

SPF-15 SUNSCREEN- octocrylene, avobenzone lotion
Continental Manufacturing Chemist, 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.

Broad-Spectrum SPF-15 Lotion

Active ingredients

Octocrylene 10%

Avobenzone 3%

Uses

Helps Prevent Sunburn

Purpose

Helps prevent sunburn

Warnings

FOR EXTERNAL USE ONLY

Do not use

in eyes, if this happens rinse thoroughly with water.

Stop use and ask a doctor if

if skin irritation develops

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center

Ask a doctor

before using on children under 6 months

Directions

Apply liberally 15 minutes before sun exposure

Use a water resistant sunscreen if swimming or sweating

Reapply at least every 2 hours

Storage

Store at 20-25C (68-77F)

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Gel, Benzyl Alcohol, Carbopol, Cetyl Alcohol, Fragrance, (Glyceryl Stearate and PEG 100 Stearate), Methyl Paraben, PEG-40 Stearate, Phenoxyethanol, (Polyacrylamide and C13-14 Isoparaffin and Laureth-7), Propyl Paraben, Purified Water, Shea Butter, Sodium Hydroxide, Sorbitan Monooleate, Stearic Acid, Tetrasodium Ethylenediaminetetraacetate, Vitamin E

Principal Display Panel

Product

SUNSCREEN - Broad Spectrum SPF-15

DRUG FACTS

ACTIVE INGREDIENTS:
Octocrylene 10%, Avobenzone 3%

Uses: Helps Prevent Sunburn

WARNINGS: FOR EXTERNAL USE ONLY
Do not use in eyes; if this happens rinse thoroughly with water
Stop Use and Ask a Doctor if skin irritation develops

KEEP OUT OF REACH OF CHILDREN
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DIRECTIONS:
Apply liberally 15 minutes before sun exposure
Use a water resistant sunscreen if swimming or sweating
Reapply at least every 2 hours
Children under six months: Ask a doctor
STORE at 20-25C (68-77F)

INACTIVE INGREDIENTS:
Aloe barbadensis (Aloe Vera) gel, Benzyl Alcohol, Carbomer, Cetyl Alcohol, Fragrance, (Glyceryl Stearate and PEG-100 Stearate), Methyl Paraben, PEG-40 Stearate, Phenoxyethanol, (Polyacrylamide and C13-14 Isoparaffin and Laureth-7), Propyl Paraben, Purified Water, Shea Butter, Sodium Hydroxide, Sorbitan Monooleate, Stearic Acid, Tetrasodium ethylenediaminetetraacetate, Vitamin E

Manufactured By
Continental Manufacturing Chemist, Inc.
912 S State Street, Madrid, IA 50156

SUNSCREEN LOTION SPF 15
ITEM# D-048 LOT #
RETEST DATE:

GROSS WT: _____ LB. ____
TARE WT: _____ LB. ____
NET WT: _____ LB. ____

MANUFACTURED BY:
CONTINENTAL MANUFACTURING
CHEMIST, INC.
MADRID, IA 50156

DEDICATED TOTE
RINSE WITH WATER AND RETURN TO
MANUFACTURER

SPF-15 Labels

Labels

Manufactured By

Continental Manufacturing Chemist, Inc.
912 S. State Street, Madrid, IA 50156

SPF-15 SUNSCREEN

octocrylene, avobenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49794-048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100.000 g in 1.0 L
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.000 g in 1.0 L

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPa.S) (UNII: 5F4963KLHS)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49794-048-99	1100 L in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/16/2012	

Labeler - Continental Manufacturing Chemist, Inc. (005278007)

Revised: 7/2012

Continental Manufacturing Chemist, Inc.