

**GIN-III ALPHA AND OMEGA GIN SUN- zinc oxide, titanium dioxide cream**  
**Hanwool Life Sciences. 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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**GIN-III Alpha and Omega GIN Sun Cream**

**Active Ingredients**

Zinc Oxide (4%)

Titanium Dioxide (1.6%)

**Purpose**

Sunscreen

**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.

**Warnings**

For external use only

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 and ask doctor if rash or irritation on skin develops and lasts.

☐ Store at room temperature

**Directions**

Apply the adequate amount on the palm of the hands and pat lightly with the fingertips.

• 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 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

**Uses**

Helps prevent sunburn

**Inactive Ingredients**

Water, Ethylhexyl Methoxycinnamate, Dipropylene Glycol, Butylene Glycol, C12-15 Alkyl Benzoate,

Cetearyl Alcohol, Ethylhexyl Salicylate, Isoamyl p-Methoxycinnamate, Niacinamide, Cyclomethicone, Cyclopentasiloxane, Cyclohexasiloxane, Dicaprylyl Carbonate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Polysorbate 60, Butyl Methoxydibenzoylmethane, Cetearyl Olivatate, Sorbitan Stearate, Sorbitan Olivatate, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Polyacrylate-13, Silica, Polyisobutene, Usnea Barbata (Lichen) Extract, Zanthoxylum Piperitum Fruit Extract, Pulsatilla Koreana Extract, Fragrance (Parfum), Triethoxycaprylylsilane, Ginsenosides, Xanthan Gum, Saponins, Caprylyl Glycol, Disodium EDTA, Adenosine, Dimethicone, Polysorbate 20, 1,2-Hexanediol, Propanediol, Illicium Verum (Anise) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Rosmarinus Officinalis (Rosemary) Extract, Aspalathus Linearis Extract, Thymus Vulgaris (Thyme) Extract, Salvia Officinalis (Sage) Extract, Aloe Barbadensis Leaf Juice, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Eucalyptus Globulus Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Symphytum Officinale Leaf Extract

### **GIN-III Alpha and Omega GIN Sun Cream**



GIN-III ALPHA AND OMEGA GIN SUN			
zinc oxide, titanium dioxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71135-100
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2 g in 50 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.8 g in 50 mL
<b>Inactive Ingredients</b>		
<b>Ingredient Name</b>	<b>Strength</b>	
<b>WATER</b> (UNII: 059QF0KO0R)		
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51)		
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)		
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)		
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)		
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)		
<b>OCTISALATE</b> (UNII: 4X49Y0596W)		
<b>AMILOXATE</b> (UNII: 376KTP06K8)		
<b>Niacinamide</b> (UNII: 25X51I8RD4)		
<b>Cyclomethicone</b> (UNII: NMQ347994Z)		
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)		
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)		
<b>BEMOTRIZINOL</b> (UNII: PWZ1720CBH)		
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)		
<b>AVOBENZONE</b> (UNII: G63QQF2NOX)		
<b>Cetearyl Olivat</b> (UNII: 58B69Q84JO)		
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)		
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)		
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)		
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)		
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)		
<b>USNEA BARBATA</b> (UNII: D6DVA9TCAP)		
<b>ZANTHOXYLUM PIPERITUM FRUIT PULP</b> (UNII: 7PFC2VA251)		
<b>PULSATILLA KOREANA ROOT</b> (UNII: FY35I16MPL)		
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)		
<b>GINSENO SIDES</b> (UNII: 3K198YD54P)		
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)		
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)		
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)		
<b>Adenosine</b> (UNII: K72T3FS567)		
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)		
<b>Polysorbate 20</b> (UNII: 7T1F30V5YH)		
<b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)		
<b>Propanediol</b> (UNII: 5965N8W85T)		
<b>STAR ANISE FRUIT</b> (UNII: CK15HA8438)		
<b>LAVANDULA ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)		
<b>ROSEMARY</b> (UNII: IJ67X351P9)		
<b>ASPALATHUS LINEARIS WHOLE</b> (UNII: O17JQA1A9Z)		
<b>THYME</b> (UNII: CW6570BU4N)		
<b>SALVIA OFFICINALIS ROOT</b> (UNII: 236QY0A1BL)		
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)		
<b>HAMAMELIS VIRGINIANA TOP</b> (UNII: UDA30A2JJY)		
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)		

CHAMOMILE (UNII: FGL3685T2X)

COMFREY LEAF (UNII: DG4F8T839X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71135-100-02	1 in 1 PACKAGE	12/12/2016	
1	NDC:71135-100-01	50 mL in 1 TUBE; 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	12/12/2016	

**Labeler** - Hanwool Life Sciences. Co., Ltd (557789808)

**Registrant** - Hanwool Life Sciences. Co., Ltd (557789808)

### Establishment

Name	Address	ID/FEI	Business Operations
Hanwool Life Sciences. Co., Ltd		557789808	manufacture(71135-100)

Revised: 12/2016

Hanwool Life Sciences. Co., Ltd