

**SUN TOTAL PROTECTOR COLOR 30 LIGHT TINT - zinc oxide, octisalate,  
octinoxate cream  
MD Formulations**

*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.*

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**Total Protector Color 30 light tint**

Zinc Oxide - 7.8%

Octinoxate - 7.5%

Octisalate - 4.0%

Zinc Oxide - 7.8% Sunscreen

Octinoxate - 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.

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

**Warnings :** For external use only.

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.

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 20-25C (68 - 77F) **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, Tricetyl PVP, PEG-100 stearate, Tocopheryl Acetate, Allantoin, Dimethicone, Xanthan Gum, Cetyl Hydroxyethylcellulose, Disodium EDTA, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, Methylidibromo Glutaronitrile, Phenoxyethanol, Methylparaben, Propylparaben, MICA (CI 77019), Bismuth Oxochloride (CI 77163), Iron Oxides (CI 77489)

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

NDC 66078-503-25



<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Zinc Oxide (CI 77947) - 7.8%	Sunscreen
Octinoxate - 7.5%	Sunscreen
Octisalate - 4.0%	Sunscreen
<b>Uses</b> to help prevent sunburn and for the temporary protection of sunburn.	
<b>Warnings</b> For external use only.	
<b>When using this product</b> do not use in or near the eyes. If product gets into eyes, rinse thoroughly with water.	
<b>Stop use and ask a doctor if</b> irritation or rash appears and lasts.	
<b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>See Carton for complete information</b>	


FACE / VISAGE

SUN

total protector  
color 30  
dual-purpose  
daily protection  
light tint

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

75ml (2.5oz.)

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Boro Escentuels UK Ltd., SS13 1ND, UK  
www.mdformulations.com  
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md formulations®



light tint

**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 et 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.

**Méfaits 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.

NDC 66078-603-26



**SPF 30**

md formulations®

**SUN**

total protector  
color 30  
dual-purpose  
daily protection  
light tint

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

FACE / VISAGE

75 ml (2.5 fl. oz.)

**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
- hipoleigénica
- 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 77947) - 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, Tricantaryl PVP, PEG-100 Stearate, Tocopheryl Acetate, Allantoin, Dimethicone, Xanthan Gum, Cetyl Hydroxyethylcellulose, Disodium EDTA, Diazolidinyl Urea, Isododecanyl Butylcarbamate, Methylsiloxane Glutaronitrile, Phenoxyethanol, Methylparaben, Propylparaben, Mica (CI 77019), Bismuth Oxycarbonate (CI 77163), Iron Oxides (CI 77489)

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## SUN TOTAL PROTECTOR COLOR 30 LIGHT TINT

zinc oxide, octisalate, octinoxate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66078-503
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.8 mL in 100 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4 mL in 100 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66078-503-25	42 in 1 CASE		
1		1 in 1 CARTON		
1		75 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/20/2007	

**Labeler** - MD Formulations (087008363)**Registrant** - Harmony Labs, Inc. (105803274)**Establishment**

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

Revised: 8/2010

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