STERILLIUM RUB FRAGRANCE FREE- alcohol liquid 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 Rub Fragrance Free NDC 65616-008

Active ingredient

Ethyl Alcohol 85% w/w

Purpose

Antiseptic

Uses

- surgical hand antiseptic
- significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care

Warnings

For external use only.

Flammable, keep away from fire or flame.

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

When using this product and contact with the eyes occurs, flush immediately 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
- for the first use of the day, use a nail pick
- dispense approx. 2 mL into hand, dip fingers of opposite hand into palm, working product under nails and into cuticles
- repeat procedure with other hand
- with hands still moist spread around the hand and lower 1/3 of the forearm
- reapply the product to the hands, paying particular attention to fingers, cuticles, and interdigital spaces
- following application, rub hands until dry
- hands should remain moist for entire application time, approx. 1.5 minutes.

Inactive ingredients

Water, Isopropyl Alcohol, Myristyl Alcohol, Glycerin

BODE

Sterillium Rub

Fragrance-Free

Procedural Rub

SURGICAL

HAND ANTISEPTIC

85% w/w ethyl alcohol with emollients Indication: Significantly reduces the number of micro-organisms on the hands and forearms

Fast-acting. Dermatologically tested.

prior to surgery or patient care.

Gentle to skin.

Read Drug Facts panel before use.

Lot:

Use by:

Questions? Call 1-800-MEDLINE

NDC 65616-008-06

1000 mL 33.8 fl.oz.



container label_B



container label F



Drug Facts Active ingredient Ethyl Alcohol 85 % w/w Purpose ■ surgical hand antiseptic ■ significantly reduces the number of micro-organisms on the hands and forearms prior to surgery *Wornings* For external use only. Flammable, keep away from fire or flame. Do not use in or near the eyes or on mucous rembranes. When using this product and contact with the eyes occurs, flush immediately with water. Stop use and ask a doctor if mirritation and redness develop ■ condition persists for more than 72 hours

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Inactive ingredients

Water, Isopropyl Alcohol, Myristyl Alcohol Glycerin.

container label_Bsp



container label_Fsp

STERILLIUM RUB FRAGRANCE FREE

alcohol liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:65616-008

Route of Administration TOPICAL

Active Ingredient/Active Moiety

I	Ingredient Name	Basis of Strength	Strength	
I	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	89.5 mL in 100 mL	

Inactive Ingredients

indicate ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
MYRISTYL ALCOHOL (UNII: V42034O9PU)		
GLYCERIN (UNII: PDC6A3C0OX)		

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:65616-008- 06	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2019	
NDC:65616-008-	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2019	

Marketing Information

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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