

BENCHMARKS DERMA SHIELD- dimethicone aerosol

Delta Kits Inc

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.

Benchmarks Derma Shield

Active ingredient

Dimethicone, 2.7%

Purpose

Skin protectant

Do not use on:

- deep or puncture wounds
- animal bites
- serious burns
- Keep out of reach of children

Uses

- helps prevent and temporarily protects and helps relieve chafed, chapped, or cracked skin
- helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

Flammable:

- Do not use near flame or spark or while smoking
- Contents under pressure
- Do not puncture or incinerate
- Do not store at temperature above 120 °F

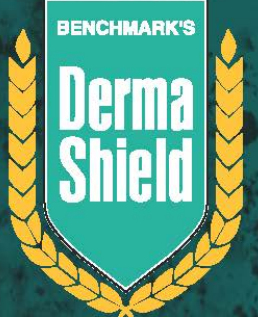
Directions

- Apply as needed
- Children under 6 months: ask a doctor
- Wash and dry skin area
- Shake can vigorously
- Invert can and apply "golf ball" size amount in palm
- Rub thoroughly onto the skin
- Allow to dry

Inactive ingredients

Water, Propane, Butane, Palmitic acid, Palm Kernel acid, Isopropyl Myristate, Glycerin, VP/VA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Cetareth-20, Hydroxyethylcellulose,

Perfluorinated Polyether, Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid



THE ULTIMATE SKIN PROTECTANT™

Net Weight
2oz (57g) e

Manufactured in the United Kingdom

Expiration date and lot number printed on container



Provides a non-toxic and non-greasy, invisible layer on all skin areas.

Helps maintain the skin's natural moisture balance.

Gives up to four hours maximum protection (Duration of protection is dependent upon proper application).

Withstands repeated washings.

Allows skin to breathe and perspire naturally.

Is safe for all skin areas.

Clinically and laboratory tested.

Can be used underneath gloves.

CFC Free.

Distributed by:
Derma Shield, Inc.
1090 Bailey Hill Rd, Suite B,
Eugene, OR 97402
385-313-0795

Drug Facts

Active ingredient	Purpose
Dimethicone 2.7%	Skin protectant

Uses

- helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin
- helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

Flammable: ■ Do not use near flame or spark or while smoking ■ Contents under pressure ■ Do not puncture or incinerate ■ Do not store at temperature above 120°F

When using this product ■ do not get into eyes

Stop use and ask a doctor if:

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

Do not use on: ■ deep or puncture wounds ■ animal bites ■ serious burns

Keep out of reach of children

Directions ■ Apply as needed ■ Children under 6 months: ask a doctor ■ Wash and dry skin area ■ Shake can vigorously ■ Invert can and apply "golf ball" size amount in palm ■ Rub thoroughly onto the skin ■ Allow to dry

Inactive ingredients Water, Propane, Butane, Palmitic acid, Palm Kernel acid, Isopropyl Myristate, Glycerin, VP/VA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Perfluorinated Polyether, Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.

BENCHMARKS DERMA SHIELD

dimethicone aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70557-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (4000 MP.A.S AT 1%) (UNII: ZYD53NBL45)	

METHYLPARABEN (UNII: A2I8C7HI9T)
PALM KERNEL ACID (UNII: 79P21R4317)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM BENZOATE (UNII: OJ245FE5EU)
COPOVIDONE K25-31 (UNII: D9C330MD8B)
EDETATE SODIUM (UNII: MP1J8420LU)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
WATER (UNII: 059QF0KO0R)
CETYL ALCOHOL (UNII: 936JST6JCN)
ISOBUTANE (UNII: BXR49TP611)
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)
PALMITIC ACID (UNII: 2V16EO95H1)
PERFLUOROPOLYMETHYLISOPROPYL ETHER (UNII: X6324K3MBW)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPANE (UNII: T75W9911L6)
BUTANE (UNII: 6LV4FOR43R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70557-002-01	57 g in 1 CAN; Type 0: Not a Combination Product	04/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/27/2016	

Labeler - Delta Kits Inc (180476731)