

AHAVA ACTIVE DEADSEA MINERALS MINERAL SUNCARE SPF 30- octocrylene spray
AHAVA - Dead Sea Laboratories 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.

Active Ingredient Section

Drug Facts

Active Ingredients Avobenzone (3%) Ensulizole (1%) Octisalate (2%) Octocrylene (10%)
Titanium Dioxide (1.52%)

Purpose Section

Purpose Sunscreen

Keep Out of reach of Children Section

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

Uses Section

Uses

- * helps prevent sunburn
- * higher SPF gives more sunburn protection

Warnings Section

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 or irritation develops and lasts **If swallowed,** get medical help or contact a Poison Control Center right away.

Directions Section

Directions

- * shake before using
- * apply liberally 30 minutes before sun exposure and as needed
- * children under 6 months of age: ask a doctor

Inactive Ingredient Section

Inactive ingredients: Aqua (Water), C12-15 Alkyl Benzoate, Cyclomethicone, Propanediol, Methylene Bis-Benzotriazolyl Tetramethbutylphenol, Trimethoxycaprlylsilane, Sodium Hydroxide, Caprylic/Capric Triglyceride, Phenyl Trimethicone, Tricontanyl PVP, Phenoxyethanol, 1,2-Hexandiol,

Caprylyl Glycol, Cetearyl Alcohol, Parfum (Fragrance), Tocopheryl (Vitamin E) Acetate, Ethylhexylglycerin, Aloe Barbadensis Leaf Extract, Panthenol (Pro-Vitamin B5), Disodium EDTA, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Allantoin, Polyglyceryl-10 Pentastearate, Behenyl Alcohol, Sodium Stearoyl Lactylate, Potassium Cetyl Phosphate, Dunaliella Salina (Dead Sea Alga) Extract, Maris Sal (Dead Sea Water)

The Osmoter™ Dead Sea Water

Major Elements /in mg/L:

| | | |
|-----------|----|--------|
| Magnesium | Mg | 92,000 |
| Calcium | Ca | 35,000 |
| Bromine | Br | 14,000 |
| Sodium | Na | 2,700 |
| Potassium | K | 2,100 |

Micro Elements /in ppml:

| | | |
|-----------|----|-----|
| Strontium | Sr | 670 |
| Boron | B | 120 |
| Lithium | Li | 40 |
| Manganese | Mn | 10 |
| Barium | Ba | 9 |

Other information Section

Other information

* provides moderate protection against sunburn

Package Label

The AHAVA Osmoter™ A gift from nature, Dead Sea minerals are known to improve your skin's well-being and youthfulness.

The osmoter™ is a unique blend of minerals contained in all AHAVA products. It optimizes cell metabolism, strengthens skin against UV damage, and significantly increases moisture to keep your skin looking young and supple.

AHAVA ACTIVE DEAD SEA MINERALS SPRAY spf 30 mineral SUNCARE

Sun Protection Anti-Aging Moisturizing Spray

* moderate UVA/UVB sunscreen

* very water resistant

suitable for children

250 ml / 8.5 fl. oz

Sun protection Anti-Aging moisturizing Spray SPF 30 enriched with Mineral Skin Osmoter™

Protect your skin from the damages of the sun with this quality blend (Multi-Layer Protection System™) of highly effective sunscreens. Dead Sea minerals and seaweed, essential vitamins and moisturizing agents, all proven to be efficient in fighting premature aging. An easy-to-apply light milk.

* Mineral Skin Osmoter™ - Ahava unique blend of Dead Sea minerals proven to reduce the damage of sun radiation.

Suitable for children. Approved for sensitive skin. Allergy tested. Mineral oil free. Paraben free.

Absorbs more than 90% of UVA rays (according to the Australian standards). Retains SPF after 80 minutes of activity in the water.

Ahava advice: Avoid exposing children under 6 months of age to the sun. The use of a high sun

protection factor for children is recommended (SPF 30 and up). Avoid extended exposure to the sun, even while using this product.

www.ahava.com

Against animal testing PARABEN FREE ALLERGY TESTED

A product of AHAVA Dead Sea Laboratories, Ltd. Dead Sea, israel. Manufactures by Zohar Cosmetics Ltd. POB 16 Yerucham, israel.

In USA: Ahava NA, 411 5th Ave. NY, 10016 1-800-366-7254

The AHAVA Osmoter™

A gift from nature, Dead Sea minerals are known to improve your skin's well-being and youthfulness.

The Osmoter™ is a unique blend of minerals contained in all AHAVA products. It optimizes cell metabolism, strengthens skin against UV damage, and significantly increases moisture to keep your skin looking young and supple.

| The Osmoter™ Dead Sea Water | | | |
|--------------------------------|-----------|--------------------------|--------|
| Major Elements (in mg/l): | | Micro Elements (in ppm): | |
| Magnesium | Mg 92,000 | Strontium | Sr 670 |
| Calcium | Ca 35,000 | Boron | B 120 |
| Bromine | Br 14,000 | Lithium | Li 40 |
| Sodium | Na 2,700 | Manganese | Mn 10 |
| Potassium | K 2,100 | Barium | Ba 9 |

Sun Protection Anti-Aging Moisturizing Spray SPF 30 enriched with Mineral Skin Osmoter™*

Protect your skin from the damages of the sun with this quality blend (Multi-Layer Protection System™) of highly effective sunscreens, Dead Sea minerals and seaweed, essential vitamins and moisturizing agents, all proven to be efficient in fighting premature aging. An easy-to-apply light milk.

*Mineral Skin Osmoter™- Ahava unique blend of Dead Sea minerals proven to reduce the damage of sun radiation.

Suitable for children. Approved for sensitive skin. Allergy tested. Mineral oil free. Paraben free. Absorbs more than 90% of UVA rays (according to the Australian standards). Retains SPF after 80 minutes of activity in the water.

Ahava advice: Avoid exposing children under 6 months of age to the sun. The use of a high sun protection factor for children is recommended (SPF 30 and up). Avoid extended exposure to the sun, even while using sun protection product.

Spray de Protection Solaire Anti-Âge IP 30 enrichi au Mineral Skin Osmoter™*

Ce 'Système de haute protection multi-strates' est composé de filtres solaires de qualité supérieure, d'algues et minéraux de la Mer Morte, de vitamines essentielles et d'agents hydratants. Formulé pour le respect des peaux sensibles, ce soin hydratant à texture veloutée lutte contre le vieillissement prématuré de l'épiderme et le protège efficacement des rayons solaires.

Utilisation: Secouez avant usage. Appliquer par couche généreuse 30 minutes avant exposition au soleil. Réappliquer fréquemment.

*Mineral Skin Osmoter™- Composé unique de minéraux de la Mer Morte testé pour réduire les méfaits des radiations solaires.

Recommandé pour les enfants. Convient aux peaux sensibles. Soumis à des tests d'allergie. Absorbe plus de 90% des rayons UVA (selon les standards Australiens). Sans parabènes.

Conseils Ahava: Evitez toute exposition au soleil des bébés de moins de 6 mois. L'utilisation d'une haute protection solaire est fortement recommandée pour les enfants (minimum IP30). Evitez les expositions prolongées au soleil, malgré l'utilisation de soins protecteurs.

Anti-Aging Sonnenschutz Feuchtigkeitsspray LSF 30 (hohes Schutzniveau) angereichert mit Mineral Skin Osmoter™*

Schützen Sie Ihre Haut vor sonnenbedingten Schäden mit dieser qualitativ wertvollen Mischung (Multi-Layer Protection System™) aus hochwirksamen Sonnenfiltern, Mineralien und Algen aus dem Toten Meer, essenzielle Vitaminen und Feuchtigkeitsspendern, die ihre Wirkung im Kampf gegen die vorzeitige Hautalterung bewiesen haben.

Anwendungshinweis: Vor Gebrauch schütteln. 30 Minuten vor dem Sonnenaufenthalt auftragen und regelmäßig erneuern.

*Mineral Skin Osmoter™- Ahava's einzigartige Mischung aus Mineralien des Toten Meeres reduziert nachweislich Schäden durch Sonnenbestrahlung.

Geeignet für Kinder. Empfohlen für empfindliche Haut. Allergie getestet. Absorbiert mehr als 90% der UVA Strahlen (gem. Australischer Standard).

Ahava Anweisung: Sie sollten Kinder im Alter unter 6 Monaten nicht der Sonne aussetzen. Ein hohes Schutzniveau ist für Kinder empfehlenswert (LSF 30 und höher). Vermeiden Sie übermäßige Sonneneexposition, auch wenn Sie ein Sonnenschutzmittel verwenden.

AHAVA
ACTIVE DEADSEA MINERALS

s p r a y



Sun Protection
Anti-Aging Moisturizing Spray

| Drug Facts | |
|---|----------------|
| Active ingredients | Purpose |
| Avobenzone [3%] | Sunscreen |
| Ensulizole [1%] | Sunscreen |
| Octisalate [2%] | Sunscreen |
| Octocrylene [10%] | Sunscreen |
| Titanium Dioxide [1.52%] | Sunscreen |
| Uses | |
| <ul style="list-style-type: none"> • helps prevent 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 or irritation develops and lasts | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| <ul style="list-style-type: none"> • shake before use • apply liberally 30 minutes before sun exposure and as needed • children under 6 months of age: ask a doctor | |
| Other information | |
| • provides high protection against sunburn | |
| Inactive ingredients: Aqua [Water], C12-15 Alkyl Benzoate, Cyclomethicone, Propanediol, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Trimethoxycaprylylsilane, Sodium Hydroxide, Caprylic/ Capric Triglyceride, Phenyl Trimethicone, Tricortanyl, PVP, Phenoxethanol, 1,2-Hexandiol, Caprylyl Glycol, Cetearyl Alcohol, Parfum [Fragrance], Tocopheryl [Vitamin E] Acetate, Ethylhexylglycerin, Aloe Barbadosensis Leaf Extract, Panthenol [Pro-Vitamin B5], Disodium EDTA, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Allantoin, Polyglyceryl-10 Pentastearate, Behenyl Alcohol, Sodium Stearoyl Lactylate, Potassium Cetyl Phosphate, Dunalilella Salina [Dead Sea Algal Extract, Maris Sal [Dead Sea Water]. | |

www.ahava.com

הרכיבים לחות אנוסי-אי-יבני להגנה מקריני השמש SPF 30 מועשר ב-
Mineral Skin Osmoter™

הרכיבים הגנה רב-שכבתית (Multi-Layer Protection System™) בעל הרכב יחיד של מסנני קרינה, מינרלים ואגוזים מים המלח, ויטמינים ומרכיבים לחות שהוכחו כעילים להפחתת נזק העשמש ולהאמת תהליכי הדוקדוק העור.

הוראות שימוש: יש לנער לפני השימוש. יש להימנע מרחצה ראשונה לפני היציאה לשמש. מומלץ למרוח בעמידים ברוציפות כדי ליצור שכבה נדיבה אחידה של מקדם הגנה לכיסוי כל חלקי העור החשופים לשמש. יש להימנע כל שעותיו מומלץ במקרים של חזרה, כניסה לעים אוויר נוגד העור במבט, להימנע שוב מומלץ להימנע מחשיפת חשיקות לשמש. יש להימנע מחשיפה לשמש גם אם נעשה שימוש במקדם הגנה. יש להימנע מנוגע באזור העיניים. יש להימנע מנוגע לפני השימוש. במקרה של גירוד, יש



להפסיק את השימוש. לשימוש חיצוני בלבד. אין לבלוע. להשתמש בתמרוק רק למטרה שלשמה הוא נועד ובהתאם להוראות השימוש. אין להשתמש במוצר אם ידועה רגישות לאחד המרכיבים.
מחאים לילדים, בהשגחה מבוגר. אישר לבטל עור רגיש. נבדק לאלרגיה. עמיד במים 80 דקות. נטול שמן מינרלי, ללא סרביים.
המלצות AHAVA: יש להימנע משיפה לשמש של עור החיטוק עד גיל 6 חודשים לילדים מומלץ להשתמש במקום הגנה גבוה (SPF 30 ומעלה).
 הברקות הקלילות נפרס לפי חוקן רשות ההרפואה הישראלית FDA.
 החוקן האינטרנטי ילפי חקנת משרד הבריאות חוסם מעל 99% קריי UVA.

· high UVA/UVB sunscreen
 · very water resistant

suitable for children

250 ml / 8.5 fl. oz

A product of AHAVA Dead Sea Laboratories Ltd. Dead Sea, Israel.
 Manufactured by Zohar Cosmetics Ltd. Israel.
 In USA: AHAVA NA, 411 5th Ave, NY, 10016.
 1-800-366-7254

מכיל 250 מ"ל.
 מיוצר ע"י ז'הר קוסמטיקס (מעטופ) בע"מ ת.ד. 6 ירושם.
 משוקק ע"י AHAVA מעבדות ים המלח בע"מ, ים המלח.
 שירות לקוחות מן 9:00-18:00
 ברשת משרד הבריאות.

724231C



AHAVA ACTIVE DEADSEA MINERALS MINERAL SUNCARE SPF 30

octocrylene spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60289-030 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 25 mL in 250 mL |
| ENSULIZOLE (UNII: 9 YQ9 DI1W42) (ENSULIZOLE - UNII:9 YQ9 DI1W42) | ENSULIZOLE | 2.5 mL in 250 mL |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 5 mL in 250 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 7.5 mL in 250 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) | TITANIUM DIOXIDE | 3.8 mL in 250 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| BISOTRIZOLE (UNII: 8NT850T0YS) | |
| TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |

| |
|--|
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| PANTHENOL (UNII: WV9CM0O67Z) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| ALLANTOIN (UNII: 344S277G0Z) |
| POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH) |
| DOCOSANOL (UNII: 9G1OE216XY) |
| SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN) |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) |
| DUNALIELLA SALINA (UNII: F401DKI9A6) |
| MAGNESIUM (UNII: I38ZP9992A) |
| CALCIUM (UNII: SY7Q814VUP) |
| BROMINE (UNII: SBV4XY874G) |
| SODIUM (UNII: 9NEZ333N27) |
| POTASSIUM (UNII: RWP5GA015D) |
| STRONTIUM (UNII: YZS2RPE8LE) |
| BORON (UNII: N9E3X5056Q) |
| LITHIUM (UNII: 9FN79X2M3F) |
| MANGANESE (UNII: 42Z2K6ZL8P) |
| BARIUM (UNII: 24GP945V5T) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------|----------------------|--------------------|
| 1 | NDC:60289-030-30 | 250 mL in 1 BOTTLE, SPRAY | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part352 | 01/01/2012 | |

Labeler - AHAVA - Dead Sea Laboratories Ltd. (600056907)

Registrant - AHAVA - Dead Sea Laboratories Ltd. (600056907)