SERVO-STAT BALM - alcohol gel Enzyme Solutions, 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 Ingredient

Ethyl Alcohol 62% (v/v)

Purpose

Antiseptic

Use

for hand-washing to decrease bacteria on the skin

Warnings

For external use only

Flammable keep away from open flame

When using this product

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

irritation and redness develop

Keep out of reach of children.

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

Directions

ready to use

do not dilute

apply to hands and spread vigorously

rub lightly until dry without wiping or rinsing

Ingredients:

Water, Cetyl alcohol, Stearic Acid, Triethanolamine, Isopropyl palmitate, Carbomer, Glycerin, Lanolin, Vitamin E and Aloe

Servo-Stat Balm

Antiseptic Hand Wash

11122R-A1000

1000 ml (33.8 fl oz.)

Servo-Stat BalmTM Antiseptic Hand Wash

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Batch #:

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HMIS RATINGS: Flammability: 3, Health: 1, Reactivity: 0, Personal Protection: A. This HMIS RATINGS: Flammability: 3, Health: 1, Reactivity: 0, Personal Protection: A. This product is designed exclusively for healthcare and institutional use by trained personal. This Product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise Manufactured by

ENZYME SALUTIONS®

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SERVO-STAT BALM

alcohol gel

Droduct	Information
Product	iniormation

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:76378-016

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 903K93S3TK)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3 M)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
LANOLIN (UNII: 7EV65EAW6H)		
ALPHA-TO CO PHERO L (UNII: H4N8 55PNZ1)		
ALOE (UNII: V5VD430 YW9)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76378-016-01	118 mL in 1 BOTTLE		
2	NDC:76378-016-02	1000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/01/2011	

Labeler - Enzyme Solutions, Inc. (004994559)

Establishment

Establishment				
Name	Address	ID/FEI	Business Operations	
Enzyme Solutions, Inc.		004994559	manufacture	

Revised: 9/2011 Enzyme Solutions, Inc.