PERFUME ON HAND SANITIZER GEL BABYPOWDER- alcohol gel ASCENT LAB

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

alcohol

sterilization of hands, skin and so on

KEEP OUT OF REACH OF THE CHILDREN

take appropriate amount on the hand, rub and dry well

- Flammable. Keep away from fire or flame.
- For external use only.
- Do not use in eyes.
- If swallowed, get medical help promptly.
- Stop use, ask doctor lf irritation occurs.
- Keep out of reach of children.

for external use only

Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Panthenol, Dipotassium Glycyrrhizate, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate, Tocopheryl Acetate

Drug Facts

Active Ingredients

Purpose

Ethanol (Synthetic Alcohol) 70% ------

Disinfecting Agent

Uses

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin

Warning

For external use only

When using this product

- if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes
- Stop immediately and consult a doctor if you experience
 - Hypersensitivity symptoms such as erythema, itching and dermatitis.
 - 2) Skin Irritation
 - 3) Following Instructions when using medication
 - (1) For external use only (Do not use internally)
 - (2) Avoid getting into the eyes (if contact occurs, wash well with clean water)
- Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.
- Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage.
- Do not use in combination with soap or antibacterial cleansing agents.

Directions

■ Pour a small amount into hands, spread evenly and rub into the skin

Other Information

- read the directions and warnings before use
- avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive Ingredients

Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Panthenol, Dipotassium Glycyrrhizate, Aloe <u>Barbadensis</u> Leaf Juice, Sodium Hyaluronate, <u>Tocopheryl</u> Acetate

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alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77600-0002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
CARBOMER 940 (UNII: 4Q93RCW27E)			
GLYCERIN (UNII: PDC6 A3C0 OX)			

Pac	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	DC:77600-0002-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/13/2020		

Labeler - ASCENT LAB (695538849)

Registrant - ASCENT LAB (695538849)

Establishment				
Name	Address	ID/FEI	Business Operations	
ASCENT LAB		695538849	manufacture(77600-0002)	

Revised: 5/2020 ASCENT LAB