

EARTH BABY BROAD SPECTRUM SPF 30- sunscreen cream
Earth Baby, Inc.

Earth Baby Broad Spectrum SPF30+ Sunscreen

Titanium Dioxide 5%

Zinc Oxide 3%

Sunscreen.

For external use only.

Do not get into eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Apply liberally 30 minutes before sun exposure.

Reapply after 40 minutes, after towel drying, swimming, or perspiring, atleast every 2 hours.

Children under six months of age, ask a doctor

Sun Alert. Limiting sun exposure, wearing protective clothing, and using suncreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Store away from excessive heat and direct sunlight.

Aloe Barbadensis Leaf Juice*, Octyldodecyl Neopentanoate, Carthamus Tinctorius (Safflower) Oleosomes*, Aqua/Water, Glycerin, Dicaprylyl Carbonate, Butyrospermum Parkii (Shea) Butter, Chamomilla Recutita (Matricaria) Flower/Leaf/Stem Extract*, Cyclopentasiloxane, Polyglyceryl-3-Polymethylsiloxyethyl Dimethicone, Aluminum Hydroxide, Stearic Acid, Lonicera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Flower Extract, Mangifera Indica (Mango) Fruit Extract, Sodium Hyaluronate, Cetearyl Oliviate, Sorbitan Oliviate, C20-22 Alkyl Phosphate, C20-22 Alcohols, Trisodium Ethylenediamine Disuccinate, Sclerotium Gum, Jojoba Alcohol, Potassium Jojobate, Butylene Glycol, Citric Acid, Caprylyl Glycol, 1,2-Hexanediol, Parfum/Natural Fragrance.

Helps prevent sunburn. If used as directed with other sun protection measures (See Sun Alert), decreases the risk of skin cancer and early skinaging by the sun.

<p>Drug Facts</p> <p>Active Ingredients Purpose</p> <p>Titanium Dioxide 5% Sunscreen Zinc Oxide 3% Sunscreen</p> <p>Uses</p> <p>Sunscreen. Helps prevent sunburn. If used as directed with other sun protection measures (See Sun Alert), decreases the risk of skin cancer and early skin aging by the sun.</p> <p>Warnings</p> <p>For external use only.</p> <p>When using this product</p> <ul style="list-style-type: none"> Do not get into eyes. Rinse with water to remove. <p>Stop use and ask a doctor if rash or irritation develops.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Sun alert. Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.</p> <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 30 minutes before sun exposure. ■ Reapply after 40 minutes, after towel drying, swimming, or perspiring; at least every 2 hours. Children under six months of age, ask a doctor. <p>Other information</p> <p>Store away from excessive heat and direct sunlight.</p>	<p>Inactive ingredients:</p> <p>Aloe Barbadensis Leaf Juice*, Octyldodecyl Neopentanoate, Carthamus Tinctorius (Safflower) Oleosinens*, Aqua/Water, Glycerin, Dicaprylyl Carbonate, Butyrospermum Parkii (Shea) Butter, Chamonilla floccata (Mexican) Flower/Leaf/Stem Extract*, Cyclopentasiloxane, Polyglyceryl-3-Polydimethylsiloxyethyl Dimethylsiloxane, Aluminum Hydroxide, Stearic Acid, Lonocera Japonica (Honeysuckle) Flower Extract, Lonocera Caprifolium (Honeysuckle) Flower Extract, Mangifera Indica (Mango) Fruit Extract, Sodium Hyaluronate, Cetearyl Olivato, Sorbitan Olivato, C20-22 Alkyl Phosphate, C20-22 Alcohol, Trisodium Ethylenediamine Disuccinate, Sclerotium Gum, Jojoba Alcohol, Potassium Jojobate, Butylene Glycol, Citric Acid, Caprylyl Glycol, 1,2-Hexanediol, Parfum/Natural Fragrance.</p> <p>  </p> <p> 8 97345 00107 2</p> <p>earthbaby®</p> <p>Formulated Safe + Friendly™ in California EARTH BABY, INC. Walnut, CA 91789 Made in the USA www.earthbabystore.com EB807/1</p>	<p></p> <p>BROAD SPECTRUM SPF 30+ SUNSCREEN</p> <p>organic goodness from mother earth®</p> <p>non-toxic, hypoallergenic certified organic ingredients* OleoSphere® technology Water Resistant (40 min)</p> <p></p> <p>Net Wt. 1.7 OZ/50g e</p>	<p>earthbaby®</p> <p>BROAD SPECTRUM SPF 30+ SUNSCREEN</p> <p>Beneficially enriched with mango fresh cells, honeysuckle extract, and shea butter to protect delicate skin.</p> <p>Earth Baby® represents the leading edge in efficacy and safety, combining certified organic ingredients with thoughtfully crafted formulation and award-winning OleoSphere® technology to deliver healthy benefits to baby.</p> <p>organic goodness from mother earth®</p> <ul style="list-style-type: none"> Certified Organic Ingredients* Natural Ingredients Paraben Free Artificial Color Free Formaldehyde Free, Sulfate Free BSE Free, No Animal Testing <p>Earth Baby, Organic Goodness from Mother Earth, and Formulated Safe + Friendly are registered trademarks.</p>
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EARTH BABY BROAD SPECTRUM SPF 30

sunscreen cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62588-907
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	

C20-22 ALKYL PHOSPHATE (UNII: L4VKP0Y7RP)
GLYCERIN (UNII: PDC6A3C0OX)
ALOE (UNII: V5VD430YW9)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
MANGIFERA INDICA WHOLE (UNII: U34MFR958F)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IU0)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
C20-22 ALCOHOLS (UNII: O4M0347C6A)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62588-907-02	1 in 1 BOX	02/01/2019	
1		50 g 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	02/01/2019	

Labeler - Earth Baby, Inc. (079298651)

Establishment

Name	Address	ID/FEI	Business Operations
KDC/ONE SOCAL LABORATORIES, LLC		118384240	manufacture(62588-907)