ANTISEPTIC WIPE- alcohol cloth DJO LLC

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 ingredients

Ethyl Alcohol 66.5%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin whenever soap and water is not readily available
- helps prevent the risk of cross-contamination of bacteria that potentially can cause disease or infection

Warnings

For external use only. Flammable, keep away from fire or flame

Do not use

• in the eyes, if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

irritation or redness develop and 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

- tear open packet and remove towelette
- wipe hand, finger and wrist areas thoroughly with towelette for 15 seconds
- dispose of used towelette properly
- children under 6 years of age should be supervised when using this product

Inactive ingredients

aloe vera, fragrance, purified water, triethanolamine

Principal Display Panel - 100 Wipes Box Label

HAND WIPES

GERM

WAR[®]

KILLS 99.99%

OF GERMS

WAGING WAR ON GERMS AND BACTERIA

100 WIPES (5IN X 8IN)



Principal Display Panel - 1 Wipe Pouch Label

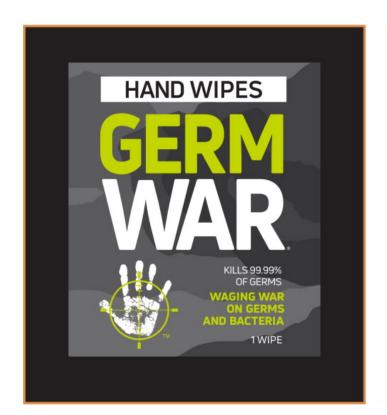
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ANTISEPTIC WIPE

alcohol cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80950-3111

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)

alcohol

665 mL in 100 L

Inactive Ingredients

Ingredient Name
Strength

aloe (UNII: V5VD430YW9)

water (UNII: 059QF0KO0R)

trolamine (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80950-3111- 1	100 in 1 BOX	12/14/2020	
1		1 in 1 PACKET		
1		0.0017 L in 1 APPLICATOR; Type 0: Not a Combination		

Pro	duct					
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	12/14/2020				

Labeler - DJO LLC (081840873)

Registrant - Safetec of America, Inc. (874965262)

Revised: 6/2020 DJO LLC