SURGICEPT WATERLESS, SURGICAL HANDSCRUB AND HEALTHCARE PERSONNEL HANDWASH- ethyl alcohol solution HEALTHPOINT, LTD

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.

SURGICEPT WATERLESS Surgical Hand Scrub & Healthcare Personnel Handwash – alcohol solution

CareFusion

Drug Facts

Active ingredient

Ethyl alcohol 70% w/w

Purpose

Antiseptic

Uses

- **Surgical Hand Scrub:** Significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care.
- **Healthcare Personnel Handwash:** Handwash to help reduce bacteria that potentially can cause disease. Recommended for repeated use.

Warnings

- Flammable, keep away from fire or flame.
- For external use only.
- Do not use
 - if you are allergic to or have a known or suspected hypersensitivity to any ingredient in this product.
 - on or near the eyes, mucous membranes or mouth. If product gets into the eyes, flush immediately with water.
- **Stop use and ask a doctor if** irritation, redness or allergic reaction occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• **Surgical Hand Scrub:** Clean under nails with a nail pick. Nails should be maintained with a 1mm free edge. Apply to clean, dry hands. (1) Dispense sufficient quantity of SURGICEPT to cover one hand (approx. 2ml) into cupped palm. Dip the fingertips of your opposite hand into SURGICEPT and work under the nails. Spread remainder of SURGICEPT on hand and lower two-thirds of forearm. (2) Repeat Step 1 with other hand and forearm. (3) Dispense an additional sufficient quantity (approx. 2ml) of SURGICEPT and apply to all surfaces of hands up to wrists, paying particular attention to nails, cuticles, and interdigital spaces. Allow to dry before doming gloves. Do not dry with a towel.

• **Healthcare Personnel Handwash:** Wet hands thoroughly with SURGICEPT and allow to dry without wiping.

Other information

- Store upright at 20-25°C (68-77°F)
- Avoid freezing and excessive heat.
- Protect from light until use.

Inactive ingredients

Behentrimonium methosulfate, benzalkonium chloride, butylene glycol, cetyl alcohol, chlorhexidine gluconate, ethylhexylglycerin, isopropyl alcohol, phenoxyethanol, polyquaternium-10, PPG-3 myristyl ether, water.

Questions?

Please call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST) or visit our web site **www.surgicept.com**.

PRINCIPAL DISPLAY PANEL

NDC 0064-1080-59

Surgicept ®

Ethyl alcohol 70% w/w

WATERLESS Surgical Hand Scrub & Healthcare Personnel Handwash

2 fl oz (59 ml) 129464-1010

Marketed by:

CareFusion, Leawood, KS 66211

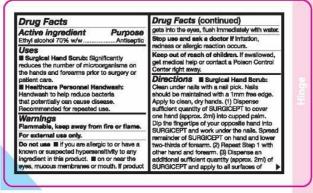
Manufactured for:

Healthpoint, Ltd., Fort Worth, TX 76107 by DPT Laboratories, Ltd., San Antonio, TX 78215

REORDER NO. 0064-1080-59 PATENT NO. 6,846,846

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL







Inside Panel

Bottom Panel

SURGICEPT WATERLESS, SURGICAL HANDSCRUB AND HEALTHCARE PERSONNEL HANDWASH

ethyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0064-1080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BEHENTRIMO NIUM METHO SULFATE (UNII: 5SHP745C61)			
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
PHENO XYETHANOL (UNII: HIE49 2ZZ3T)			
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)			

Product Characteristics			
Color	white (CLEAR)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0064-1080- 59	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2006		
2	NDC:0064-1080- 11	1150 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2006		
3	NDC:0064-1080- 80	1 in 1 CARTON	01/01/2006	0 2/28/20 15	
3		800 mL in 1 BAG; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 1/0 1/20 0 6		

Labeler - HEALTHPOINT, LTD (965634504)

Establishment				
Name	Address	ID/FEI	Business Operations	
DPT LABORATORIES, LTD		832224526	manufacture(0064-1080)	

Revised: 9/2017 HEALTHPOINT, LTD