

NO7 DUAL ACTION TINTED MOISTURISER MEDIUM- avobenzonone, octisalate and octocrylene emulsion
Boots Retail USA 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.

Tinted Moisturiser

active ingredients

Drug Facts

Active Ingredients Avobenzonone 3%, Octisalate 2%, Octocrylene 4%

Purpose Sunscreen

Purpose section

Uses

helps prevent sunburn

Warnings.

Warnings

For external use only

Do not use on damaged or broken skin

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

Ask 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 Center right away.

Indications.

Directions

apply liberally 15 minutes bfore 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.

Inactives.

Inactive ingredients

Aqua (Water), C12-15 alkyl benzoate, Glycerin, Butylene glycol, Cyclopentasiloxane, Mica, Glyceryl stearate, Petrolatum, Paraffinum liquidum (Mineral oil), Dimethicone, Cetearyl alcohol, PEG-100 stearate, Cyclohexasiloxane, Tribehenin, Rosa moschata seed oil, Phenoxyethanol, Alcohol denat., Methylparaben, Sodium stearyl lactylate, Ascorbyl glucoside, Polacrylamide, Xanthan gum, Ethylparaben, Sodium polacrylate, C13-14 isoparaffin, Sodium hyaluronate, Tetrasodium ETA, Potassium hydroxide, Laureth-7, Dimethylmethoxy chromanol, Phyllanthus emblica fruit extract, Ceramide 3, Ginkgo biloba leaf extract, Ascorbyl palmitate, (+/- (May contain) CI 77891 (Titanium dioxide), CI 77492 (Iron oxides), CI 77491 (Iron oxides), CI 77499 (Iron oxides).

Questions.

USA: Questions? 1-866-75-BOOTS.

Description.

Beautiful Protection.

Achieve natural, skin perfecting colour with this sheer, light diffusing, tinted moisturiser. It delivers all day hydration and a powerful antioxidant complex to defend your skin from the ageing effects of the sun and the environment.

For Best Results: Shake well before use. Smooth on evenly, just like your usual moisturiser.

Hypo-allergenic: Because all skin can have sensitive moments, all our foundation products are hypo-allergenic using ingredients we know and trust.

Information for patients.

The Boots Company PLC Nottingham England NG2 3AA

Dist by Boots Retail USA Inc Norwalk CT 06851 USA

Made in France

www.boots.com

Jar front and active ingredients.

No7 Dual Action Tinted Moisturiser Sunscreen Broad Spectrum SPF 15

All skin types

Long lasting hydration, environmental protection and beautiful sheer colour

Hypo-allergenic

50ml 1.6 US Fl Oz

Active ingredients: Avobenzone 3%, Octisalate 2%, Octocrylene 4%.

Warnings.

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

Description.

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carton label.

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avobenzone, octisalate and octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68472-141
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 g in 50 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
MICA (UNII: V8A1AW0880)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
ROSA MOSCHATA SEED OIL (UNII: T031ZE559T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
POLYACRYLAMIDE (1300000 MW) (UNII: SC5Y4X78TG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYL PARABEN (UNII: 14255EXE39)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
LAURETH-7 (UNII: Z95S6G8201)	
PHYLLANTHUS EMBLICA FRUIT JUICE (UNII: K8SGU56WPQ)	
CERAMIDE 3 (UNII: 4370DF050B)	
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

FERRIC FERROCYANIDE (UNII: TLE294X33A)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68472-141-01	1 in 1 CARTON		
1		50 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/29/2012	

Labeler - Boots Retail USA Inc (143151533)

Registrant - The Boots Company PLC (218622660)

Establishment

Name	Address	ID/FEI	Business Operations
BCM Cosmetique SAS		275359578	manufacture(68472-141)

Revised: 10/2012

Boots Retail USA Inc