ANTISEPTIC- alcohol, benzocaine liquid
Safetec of America, 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.

Drug Facts

Active Ingredients

Ethyl alcohol 50.0%

Benzocaine 6.0%

Purpose

First Aid Antiseptic

Topical Analgesic

Uses

First aid to help prevent infection in minor scrapes and temporary relief of itching of insect bites

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use

- over large areas of the body
- in eyes
- over raw or blistered areas

Stop use and ask doctor if conditions worsen or persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away

Directions

Adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
Children under 2 years of age: Consult a doctor.

Inactive ingredients

benzalkonium chloride, menthol, purified water

PRINCIPAL DISPLAY PANEL – pouch label

NDC 61010-7200-0

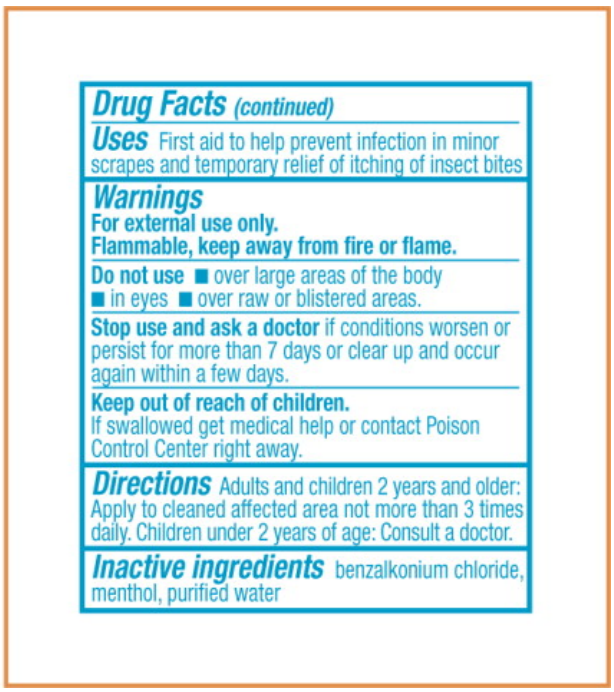
Safetec

Sting Relief
Insect Bite
Antiseptic and Pain Reliever

Contents: 1 single-use, premoistened towelette

Manufactured by SAFETEC OF AMERICA, Inc.
Buffalo, NY 14215 800-456-7077 www.safetec.com

EXP. LOT



ANTISEPTIC

alcohol, benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-7200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	500 mg in 1 g
benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)	benzocaine	60 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride (UNII: F5UM2KM3W7)	
menthol (UNII: L7T10EIP3A)	

water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-7200-0	0.8 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/12/2011	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE

Revised: 5/2011 Safetec of America, Inc.