

WATERFUL SUN- ethylhexyl methoxycinnamate, octocrylene, ethylhexyl salicylate, butyl methoxydibenzoylmethane gel

ARI&J 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.

Ethylhexyl Methoxycinnamate, Octocrylene, Ethylhexyl Salicylate, Butyl Methoxydibenzoylmethane
Water, Butylene Glycol, etc

- Sunscreen
- protects skin from UV rays
- 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 the children

apply generously 15 minutes before sun exposure

reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every two 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 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

children under 6 months of age: Ask a doctor

- 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 swallowed, get medical help or contact a Poison Control Center right away.
- do not place this product in this container in the excessive heat and direct sun.

for external use only



WATERFUL SUN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71496-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 mL

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)

AVOBENZONE

4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71496-0003-1	50 mL in 1 TUBE; Type 0: Not a Combination Product	06/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/30/2017	

Labeler - ARI&J Inc (694174441)

Registrant - ARI&J Inc (694174441)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(71496-0003)

Establishment

Name	Address	ID/FEI	Business Operations
ARI&J Inc		694174441	label(71496-0003) , pack(71496-0003)

Revised: 6/2017

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