

SOOTHE AND COOL- white petrolatum ointment
Medline Industries, LP

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.

067 Soothe and Cool Protect A&D

Active ingredient

White Petrolatum 93.5% w/w

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin or minor skin irritation associated with diaper rash and helps seal out wetness
- helps prevent and temporarily protects chafed, chapped, cracked or wind burned skin and lips
- temporarily protects minor cuts, scrapes, and burns

Warnings

For external use only

Do not use

- on deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- apply as needed

Other information

- Protect from freezeing. Avoid excessive heat.

Inactive ingredients

Corn Oil, Light Mineral Oil, Retinyl Palmitate (Vitamin A Palmitate), Ergocalciferol (Vitamin D)

Manufacturing Information

Manufactured for: Medline Industries, Inc.

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA

www.medline.com

1-800-MEDLINE

REF: MSC095094

RD19ULI

Package Label

Drug Facts

Active ingredient *Purpose*
White Petrolatum 93.5% Skin Protectant

Uses ■ Helps treat and prevent diaper rash ■ Protects chafed skin or minor skin irritation associated with diaper rash and helps seal out wetness ■ Helps prevent and temporarily protects chafed, chapped, cracked or wind burned skin and lips ■ Temporarily protects minor cuts, scrapes, and burns

Warnings

For external use only

Do not use on

- on deep or puncture wounds ■ animal bites
- serious burns

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days

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

Directions

- Apply as needed

Other information

- Protect from freezing. Avoid excessive heat

Inactive ingredients Corn Oil, Light Mineral Oil, Retinyl Palmitate (Vitamin A Palmitate), Ergocalciferol (Vitamin D)

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(01) 10080196769926



NDC: 53329-067-04

SOOTHE & COOL® **PROTECT** VITAMINS A & D SKIN PROTECTANT OINTMENT

- + For dry, cracked, or irritated skin
- + Protects and soothes minor cuts and burns



4 OZ (113 g)

SOOTHE AND COOL

white petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-067
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	935 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ERGOCALCIFEROL (UNII: VS041H42XC)	
CORN OIL (UNII: 8470G57WFM)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-067-04	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/01/2007	

Labeler - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)

Revised: 12/2022

Medline Industries, LP