

**RENARDBLANC MULTILAYER SUN BLOCK- octinoxate, octisalate, avobenzone, homosalate cream**

**Diamonie Seoul Cosmetic 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.*

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**Drug Facts**

Octinoxate 6.00%

Octisalate 4.50%

Avobenzone 2.50%

Homosalate 2.00%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure.

Reapply 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 of 15 or higher and other sun protection measures including: 1) Limited time in the sun, especially from 10 am to 2 pm. 2)

Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

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 using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Butylene Glycol, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Cetearyl Alcohol, Polyglyceryl-6 Stearate, Polyglyceryl-6 Behenate, Dimethicone, Polyacrylate-13, Cetearyl Glucoside, Sodium Polyacrylate, PEG-100 Stearate, Glyceryl Stearate, Polyisobutene, Panthenol, Ethylhexylglycerin, Allantoin, Polysorbate 20, Stearyl Alcohol, Cetyl Alcohol, Glacier Water, Cirsium (Thistle) Flower/Leaf/Stem Extract, Glycerin, 1,2-Hexanediol, Zea, Mays (Corn) Starch, Hydrolyzed Corn Starch, Hydrolyzed Corn Starch Octenylsuccinate, Butyrospermum Parkii (Shea) Butter Extract, Phenylethyl Resorcinol, Cocamidopropyl Dimethylamine, Lactic Acid, Palmitoyl Tripeptide-5, Hydrated Silica, Disodium EDTA, Phenoxyethanol, Fragrance



## RENARDBLANC MULTILAYER SUN BLOCK

octonoxate, octisalate, avobenzene, homosalate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72073-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.6 mg in 60 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	2.7 mg in 60 mL
<b>AVOBENZENE</b> (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	1.5 mg in 60 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	1.2 mg in 60 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QB13)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRVW)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
PEG-100 Stearate (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
PANTHENOL (UNII: WV9CM0O67Z)	
Ethylhexylglycerin (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
Cetyl Alcohol (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHEA BUTTER (UNII: K49155WL9Y)	
PHENYLETHYL RESORCINOL (UNII: G37UFG162O)	
COCAMIDOPROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72073-001-02	1 in 1 CARTON	02/05/2018	
1	NDC:72073-001-01	60 mL in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/05/2018	

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**Registrant** - Diamonie Seoul Cosmetic Co Ltd (694502893)

**Establishment**

Name	Address	ID/FEI	Business Operations
Englewood Lab Inc		690104005	manufacture(72073-001)

Revised: 2/2018

Diamonie Seoul Cosmetic Co Ltd