

**ISAGEL B-I-B - alcohol gel**  
**Coloplast Manufacturing US, 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.*

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**Sween®**  
**ISAGEL®**  
**ETHYL ALCOHOL**  
**NO-RINSE, ANTISEPTIC**  
**HAND CLEANSING GEL**  
**WITH ADDED**  
**MOISTURIZERS**

***Drug Facts***

***Active ingredient***

Ethyl Alcohol 60% v/v

***Purpose***

Antiseptic Handwash

**Uses** For handwashing to decrease bacteria on the skin.

***Warnings***

**Flammable, keep away from fire or flame.**

**When using this product**

- avoid contact with eyes. If eye contact occurs, flush with water.

**Stop using this product**

- if skin irritation and redness develop. If condition persists for more than 72 hours, consult a physician.

**For external use only**

**Keep this and all drugs out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

***Directions***

- Wet hands thoroughly with product and allow to dry without wiping.

***Inactive ingredients*** carbomer, glycereth-26, fragrance, PEG-12, triethanolamine, water

Meets the CDC Hand Hygiene Guideline in Healthcare Settings. For use when hands are not visibly soiled.

Manufactured by/Fabriqué par Coloplast A/S  
DK-3050 Humlebaek, Denmark  
Distributed by/Distribué par: Coloplast Corp.  
Minneapolis, MN 55411 U.S.A.  
1-800-533-0464 [www.us.coloplast.com](http://www.us.coloplast.com)  
Coloplast Canada Corp. Mississauga ON L5L 5Z9  
1-888-880-8605 [www.coloplast.ca](http://www.coloplast.ca)  
Product/Produit #7041 ©2008-10, Coloplast Corp.  
Made in the U.SA/Fabriqué aux Etats-Unis

DSP-MN-38

K8-842

**PRINCIPAL DISPLAY PANEL - 800 mL (27 fl. oz.)**

NDC 11701-025-45

**Sween**<sup>®</sup>

**ISAGEL**<sup>®</sup>

Latex Glove and CHG Compatible

ETHYL ALCOHOL

NO-RINSE, ANTISEPTIC

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UPC 3-11701-02545-3

**ISAGEL B-I-B**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11701-025
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	600 mL in 1000 mL

**Inactive Ingredients**

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERETH-26 (UNII: NNE56F2N14)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-025-45	800 mL in 1 BAG		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/15/2009	

**Labeler** - Coloplast Manufacturing US, LLC (110326675)**Registrant** - Coloplast Corp (847436391)**Establishment**

Name	Address	ID/FEI	Business Operations
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE

Revised: 6/2011

Coloplast Manufacturing US, LLC