PREMIUM ULTRA UV PURE SUN- octocrylene, ethylhexyl methoxycinnamate, diethylamino hydroxybenzoyl hexyl benzoate, ethylhexyl salicylate, bis-ethylhexyloxyphenol methoxyphenyl triazine stick
Purecell Korea Co., 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.

Octocrylene, Ethylhexyl Methoxycinnamate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Ethylhexyl Salicylate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine

Water, Butylene Glycol, etc.

Sunscreen

keep out or reach of the children

During the last step of basic skin care, dispense an appropriate amount and evenly apply to any skn that will be exposed to ultraviolet sunlight.

Do not use on damaged or broken skin.

When using this product
• Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use if following symptoms occur. (Continuing in usage may increase symptoms, ask doctor.)

1) If any red spots, swelling, itching, or skin irritation develops.

2) If direct sunlight causes irritation

Keep out of reach of children
• Do not swallow. In case of accidental ingestion, get medical help or contact a Poison Control

Center right away.

Store at room temperature
• **Close lid after use** – possibility of contamination may exists if displaced contents are replaced back to container.

for external use only

PREMIUM ULTRA UV PURE SUN

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71609-0009
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 g
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20) (DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE - UNII:ANQ870JD20)	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
BEMOTRIZINOL (UNII: PWZ1720CBH) (BEMOTRIZINOL - UNII:PWZ1720CBH)	BEMOTRIZINOL	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71609-0009-1	15 g in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2017	

Labeler - Purecell Korea Co., Ltd. (694667185)

Registrant - Purecell Korea Co., Ltd. (694667185)

Establishment

Name	Address	ID/FEI	Business Operations
Purecell Korea Co., Ltd.		557799448	label(71609-0009)

Establishment

Name	Address	ID/FEI	Business Operations
Hankook Cosmetics Manufacturing Co.,Ltd_Eumseong Factory		688235645	manufacture(71609-0009)

Revised: 8/2017 Purecell Korea Co., Ltd.