STERILLIUM COMFORT- alcohol gel BODE Chemie GmbH

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.

Sterillium Comfort Gel NDC 65616-009

Active ingredient

Ethyl Alcohol 85% v/v

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use in or near the eyes or on mucous membranes.

In case of contact, rinse thoroughly with water.

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

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

Directions

- Apply to clean, dry hands, covering entire surface, including nails
- Rub until dry
- Supervise children in the use of this product

Inactive ingredients

Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Bisabolol, Cyclomethicone, Glycerin, Isohexadecane, Isopropyl Alcohol, Myristyl Alcohol, PVP, Tetrahydroxypropyl Ethylenediamine, Water.

BODE

Sterillium Comfort Gel

HEALTHCARE PERSONNEL

HAND ANTISEPTIC

85% v/v ethyl alcohol with moisturizers

Kills > 99.999% of germs

in 15 seconds without water.

Boosts skin moisture level.

Leaves hands feeling soft and healthy.

Dermatologically tested.

Read Drug Facts panel before use.

Lot:

Use by:

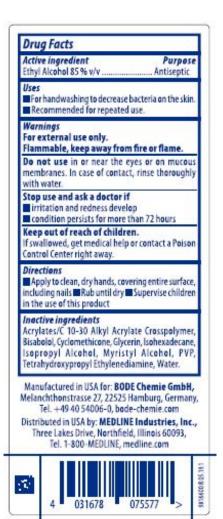
Questions? Call 1-800-MEDLINE

NDC 65616-009-06

1000 mL 33.8 fl.oz.



container label1fSCG



container label1bSCG





container label1bSCGHF

STERILLIUM COMFORT

alcohol gel

Product Information	ct Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65616-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	85 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
LEVOMENOL (UNII: 24WE03BX2T)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISO HEXADECANE (UNII: 918 X10 UF1E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

PO VIDO NE K90 (UNII: RDH86HJV5Z)	
EDETOL (UNII: Q4R969U9FR)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65616-009- 10	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019	
2	NDC:65616-009- 09	475 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2019	
3	NDC:65616-009- 06	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/31/2019	

Labeler - BODE Chemie GmbH (316039007)

Revised: 7/2019 BODE Chemie GmbH