

SHELTERED BROAD SPECTRUM SPF 55 SUNSCREEN- homosalate, oxybenzone, octisalate, avobenzone, octocrylene liquid

AMCOL Health & Beauty Solutions, Inc. DBA

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.

Sheltered Broad Spectrum Sunscreen SPF 55

HBS Code (Labeler): FP15501-50.1

Distributor: Derma Faith

Human OTC Drug

Active Ingredients:

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 2.0%

Oxybenzone 6.0%

sheltered

broad spectrum

spf 55 sunscreen

derma faith

50 ml/1.7 fl oz

sheltered

broad spectrum

spf 55 sunscreen

Directions:

Apply liberally 15 minutes prior to sun exposure to face, neck and areas exposed to the sun. Re-apply after swimming, sweating or after 2 hours.

Warning:

For external use only. UV exposure from the sun increases your risk of skin cancer and early skin aging. To reduce risk, limit time in the sun, wear protective clothing and use a broad spectrum sunscreen of SPF15 or higher.

When using this product keep out of eyes. Rinse with water to remove. If rash occurs discontinue use.

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

Derma Faith, LLC

5701 W. Slaughter Lane
A130 #337
Austin, TX 78749
Made in the U.S.A.
www.dermafaith.com
M050829

This extra care sunscreen features our patented Polargel® UV SPF boosting technology that enables improved sunscreen performance with lower sunscreen actives. Formulated with antioxidants to help fight free radicals, this non-greasy formulation provides broad-spectrum sun protection without feeling thick or oily.

Active ingredients:

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 2.0%

Oxybenzone 6.0%

Inactive ingredients:

Water, Butylene Glycol, PEG-8, Polyethylene, Dimethicone, Silica, Picea Abies Wood Extract, Sodium Ascorbyl Phosphate, Retinyl Palmitate, Tocopherol, Tocopheryl Acetate, Titanium Dioxide, Aloe Barbadensis Leaf Juice, Bentonite, Methyl Glucose Sesquistearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Polyacrylate, Kaolin, Ethylhexylglycerin, Disodium EDTA, Sodium Hydroxide, Chlorphenesin, Phenoxyethanol

150831

AMCOL Health & Beauty Solutions, Inc. DBA
301 Laser Lane Lafayette, LA 70507 | www.amcolhpc.com
lauren.haase@amcol.com

Principal Display Panel - Carton Label

sheltered

broad spectrum

spf 55 sunscreen

derma

faith

50 ml/1.7 fl oz.

sheltered

broad spectrum
spf 55 sunscreen

sheltered

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sheltered

broad spectrum
spf 55 sunscreen



50 ml/1.7 fl oz

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No Coating

Principal Display Panel - Bottle Label

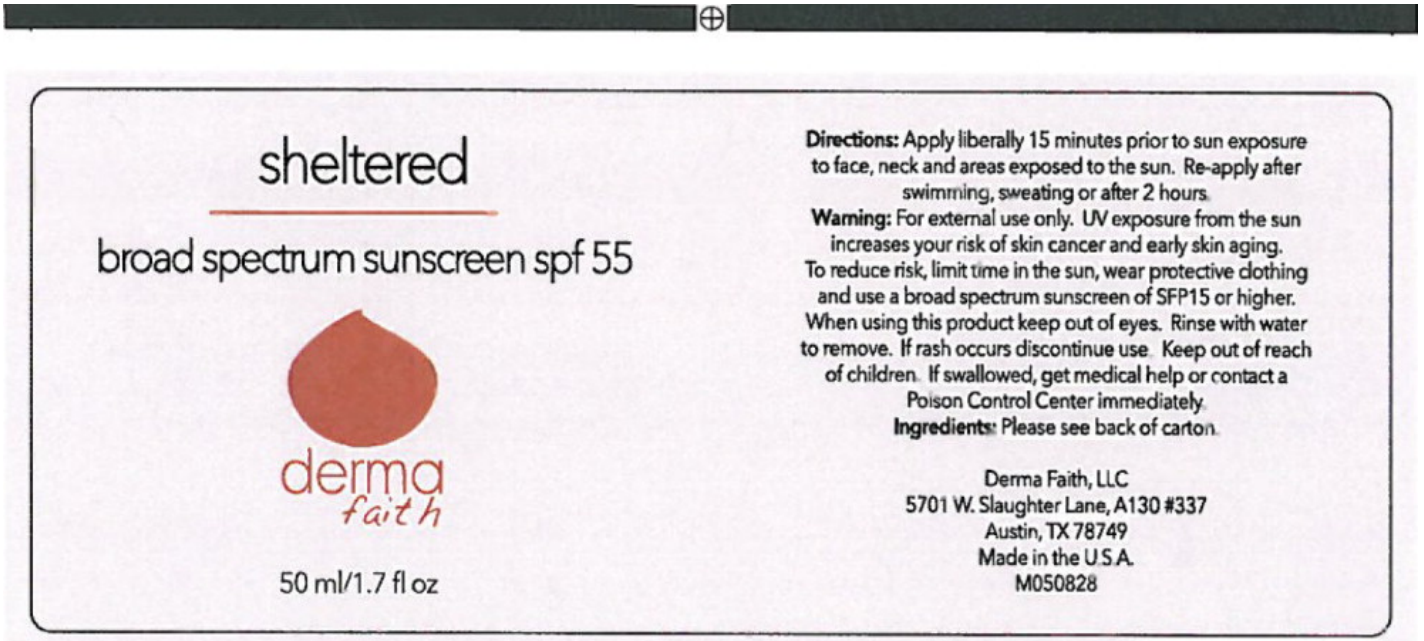
sheltered

broad spectrum sunscreen spf 55

derma

faith

50 ml/1.7 fl oz.



SHELTERED BROAD SPECTRUM SPF 55 SUNSCREEN

homosalate, oxybenzone, octisalate, avobenzone, octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
homosalate (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	100 g in 1 mL
oxybenzone (UNII: 95OOS7VE0Y) (oxybenzone - UNII:95OOS7VE0Y)	oxybenzone	60 g in 1 mL
octisalate (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	50 g in 1 mL
avobenzone (UNII: G63QQF2NOX) (avobenzone - UNII:G63QQF2NOX)	avobenzone	30 g in 1 mL
octocrylene (UNII: 5A68WGF6WM) (octocrylene - UNII:5A68WGF6WM)	octocrylene	20 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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water (UNII: 059QF0KO0R)
butylene glycol (UNII: 3XUS85K0RA)
polyethylene glycol 400 (UNII: B697894SGQ)
high density polyethylene (UNII: UG00KM4WR7)
dimethicone (UNII: 92RU3N3Y1O)
silicon dioxide (UNII: ETJ7Z6XBU4)
picea abies wood (UNII: 72GZ8K8996)
sodium ascorbyl phosphate (UNII: 836SJG51DR)
vitamin a palmitate (UNII: 1D1K0N0VVC)
tocopherol (UNII: R0ZB2556P8)
.alpha.-tocopherol acetate, DL- (UNII: WR1WPI7EW8)
titanium dioxide (UNII: 15FIX9V2JP)
aloe vera leaf (UNII: ZY81Z83H0X)
bentonite (UNII: A3N5ZCN45C)
carbomer copolymer type A (UNII: 71DD5V995L)
sodium polyacrylate (8000 mw) (UNII: 285CYO341L)
kaolin (UNII: 24H4NWX5CO)
ethylhexylglycerin (UNII: 147D247K3P)
edetate disodium (UNII: 7FLD91C86K)
sodium hydroxide (UNII: 55X04QC32I)
chlorphenesin (UNII: I670DAL4SZ)
phenoxyethanol (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68634-050-01	1 in 1 CARTON		
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2015	

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment

Name	Address	ID/FEI	Business Operations
AMCOL Health & Beauty Solutions, Inc. DBA		872684803	MANUFACTURE(68634-050) , PACK(68634-050) , LABEL(68634-050) , ANALYSIS(68634-050)