

SIMPLE VITAL VITAMIN DAY CREAM SPF 15- homosalate, octisalate, avobenzone, and octocrylene emulsion

CONOPCO Inc. d/b/a Unilever

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.

Simple Vital Vitamin Day Cream SPF 15

Active ingredients

Avobenzone 3.0%

Homosalate 12.0%

Octisalate 5.0%

Octocrylene 2.7%

Purpose

Sunscreen

Uses

Helps prevent sunburn.

If used as directed with other sun protection measures (See **Directions**), decreases the risk of skin cancer and early aging caused by the sun.

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.

Stop use and ask a doctor if rash occurs.

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

Directions

Apply liberally and evenly to face and neck 15 minutes before sun exposure.

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 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.

Reapply at least every 2 hours.

Use a water resistant sunscreen if swimming or sweating.

Children under 6 months: Ask a doctor.

Inactive ingredients

Water (Aqua, Eau)

Homosalate

Glycerin

C12-15 Alkyl Benzoate

Ethylhexyl Salicylate

Butyl

Methoxydibenzoylmethane

Silica

Octocrylene

Pentylene Glycol
Cetearyl Alcohol
Steareth-21
Steareth-2
Phenoxyethanol
Arachidyl Alcohol
Polyacrylamide
Caprylyl Glycol
Behenyl Alcohol
C13-14 Isoparaffin
Disodium EDTA
Xanthan Gum
Cetearyl Glucoside
Arachidyl Glucoside
Allantoin
Tocopheryl Acetate
Bisabolol
Panthenol
Laureth-7
Triethanolamine
Methylisothiazolinone

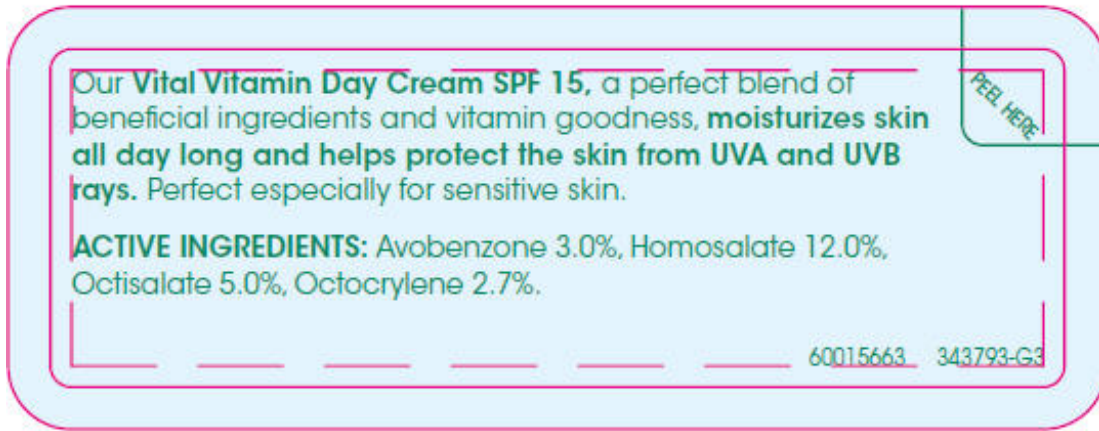
Questions or Comments?

1-866-752-4602

PDP front



PDP back



Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0% Homosalate 12.0% Octisalate 5.0% Octocrylene 2.7%	Sunscreen
Uses	
<ul style="list-style-type: none"> Helps prevent sunburn. If used as directed with other sun protection measures (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun. 	
Warnings	
<ul style="list-style-type: none"> 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. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. 	
Directions	
<ul style="list-style-type: none"> Apply liberally and evenly to face and neck 15 minutes before sun exposure. 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 Broad Spectrum SPF-value of 15 or higher and other sun 	

Drug Facts (continued)	
protection measures including:	
<ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Children under 6 months: Ask a doctor. 	
Inactive ingredients Water (Aqua, Eau), Glycerin, C12-15 Alkyl Benzoate, Silica, Polyethylene Glycol, Tocopheryl Acetate, Panthenol, Cetanol, Alcohol, Steareth-21, Steareth-2, Arachidyl Alcohol, Polyacrylamide, Caprylyl Glycol, Behenyl Alcohol, C13-14 Isoparaffin, Disodium EDTA, Xanthan Gum, Cetearyl Glucoside, Arachidyl Glucoside, Alkanton, Bisabolol, Laureth-7, Tetrahydroxymethyl Sulfonium Chloride, Phenoxyethanol.	
Other information	
<ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. 	
Questions or Comments? 1-866-752-4602	
Simple skincare contains no animal derived ingredients. Visit www.simple skincare.com	
 © UNILEVER Trumbull, CT 06611 Made in USA	
60015666 343793-G3	



Our Vital Vitamin Day Cream SPF 15, a perfect blend of beneficial ingredients and vitamin goodness, moisturizes skin all day long and helps protect the skin from UVA and UVB rays. Perfect especially for sensitive skin.

simple goodness

- VITAL VITAMINS**
PRO-VITAMIN B5 helps restore, soften and smooth. VITAMIN E moisturizer helps improve skin condition.
- SKIN LOVING NUTRIENTS**
GLYCERIN hydrates and nourishes. ALLANTOIN helps soothe and calm. BISABOLOL helps soothe and calm.
- NO PERFUME, NO DYES**
NO HARSH IRRITANTS that can upset your skin.

- Dermatologist tested
- Noncomedogenic
- Hypoallergenic

SIMPLE VITAL VITAMIN DAY CREAM SPF 15

homosalate, octisalate, avobenzone, and octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64942-1244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.12 g in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 g
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.027 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
PANTHENOL (UNII: WV9CM0067Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARETH-2 (UNII: V56DFE46J5)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DOCOSANOL (UNII: 9G10E216XY)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
ALLANTOIN (UNII: 344S277G0Z)	

LEVOMENOL (UNII: 24WE03BX2T)

LAURETH-7 (UNII: Z95S6G8201)

TROLAMINE (UNII: 9O3K93S3TK)

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64942-1244-2	1 in 1 CARTON		
1	NDC:64942-1244-1	50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2012	

Labeler - CONOPCO Inc. d/b/a Unilever (001375088)

Revised: 2/2012

CONOPCO Inc. d/b/a Unilever