

CORRECTING CREAM BROAD SPECTRUM SPF 15 ASAP- avobenzene, octinoxate, octocrylene, oxybenzone, zinc oxide lotion
AUSTRALIAN SKIN PRODUCTS PTY 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.

CC cream Broad Spectrum SPF 15

Active ingredients Purpose

Avobenzene 3%	Sunscreen
Octinoxate 4%	Sunscreen
Oxybenzone 3%	Sunscreen
Zinc Oxide 4.5%	Sunscreen

Uses: 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.

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

Stop use and ask a doctor if rash occurs.

Warnings

For external use only

Do not use on damaged or broken skin

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

Directions

Apply liberally 15 minutes before sun exposure

Reapply: at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

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 15 or higher and other sun protection measures including:

Limit time in the sun especially from 10 a.m. - 2 p.m.

Wear long-sleeve Shirts, pants, hats and sunglasses

children under 6 months ask a doctor

Inactive ingredients: Water (Aqua), Methyl Gluceth-20, Caprylic/Capric Triglyceride, Butylene Glycol, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Triacontanyl PVP, Dimethicone, Citrus Tangerina (Tangerine) Peel Oil, Camellia Sinensis Leaf Extract, Punica Granatum (Pomegranate) Fruit Extract, Phenoxyethanol, Benzyl Alcohol, Triethanolamine, Ethylhexylglycerin, Propylene Glycol, Polysorbate 20, Iron Oxide (CI 77491), Iron Oxide (CI 77492), Iron Oxide (CI 77499).

asap

the science of beautiful skin

correcting cream

with antioxidants

hydrate + protect
 Broad Spectrum SPF 15 sunscreen
 75 mL / 2.54 fl oz



CORRECTING CREAM BROAD SPECTRUM SPF 15 ASAP			
avobenzone, octinoxate, octocrylene, oxybenzone, zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7626 1-126
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MANDARIN OIL (UNII: NJO720F72R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POMEGRANATE (UNII: 56687D1Z4D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76261-126-02	1 in 1 BOX		
1	NDC:76261-126-01	75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/04/2014	

Labeler - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

Registrant - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Beauty Care Pty Ltd		749369716	manufacture(76261-126)

Revised: 8/2014

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