

**TOTAL PROTECTOR COLOR 30 MEDIUM TINT - octinoxate cream
MD Formulation**

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.

SUN Total Protector Color 30 Medium Tint

Active Ingredient	Purpose
Zinc Oxide - 7.8%	Sunscreen
Octinoxote - 7.5%	Sunscreen
Octisalate - 4.0%	Sunscreen

When using this product do not use in or near the eyes. If product gets into eyes, rinse thoroughly with water.

Warnings For external use only.

Stop use and ask a doctor if Irritation of rash appears and lasts.

If swallowed, get medical help or contact a Polson Control Center right away .

Inactive ingredients Purified Waler (Aqua), C 12-15 Alkyl Benzoate, Glyceryl Stearate, Glycerin, Steareth-2, Steareth-100, TricontanylPVP, PEG-100 Stearate, Tocopheryl Acetate, Allantoin, Dimethicone, Xanthan Gum, Cetyl Hydroxyethylcellulose, Disodium EDTA, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, Phenoxyethanol, Methylparaben, Propylparaben, Mica(CI 77019), Bismuth Oxychloride (CI 77163), Iron Oxides (CI 77489)

Active Ingredient	Purpose
Zinc Oxide - 7.8%	Sunscreen
Octinoxote - 7.5%	Sunscreen
Octisalate - 4.0%	Sunscreen

Directions Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Adults and children 6 months and over; apply liberally 15 minutes before sun or water exposure; reapply after swimming or excessive sweating or anytime after towel drying. Children under 6 months ask a doctor.

medium tint

NDG 66078-504-25



F PRODUIT DE TRAITEMENT PROFESSIONNEL

Cet écran solaire protecteur multi-usages protège la peau contre les rayons UVA et UVB. Légèrement teinté, il illumine le teint tout en accentuant la couleur naturelle de la peau. La Skin Cancer Foundation (Fondation pour le cancer de la peau) recommande l'utilisation de ce produit comme écran solaire sûr et efficace.

- testé sous contrôle dermatologique
- non-comédogène
- hypoallergénique
- sans parfum

Utilisation: Appliquer sur le visage, le cou, la poitrine et les mains, même sous le maquillage. Renouveler l'application avant toute exposition au soleil, après avoir nagé, transpiré ou s'être épongé à l'aide d'une serviette. Il est recommandé d'utiliser des produits avec écran solaire SPF 4 minimum chez les enfants de moins de 2 ans.

Métaux du soleil: Le soleil peut être dangereux pour la peau. L'utilisation régulière d'écrans solaires peut réduire les risques de cancers de la peau et autres effets nocifs provoqués par le soleil sur la peau.

Précautions d'emploi: À usage externe seulement. Éviter tout contact avec les yeux. En cas d'irritation, rincer abondamment, interrompre l'utilisation du produit et consulter un médecin. Arrêter toute utilisation en cas d'apparition de signes d'irritation ou de rougeurs. Ne pas utiliser chez les enfants de moins de 6 mois sans avis médical.

ES PRODUCTO PARA TRATAMIENTO PROFESIONAL

Proteja la piel de la exposición a los rayos UVA y UVB con este producto de doble acción: pantalla solar y color. Transparente y liviano, sus tonalidades le otorgan a la piel un brillo radiante que realza su color natural. La Fundación de Lucha contra el Cáncer de Piel recomienda este producto como una segura y efectiva pantalla solar.

- dermatológicamente testada
- no comedogénica
- hipoalérgica
- libre de fragancia

Modo de uso: Aplique sobre rostro, cuello, pecho y manos, y bajo el maquillaje. Reaplique antes de exponerse al sol, después de nadar, transpirar o de secarse con una toalla. Los niños menores de 2 años deben usar productos con pantallas solares con un factor de protección solar mínimo de 4.

Advertencia: El sol daña la piel. El empleo regular de pantallas solares puede reducir la probabilidad de daños a la piel, de algunos tipos de cáncer de piel y de otros efectos perjudiciales del sol.

Precaución: Sólo para uso externo. Evite que penetre en los ojos. Si se produce irritación, enjuague bien el producto, suspenda su uso y consulte un médico. Suspensión su uso si aparecen síntomas de irritación o urticaria. Emplee en niños menores de 6 meses sólo con recomendación médica.

US PROFESSIONAL TREATMENT PRODUCT

Protect skin with this dual-purpose sunscreen. Micronized zinc oxide protects skin from UVA and UVB rays while a sheer, light-weight tint enhances the skin's natural color.

Drug Facts

Active Ingredient	Purpose
Zinc Oxide (CI 77497) - 7.6%	Sunscreen
Octinoxate - 7.5%	Sunscreen
Octisalate - 4.0%	Sunscreen

Uses to help prevent sunburn and for the temporary protection of sunburn

Warnings For external use only.

When using this product, do not use in or near the eyes; if product gets into eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

Directions Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Adults and children 6 months and over; apply liberally 15 minutes before sun or water exposure; reapply after swimming or excessive sweating or anytime after towel drying. Children under 6 months ask a doctor.

Other Information Store at 20-25° C (68-77° F) Sun Alert: The sun causes sun damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.

Inactive ingredients Water (Aqua), C12-15 Alkyl Benzoate, Glyceryl Stearate, Glycerin, Steareth-2, Steareth-100, Tricetanyl PVR, PEG-100 Stearate, Tocopheryl Acetate, Allantoin, Dimethicone, Xanthan Gum, Cetyl Hydroxyethylcellulose, Disodium EDTA, Diazolidinyl Urea, Isododecyl Butylcarbamate, Phenoxyethanol, Methylparaben, Propylparaben, Mica (CI 77019), Bismuth Oxychloride (CI 77163), Iron Oxides (CI 77489)

md formulations®

SUN

total protector
color 30
dual-purpose
daily protection
medium tint

écran protection
maximum 30 teinté
protection de jour
multi-usage
teinté moyenne


FACE / VISAGE

75 ml (2.5 fl. oz.)

Dist. by md formulations®
San Francisco, CA 94105 US
Bare Escentuals UK Ltd., SS13 1ND, UK
www.mdformulations.com
Made in USA - 36408

Protect skin with this dual-purpose sunscreen. Sheer, light-weight tint enhances the skin's natural color.

NDC 66078-504-25



Drug Facts	
Active Ingredient	Purpose
Zinc Oxide (CI 77947) - 7.8%	Sunscreen
Octinoxate - 7.5%	Sunscreen
Octisalate - 4.0%	Sunscreen

Uses to help prevent sunburn and for the temporary protection of sunburn.

Warnings For external use only.

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Stop use and ask a doctor if irritation or rash appears and lasts.

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

See Carton for complete information

FACE / VISAGE

SUN

total protector
color 30
dual-purpose
daily protection
medium tint

écran protection
maximum 30 teinté
protection de jour
multi-usage
teinté moyenne

75 ml (2.5 oz.)

Dist. by md formulations®
San Francisco, CA 94106 USA
Ware: iscentraluk117, SS13 1NS, UK
www.mdformulations.com
Made in USA • 36406

md formulations®

TOTAL PROTECTOR COLOR 30 MEDIUM TINT

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66078-504
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 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.8 g in 100 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Allantoin (UNII: 344S277G0Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Xanthan Gum (UNII: TTV12P4NEE)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
Methylparaben (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Steareth-2 (UNII: V56DFE46J5)	

PEG-100 Stearate (UNII: YD01N1999R)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
Propylparaben (UNII: Z8IX2SC1OH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
Mica (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66078-504-25	42 in 1 CASE		
1		1 in 1 CARTON		
1		81 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/28/2005	

Labeler - MD Formulation (087008363)

Registrant - Harmony Labs, Inc. (105803274)

Establishment			
Name	Address	ID/FEI	Business Operations
Harmony Labs, Inc.		105803274	manufacture, label, pack, relabel, repack