

**SOLFUL FACE SUNLOTION- homosalate, avobenzone, otisalate,  
octocrylene lotion  
KARA BEAUTY INC**

-----  
**83918-001\_solful face sun lotion**

Sunscreen

Homosalate 10%, Octocrylene 5%, Octisalate 4%, Avobenzone 3%

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, Dipropylene Glycol, Silica, Diphenylsiloxy Phenyl Trimethicone, Isohexadecane,  
Butyloctyl Salicylate, Polysorbate 80, Dimethicone/Phenyl Vinyl Dimethicone  
Crosspolymer, Benzyl Glycol, Glyceryl Stearate, PEG-100 Stearate, Acrylates/C10-30  
Alkyl Acrylate Crosspolymer, Arginine, Xanthan Gum, Centella Asiatica Extract, Butylene  
Glycol, Ethylhexylglycerin, Propanediol, Bambusa Vulgaris Leaf Extract, Oldenlandia  
Diffusa Extract, Sodium Hyaluronate Crosspolymer, Lonicera Caprifolium (Honeysuckle)  
Extract, 1,2-Hexanediol, Hydrolyzed Glycosaminoglycans, Yeast Extract, Limonia  
Acidissima Extract, Glycerin, Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid,  
Madecassic Acid, Asiaticoside, Asiatic Acid, Caprylyl Glycol, Hyaluronic Acid, Ascorbyl  
Glucoside, Sodium Ascorbyl Phosphate, Magnesium Ascorbyl Phosphate,  
Tetrahexyldecyl Ascorbate, Sodium Riboflavin Phosphate, Fragrance, Citral, Benzyl  
Salicylate, Linalool, Limonene

Protect the product in the container from excessive heat and direct sun



## SOLFUL FACE SUNLOTION

homosalate, avobenzone, otisalate, octocrylene lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:83918-001

## Route of Administration

TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 100 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 50 mg in 1 mL  |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 40 mg in 1 mL  |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 30 mg in 1 mL  |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)   |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)  |          |
| <b>DIPHENYLSILOXY PHENYL TRIMETHICONE</b> (UNII: I445L28B12)                         |          |
| <b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)  |          |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)                                      |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)   |          |
| <b>DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER</b> (UNII: ST6ZC4KVH2)          |          |
| <b>ETHYLENE GLYCOL MONOBENZYL ETHER</b> (UNII: 06S8147L47)                           |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                                      |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)   |          |
| <b>ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S)</b> (UNII: 8Z5ZAL5H3V) |          |
| <b>ARGININE</b> (UNII: 94ZLA3W45F)   |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |          |
| <b>CENTELLA ASIATICA TRITERPENOIDS</b> (UNII: 4YS74Q4G4J)                            |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)   |          |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)  |          |
| <b>BAMBUSA VULGARIS LEAF</b> (UNII: EMY54R518C)                                      |          |
| <b>SCLEROMITRION DIFFUSUM WHOLE</b> (UNII: 291PPU5K9I)                               |          |
| <b>PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER</b> (UNII: 788QAG3W8A)     |          |
| <b>LONICERA CAPRIFOLIUM FLOWER</b> (UNII: 5N1WD9784U)                                |          |
| <b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)   |          |
| <b>HYDROLYZED GLYCOSAMINOGLYCANS (BOVINE; 50000 MW)</b> (UNII: 997385V0VV)           |          |
| <b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)   |          |
| <b>LIMONIA ACIDISSIMA WHOLE</b> (UNII: MU5C4X2819)                                   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)   |          |
| <b>MADECASSIC ACID</b> (UNII: M7O1N24J82)  |          |
| <b>ASIATICOSIDE</b> (UNII: PKO39VY215)   |          |
| <b>ASIATIC ACID</b> (UNII: 9PA5A687X5)   |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)  |          |
| <b>HYALURONIC ACID</b> (UNII: S270N0TRQY)  |          |
| <b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)   |          |
| <b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836S5JG51DR)                                 |          |
| <b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)                               |          |

|   |  |
|---|--|
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)               |  |
| <b>RIBOFLAVIN 5'-PHOSPHATE SODIUM ANHYDROUS</b> (UNII: 957E53W42) |  |
| <b>CITRAL</b> (UNII: T7EU009VPP)                                  |  |
| <b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)                       |  |
| <b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)                        |  |
| <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)                          |  |

| <b>Packaging</b> |                  |   |                      |                    |
|------------------|------------------|---|----------------------|--------------------|
| #                | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
| 1                | NDC:83918-001-02 | 1 in 1 CARTON   | 12/27/2023           |                    |
| 1                | NDC:83918-001-01 | 50 mL in 1 CONTAINER; Type 0: Not a Combination Product |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug           | M020                                     | 12/27/2023           |                    |

**Labeler** - KARA BEAUTY INC (056308932)

**Registrant** - KARA BEAUTY INC (056308932)

| <b>Establishment</b> |         |           |                        |
|----------------------|---------|-----------|------------------------|
| Name                 | Address | ID/FEI    | Business Operations    |
| Rebom Co., Ltd.      |         | 695951708 | manufacture(83918-001) |

Revised: 12/2023

KARA BEAUTY INC