GERMFREE HAND SANITIZING- alcohol spray Tallon Enterprises 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.

GermFree Hand Sanitizing Spray

Active Ingredient(s)

Ethyl Alcohol 80% 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

- in 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 at 1-800-222-1222.

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

aloe vera, glycerin, hydrogen peroxide, peppermint & eucalyptus essential oil, vitamin E

Package Label - Principal Display Panel







GERMFREE HAND SANITIZING

alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80150-702
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
l	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
PEPPERMINT OIL (UNII: AV092KU4JH)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
EUCALYPTUS OIL (UNII: 2R04ONi662)			
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:80150-702-	20 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/2020	

Labeler - Tallon Enterprises LLC (117624756)

Revised: 11/2020 Tallon Enterprises LLC