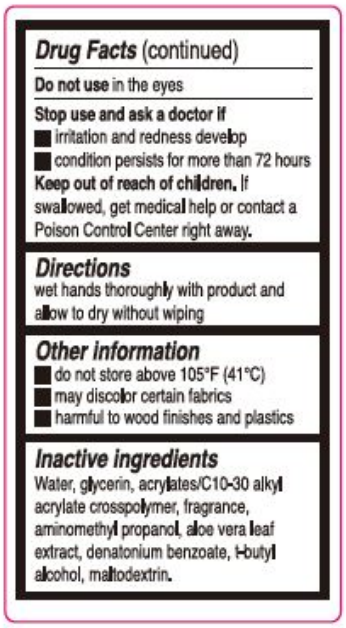
Inactive ingredients

Water, glycerin, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, aminomethyl propanol, Aloe vera leaf extract, denatonium benzoate, t-butyl alcohol, maltodextrin

Package Labeling



SIZE:3.65 x 6.7 CM



OPLUS ANTISEPTIC INSTANT HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79204-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79204-000-00	95 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/31/2020	

Labeler - TDC USA Inc (054204290)

Establishment

Name	Address	ID/FEI	Business Operations
Opal Cosmetics (Huizhou) Limited		528178475	manufacture(79204-000)

Revised: 7/2020 TDC USA Inc