

SPF 30 MINERAL SUNSCREEN FACE NECK- zinc oxide cream
OJAS, LLC

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.

Active Ingredients:

ZINC OXIDE 18.6%

Purpose: Sunscreen

Uses:

- High protection against sunburn.
- Higher SPF gives more sunburn protection.

Warnings: For external use only.

When using this product keep out of eyes. Rinse with to remove.

Stop use and ask a doctor if rash occurs.

Do not use on damaged or broken skin.

Keep out of reach of children.

Directions:

- Apply generously 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply as needed or after towel drying, swimming or perspiring.
- children under 6 months of age: ask a doctor.

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

INACTIVE INGREDIENTS

Water (Aqua), Cyclopentasiloxane, Butylene Glycol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Sorbitan Stearate, Dimethicone, Cetyl Alcohol, Caprylic/Capric Triglyceride, Organic Butyrospermum Parkii (Shea) Butter, Polyacrylamide, C13-14 Isoparaffin, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Hyaluronate, Dipotassium Glycyrrhizate, Tocopheryl Linoleate/Oleate, Physalis Angulata Extract, Teprenone, Leontopodium Alpinum Meristem Cell Culture, Polygonum Aviculare Extract, Imperata Cylindrica Root Extract, Arabidopsis Thaliana Extract, Plankton Extract, Micrococcus Lysate, Organic Camellia Sinensis Leaf Extract, Phoenix Dactylifera (Date) Fruit Extract, Sodium Lactate, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Organic Aloe Barbadensis Leaf Juice Powder, Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Laureth-7, Xanthan Gum, Carbomer, PEG-8, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Disodium EDTA.

**SPF 30
BROAD - SPECTRUM
MINERAL SUNSCREEN
FACE + NECK**

WEIGHTLESS HYDRATION
WRINKLE PREVENTION
DNA PROTECTION

*Zinc Oxide
Hyaluronic Acid
Organic Shea Butter*

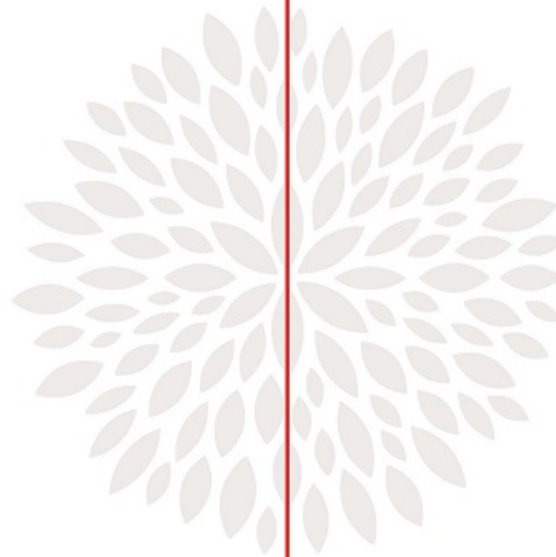
Nourish and protect your most delicate skin with an SPF 30 sunscreen specifically for the face and neck. Our **3E PROTECTION SERUM** helps reduce wrinkles while mineral UVA / UVB broad - spectrum sunscreen prevents future damage.



50 ml / 1.7 fl oz

Made in the USA | Distributed by OJAS, LLC
OjasSkin.com

OJAS
SUN ESSENTIAL



**SPF 30
MINERAL SUNSCREEN
FACE + NECK**



Drug Facts

Active Ingredients	Purpose
Zinc Oxide (18.6%)	Sunscreen

Uses

- High protection against sunburn.
- Higher SPF gives more sunburn protection.

Warnings

For external use only.
When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Do not use on damaged or broken skin. Keep out of reach of children.

Directions

- Apply generously 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply as needed or after towel drying, swimming, or perspiring.
- Children under 6 months of age: ask a doctor.

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 am-2 pm.
- Wear long sleeved shirts, pants, hats, and sunglasses.

Other Information

Sun alert: limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

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

Inactive Ingredients

Water (Aqua), Cyclopentasiloxane, Butylene Glycol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Sorbitan Stearate, Dimethicone, Cetyl Alcohol, Caprylic/Capric Triglyceride, Organic Butyrospermum Parkii (Shea) Butter, Polyacrylamide, C13-14 Isoparaffin, Triethoxysilyl ethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Hyaluronate, Dipotassium Glycyrrhizate, Tocopheryl Linoleate/Oleate, Physalis Angulata Extract, Terpenone, Leontopodium Alpinum Meristem Cell Culture, Polygonum Aviculare Extract, Imperata Cylindrica Root Extract, Arabidopsis Thaliana Extract, Plankton Extract, Micrococcus Lysate, Organic Camellia Sinensis Leaf Extract, Phoenix Dactylifera (Date) Fruit Extract, Sodium Lactate, Palmityl Tripeptide-1, Palmitoyl Tetrapeptide-7, Organic Aloe Barbadosis Leaf Juice Powder, Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Laureth-7, Xanthan Gum, Carbomer, PEG-8, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Disodium EDTA.

SPF 30 MINERAL SUNSCREEN FACE NECK

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70867-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	15 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
UBIDECARENONE (UNII: EJ27X76M46)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
TEPRENONE (UNII: S8S8451A4O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ACTINIDIA CHINENSIS ROOT (UNII: 1L6O0O338I)	
ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
LEONTOPODIUM ALPINUM FLOWER (UNII: MWN6IZU3XM)	
ARABIDOPSIS THALIANA (UNII: A13L60HQ81)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70867-104-52	1 in 1 CARTON	07/26/2016	
1	NDC:70867-104-11	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 final	part352	07/26/2016	

Labeler - OJAS, LLC (080118329)

Registrant - OJAS, LLC (080118329)