

BENCHMARKS DERMA SHIELD- dimethicone aerosol
STAR COLOUR LABORATORIES

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.

Active Ingredient(s)

Dimethicone, 2.7%

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

Purpose

Skin protectant

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

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" sized amount in palm
- Rub thoroughly onto the skin
- Allow to dry

Inactive ingredients

Water, Propane, Butane, Palmitic acid, Palm Kernal acid, Isopropyl Myrisate, Glycerin, VP/VA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Cetearth-20, Hydroxyethylcellulose, Perfluoriated Polyether, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolindinyl Urea, Methylparaben, Propylparaben,

Sodium Benzoate, Potassium Sorbate, Citric Acid

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Derma Shield 2oz Aerosol USA

BENCHMARK'S
Derma Shield

THE ULTIMATE SKIN PROTECTANT™

Net Weight
2oz (57g) e

Manufactured in the United Kingdom

Expiration date and lot number
printed on container

5 031124 000213

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 Dimethicone 2.7%	Purpose 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, VPVA Copolymer, Isobutane, Triethandamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Perfluorinated Polyether, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.	

Derma Shield 6oz Aerosol USA



Net Weight
6oz (170g) 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.



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 Barbadensis Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.

Distributed by:

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

Derma Shield 17oz Aerosol USA



THE ULTIMATE SKIN PROTECTANT™

Net Weight
17oz (1lb 1oz) (482g) 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.



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, VPWA Copolymer, Isobutane, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Perfluorinated Poly ether, Aloe Barbadianus Leaf Juice, Tocopheryl Acetate, Lanolin, Tetrasodium EDTA, Propylene Glycol Diazolidinyl Urea, Methylparaben, Propylparaben, Sodium Benzoate, Potassium Sorbate, Citric Acid.

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

BENCHMARKS DERMA SHIELD

dimethicone aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80905-001
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 MPAS AT 1%) (UNII: ZYD53NBL45)
METHYL PARABEN (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: 0RE8K4LNJS)
PALMITIC ACID (UNII: 2V16EO95H1)
PERFLUOROPOLYMETHYLISOPROPYL ETHER (UNII: X6324K3MBW)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPANE (UNII: T75W9911L6)
BUTANE (UNII: 6LV4FOR43R)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80905-001-03	482 g in 1 CAN; Type 0: Not a Combination Product	10/09/2020	
2	NDC:80905-001-02	170 g in 1 CAN; Type 0: Not a Combination Product	10/09/2020	
3	NDC:80905-001-01	57 g in 1 CAN; Type 0: Not a Combination Product	10/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/09/2020	

Labeler - STAR COLOUR LABORATORIES (215970015)

Establishment

Name	Address	ID/FEI	Business Operations
STAR COLOUR LABORATORIES		215970015	manufacture(80905-001)

