

BOTANICS SKIN CALMING DAY ULTRA CALM SUNSCREEN BROAD SPECTRUM SPF 15- avobenzone, octisalate, octocrylene cream
BCM Ltd

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.

Carton Active Ingredients Section

Active Ingredients

Avobenzone 3%

Octisalate 3%

Octocrylene 5%

Purpose Sunscreen

Uses

Uses - helps prevent sunburn.

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

Ask a doctor

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

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

Directions

Directions for sunscreen use

apply liberally 15 minutes before sun exposure

reapply at least every 2 hours

use a water resistant sunscreen if swimming or sweating

children under 6 months of age: Ask a doctor

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

limit time in the sun, especially from 10 a.m. – 2 p.m.

wear long-sleeved shirts, pants, hats, and sunglasses

Storage

Other information - protect the product in this container from excessive heat and direct sun

Inactive ingredients

Aqua (Water), C12-15 alkyl benzoate, Glycerin, Dimethicone, Cetearyl glucoside, Isostearyl isostearate, Tribehenin, Butyrospermum parkii (Shea) butter, Propylene glycol, Cetearyl alcohol, Sodium polyacrylate, Potassium cetyl phosphate, Phenoxyethanol, Dimethicone crosspolymer, Caprylyl glycol, Parfum (Fragrance), Citric acid, Dipropylene glycol, Sodium benzoate, Acrylates/vinyl isodecanoate crosspolymer, Ethylhexylglycerin, Potassium sorbate, Tetrasodium EDTA, Sorbitol, Tilia cordata flower extract, Althaea officinalis root extract, Tocopheryl acetate, Silica

Description

Immediately calms sensitive skin and with continued use reduces skin reactivity.

Active plant extract, Marshmallow, contains natural sugars and polyphenols to help calm skin and leave it less sensitive.

Directions: Use every morning after cleansing. Colour may vary due to natural ingredients. Formulated without parabens.

Information

Made in the UK.

The Boots Company PLC Nottingham England NG2 3AA

Dist. in the USA by Boots Retail USA Inc. Norwalk CT 06851 USA

www.boots.com

Jar label

Boots Botanics The Power of Plants

Skin Calming Day Cream Sunscreen Broad Spectrum SPF 15

50ml e 1.69 US Fl. Oz.

Active ingredients: Avobenzone 3%, Octisalate 3%, Octocrylene 5%

Warnings

Avoid contact with eyes. If product gets into the eyes, rinse well with water immediately.

Description

Directions: Use every morning after cleansing

Information

The Boots Company PLC

Nottingham England NG2 3AA

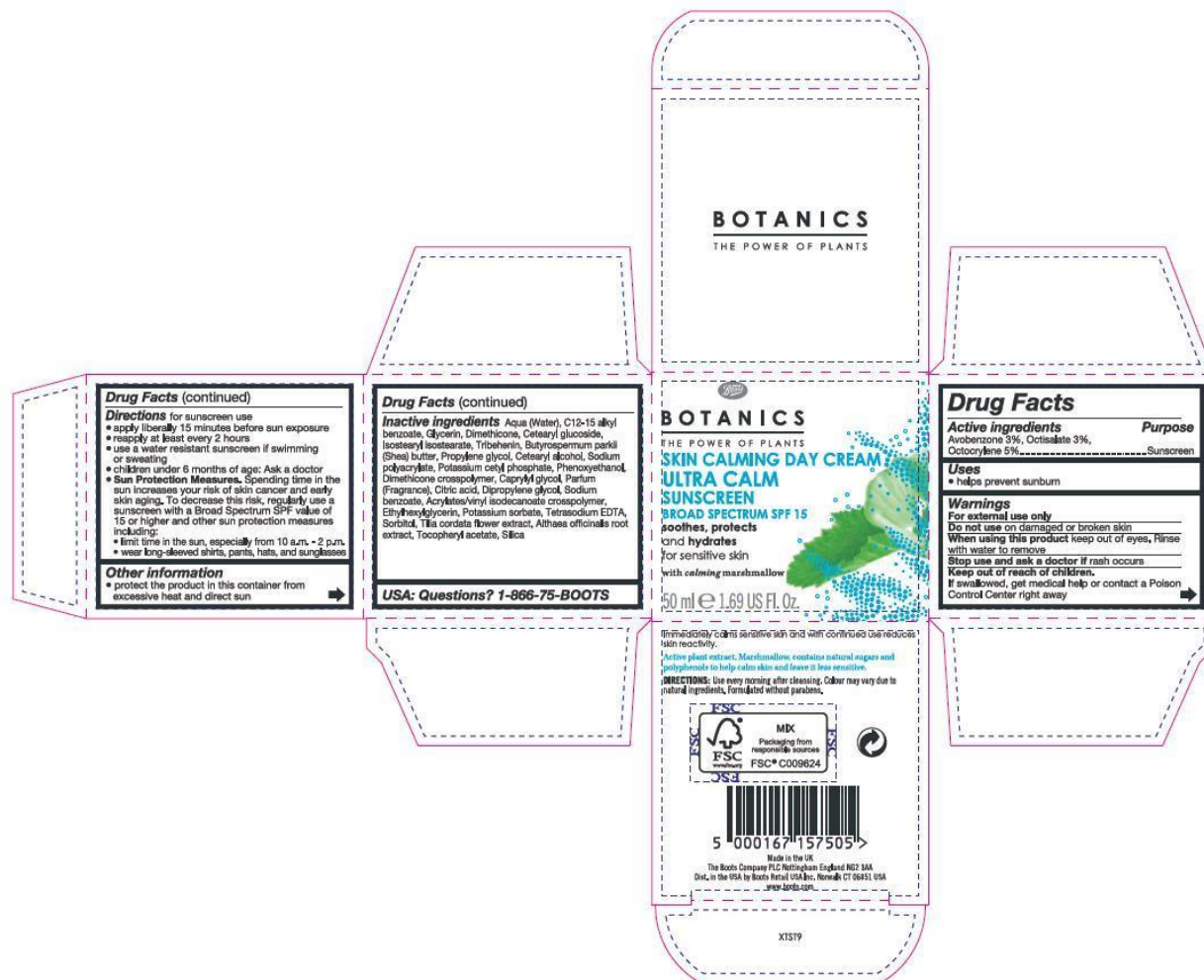
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Carton

Carton label



BOTANICS SKIN CALMING DAY ULTRA CALM SUNSCREEN BROAD SPECTRUM SPF 15

avobenzone, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11489-081
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	1.5 g in 50 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5 g in 50 g
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SHEA BUTTER (UNII: K49155WL9Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SORBITOL (UNII: 506T60A25R)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11489-081-01	1 in 1 CARTON		
1		50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/14/2013	

Labeler - BCM Ltd (230780322)

Registrant - The Boots Company Plc (218622660)

Establishment

Name	Address	ID/FEI	Business Operations
BCMLtd		230780322	manufacture(11489-081) , analysis(11489-081)

Revised: 12/2012

BCMLtd