

ANTI BACTERIAL HAND SANITIZER- alcohol liquid

Michaels Stores Procurement Company

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.

Drug Facts

Active Ingredient

Alcohol 62%

Purpose

Antiseptic

Use

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

■ For external use only ■ Flammable, keep away from fire & flame ■ Does not contain grain alcohol; do not drink. If taken internally will produce serious gastric disturbances

When using this product

■ Avoid the eyes and mucous membranes ■ In the case of eyes or mucous membrane contact, rinse area thoroughly with water

Stop use and ask a doctor if

■ Condition worsens ■ Redness or irritation develops ■ If condition persists for more than 3 days

Keep out of reach of children

If swallowed contact a doctor or Poison Control Center immediately.

Directions

■ Rub dime sized amount between hands until dry ■ Supervise children in the use of this product ■ In the case of eye contact, rinse eyes thoroughly with water

Other information

■ Store below 105°F ■ May discolor some fabrics

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Blue 1, Fragrance, PEG-40 Hydrogenated Castor Oil,

Red 4, Red 33, Triethanolamine, Water

Package Label



PEEL
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Drug Facts (continued)

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DISTRIBUTED BY MSPCI
 8000 BENT BRANCH DRIVE
 IRVING, TX 75063
 1-855-450-4467
 Designed in the U.S.A.
 Made in China

1 fl oz / 30 ml

ANTI BACTERIAL HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60675-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60675-008-30	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/18/2016	

Labeler - Michaels Stores Procurement Company (030791425)

Revised: 7/2016

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