

SUN THERAPE FACE AND BODY SPF-35- avobenzone, octinoxate, octisalate, oxybenzone lotion
PHARMAGEL INTERNATIONAL INC

PHARMAGEL - SUN THERAPE FACE AND BODY (67879-309)

ACTIVE INGREDIENTS

Avobenzone.....	3.0%
Octinoxate.....	7.5%
Octisalate.....	5.0%
Oxybenzone.....	3.0%

PURPOSE

SUNSCREEN

USES

- Helps prevent sunburn
- 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

WARNINGS

- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with warm water to remove
- Stop use and ask doctor if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions For Sunscreen Use:

- Apply liberally and evenly 15 minutes before sun exposure
- 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 broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses
 - Reapply at least every 2 hours
 - Use a water resistant sunscreen if swimming or sweating
 - Children under 6 months: Ask a doctor

INACTIVE INGREDIENTS:

WATER (AQUA), ETHYLHEXYL PALMITATE, PROPYLENE GLYCOL, GLYCERYL STEARATE, PEG-100 STEARATE, CETEARYL ALCOHOL, DIMETHICONE, PALMITIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, PHENOXYETHANOL, STEARIC ACID, MYRISTYL MYRISTATE, CAPRYLYL GLYCOL, HYDROXYETHYLCELLULOSE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ETHYLHEXYLGLYCERIN, ALLANTOIN, HEXYLENE GLYCOL, MYRISTYL LAURATE, PANTHENOL, TETRASODIUM EDTA, AMINOMETHYL PROPANOL, GLYCERIN, GLYCOLIC ACID, BUTYLENE GLYCOL, MORUS ALBA LEAF EXTRACT, CAMELLIA SINENSIS (BLACK TEA) LEAF EXTRACT, ELETARIA CARDAMOMUM SEED EXTRACT, JASMINUM OFFICINALE FLOWER/LEAF EXTRACT, ROSE EXTRACT, MYRISTIC ACID, BORAGO OFFICINALIS SEED OIL, BUTYLOCTYL SALICYLATE, COCOS NUCIFERA (COCONUT) OIL, DIMETHYLAMINOETHANOL TARTRATE, KOJIC ACID, MACADAMIA TERNIFOLIA (MACADAMIA) SEED OIL, MAGNESIUM ASCORBYL PHOSPHATE, NIACIN, PERSEA GRATISSIMA (AVOCADO) OIL, PHYLLANTHUS EMBLICA FRUIT EXTRACT, TOCOPHERYL ACETATE, ALOE BARBADENSIS (ALOE VERA) LEAF JUICE, UNDECYLENOYL PHENYLALANINE, GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT, ARACHIDIC ACID, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, BHT, ABIES BALSAMEA (BALSAM CANADA) EXTRACT, CANANGA ODORATA (YLANG) FLOWER EXTRACT, COFFEA ARABICA LEAF/SEED EXTRACT, CUCUMIS MELO CANTALUPENSIS FRUIT EXTRACT, FERULA GALBANIFLUA GUM EXTRACT, HYACINTHUS ORIENTALIS (HYACINTHUS) FLOWER EXTRACT, PYRUS MALUS (APPLE) FRUIT EXTRACT, CYPERUS ROTUNDUS ROOT EXTRACT, ACHILLEA MILLEFOLIUM (YARROW) EXTRACT, ECHINACEA ANGUSTIFOLIA (ECHINACEA) EXTRACT, HYDRASTIS CANADENSIS (GOLDEN SEAL) EXTRACT, SIMMONDSIA CHINENSIS (JOJOBA) SEED EXTRACT, ROSA CANINA (ROSE HIP) FRUIT EXTRACT, GINKGO BILOBA LEAF EXTRACT, LIMONIUM GERBERI EXTRACT, SODIUM BENZOATE, LACTIC ACID, UNDECYLENIC ACID, POTASSIUM SORBATE, YELLOW 6 (CI 15985), LECITHIN, PLANKTON EXTRACT, CHLORPHENESIN, RED 40 (CI 16035), BENZOIC ACID, SORBIC ACID

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

Questions or Comments?

Call toll free 800-882-4889

3/8" actual print height

SUN THERAPÈ®

pharmagel®

Face & Body

MOISTURIZER

PLUS SUNSCREEN

ULTRA SHEER

AGE DEFYING

TOTAL CARE

Soin intégral hydratant et protection solaire anti-âge

Crema hidratante integral ultraligera & protección solar antiedad

BROAD SPECTRUM SPF 35

4.25 fl. oz. | 125 ml e

Advanced moisturizer provides broad spectrum protection. For smoother, radiant, younger looking skin.

Drug Facts	
Active Ingredients (Purpose: Sunscreen)	
Avobenzone.....	3.0%
Octinoxate.....	7.5%
Octisalate.....	5.0%
Oxybenzone.....	3.0%
Uses:	
• helps prevent sunburn • 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	
Warnings:	
For external use only	
Do not use on damaged or broken skin	
When using product keep out of eyes. Rinse with warm water to remove.	
Stop use and ask doctor if rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions:	
• Apply liberally 15 minutes before sun exposure	
• Reapply • after 40 minutes of swimming or sweating	
• immediately after towel drying • at least every 2 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 broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses	
• Children under 6 months: Ask a doctor	
Inactive Ingredients:	
Water, Glycerin, Ethylhexyl Palmitate, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Cetyl Alcohol, Dimethylsiloxane, Talcum Acid, Caprylic/Capric Triglyceride, Phenoxethanol, Stearic Acid, Methyl Methacrylate, Copolyol G, Octyl Hydroxystyrene, Acrylate/C10-30 Alkyl Acrylate Copolymer, Ethylhexylglycerin, Allantoin, Hexylene Glycol, Methyl Lauroyl, Sorbitol, Sorbitolum COB, Aramethoxy Propyl, Glycolic Acid, Butylene Glycol, Mica, Aloe Leaf Extract, Cornelia Sereno (Black Tea) Leaf Extract, Echinacea Condensate Seed Extract, Camellia Oleifera Flower Leaf Extract, Rose Extract, Myricic Acid, Boragin Officinalis Seed Oil, Beryllium Sulfate, Sodio Hydroxide (Coccol), Sil Dimethylsilyloxydimethyl Tetrato, Kojic Acid, Biotinodino Terfenolol (Moxidomino) Seed Oil, Magnesium Ascorbyl Phosphate, Magn. Persa. Centaurea (Rosca) Oil, Phyllanthus Emblica Fruit Extract, Trichostema Atractodes Aloe Babooside (Aloe Vera) Leaf Juice, Urtica dioica (Preparation), Glycyrrhiza Glabra (Licorice) Root Extract, Ascorbic Acid, Cornelia Sereno (Green Tea) Leaf Extract, SPT, Aloe Babooside (Babaooside) Extract, Camanga Odorata (Tangerine) Flower Extract, Coffea Arabica Leaf/Seed Extract, Cucumis Melo Comaripense Fruit Extract, Ficus Spicifera Gum Extract, Hesperidium Orientale (Hyacinth) Flower Extract, Pyrus Malus (Apple) Fruit Extract, Opuntia Inimada Fruit Extract, Arabis Hirsutissima (Yarrow) Extract, Callitriche Angustifolia (Calmico) Extract, Hibiscus Grandiflorus (Garden Soft) Extract, Serratula Chamaejasme (Jocko) Seed Extract, Rosa Damascena (Rose Hip) Fruit Extract, Grap. Baccata Leaf Extract, Linum catharticum (Flax) Seed, Sulfur, Benzoin, Lactic Acid, Uracilic Acid, Potassium Sorbate, Yellow E (D1 19088), Lecithin, Flankia Extract, Gluconolactone, Red 40 (D1 30250), Benzoic Acid, Salicylic Acid	
Other information	
• Protect this product from excessive heat and direct sun	
Questions or comments: Call toll free 800.882.4889	

©Pharmagel International Inc.
Chattsworth, CA 91311 USA
Pharmagel Ltd. Wrexham,
TR21 0RS, UK
RP, Innovent Research
Glasgow, G20 9RT, UK
www.pharmagel.net STFB-1



SUN THERAPE FACE AND BODY SPF-35

avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67879-309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PALMITIC ACID (UNII: 2V16EO95H1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MYRISTYL LAURATE (UNII: 58U0NZN2BT)	
PANTHENOL (UNII: WW9CM0O67Z)	
EDETATE SODIUM (UNII: MP1J8420LU)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MORUS ALBA LEAF (UNII: M8YIA49Q2P)	
TEA LEAF (UNII: GH42T47V24)	
CARDAMOM (UNII: 8BC4CUT4JL)	
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)	
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
BORAGE OIL (UNII: F8XAG1755S)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DEANOL BITARTRATE (UNII: D240J05W14)	
KOJIC ACID (UNII: 6K23F1TT52)	
MACADAMIA OIL (UNII: 515610SU8C)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
NIACIN (UNII: 2679MF687A)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
UNDECYLENOYL PHENYLALANINE (UNII: 271P08C6OD)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ARACHIDIC ACID (UNII: PQB8MJD4RB)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BALSAM FIR LEAFY TWIG (UNII: H1TFV1454Z)	

CANANGA ODORATA FLOWER (UNII: 76GTF6Z97M)
ARABICA COFFEE BEAN (UNII: 3SW678MX72)
CANTALOUPE (UNII: 8QF5D5H6UH)
GALBANUM (UNII: C690YC9N2Z)
HYACINTHUS ORIENTALIS FLOWER (UNII: Y740K1LEA3)
APPLE (UNII: B423VGH5S9)
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)
GOLDENSEAL (UNII: ZW3Z11D0JV)
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)
GINKGO (UNII: 19FUJ2C58T)
LIMONIUM GERBERI FLOWERING TOP (UNII: V4O4C05BJ2)
SODIUM BENZOATE (UNII: OJ245FE5EU)
LACTIC ACID (UNII: 33X04XA5AT)
UNDECYLENIC ACID (UNII: K3D86KJ24N)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)
CHLORPHENESIN (UNII: I670DAL4SZ)
FD&C RED NO. 40 (UNII: WZB9127XOA)
BENZOIC ACID (UNII: 8SKN0B0MIM)
SORBIC ACID (UNII: X045WJ989B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67879-309-51	1 in 1 BOX	06/10/2016	
1	NDC:67879-309-12	125 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 Drug	M020	06/18/2015	

Labeler - PHARMAGEL INTERNATIONAL INC (603215182)