DAYTIME DEFENSE SPF 30- zinc oxide cream CoValence, 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.

Drug Facts

Active Ingredients: Zinc Oxide 13.5%

Purpose: Sunscreen

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

Use:

• Helps prevent sunburn

• For skin highly sensitive to 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.
- 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.

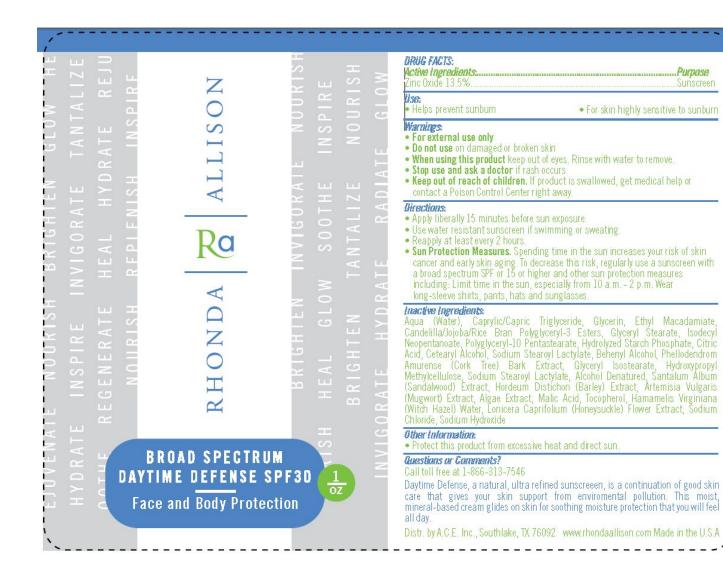
Directions:

- Apply liberally 15 minutes before sun exposure.
- Use water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- **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 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-sleeve shirts, pants, hats and sunglasses.

Inactive Ingredients:

Aqua (Water). Caprylic/Capric Triglyceride, Glycerin, Ethyl Macadamiate, Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters, Glyceryl Stearate, Isodecyl Neopentanoate, Polyglyceryl-10 Pentastearate, Hydrolyzed Starch Phosphate, Cirtric Acid, Cetearyl Alcohol, Sodium Stearoyl Lactylate, Behenyl Alcohol, Phellodendrom Amurense (Cork Tree) Bark Extract, Glyceryl Isostearate, Hydroxypropyl Methylcellulose, Sodium Stearoyl Lactylate, Alcohol Denatured, Santalum Album (Sandalwood) Extract, Hordeum Distichon (Barley) Extract, Artemisia Vulgaris (Mugwort) Extract, Algae Extract, Malic Acid, Tocopherol, Hamamelis Virginiana (Witch Hazel) Water, Lonicera Caprifolium (Honeysuckle) Flower Extract, Sodium Chloride, Sodium Hydroxide

Principal Display Panel:



DAYTIME DEFENSE SPF 30

zinc oxide cream

Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:66915-611 Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	.135 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER		
MEDIUM-CHAIN TRIGLYCERIDES		
ETHYL MACADAMIATE		
ISO DECYL NEO PENTANO ATE		
GLYCERIN		

GLYCERYL MONOSTEARATE	
BARLEY	
LAVENDER O IL	
SANDALWOOD	
PHELLO DENDRO N AMURENSE BARK	
ARTEMISIA VULGARIS ROOT	
.ALPHATOCOPHEROL, DL-	
MALIC ACID, L-	
LONICERA CAPRIFOLIUM FLOWER	
LONICERA JAPONICA FLOWER	
GLYCERYL ISOSTEARATE	
SODIUM STEAROYL LACTYLATE	
DOCOSANOL	
CETOSTEARYL ALCOHOL	
POLYHYDRO XYSTEARIC ACID (2300 MW)	
SO DIUM CHLO RIDE	
HAMAMELIS VIRGINIANA TOP WATER	
ALCOHOL	
CITRIC ACID MONO HYDRATE	
FYTIC ACID	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66915-611-01	200000 g in 1 DRUM		
2	NDC:66915-611-02	30 g in 1 BOTTLE, PLASTIC		
3	NDC:66915-611-03	120 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/26/2012	

Labeler - CoValence, Inc. (070653204)

Registrant - Co Valence, Inc. (070653204)

Establishment				
Name	Address	ID/FEI	Business Operations	
Co Valence, Inc.		070653204	manufacture(66915-611)	

Revised: 4/2012 CoValence, Inc.