

**SUN TOTAL PROTECTOR COLOR 30 DARK TINT - sun total protector color 30 dark tint 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 dark 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:** Purified Water (Aqua), C12-15 Alkyl Benzoate, Glyceryl Stearate, Glycerin, Stearyl-2, Stearyl-100, Tricetyl PVP, PEG-100 stearate, Tocopheryl Acetate, Allantoin, Dimethylsiloxane, Xanthan Gum, Cetyl Hydroxyethylcellulose, Disodium EDTA, Diazolidinyl Urea, Isopropyl Butylcarbamate, Methylparaben, Propylparaben, Mica (CI 77019), Bismuth Oxide (CI 77163), Iron Oxides (CI 77489)

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

NDC 66078-505-25



**Drug Facts**

<i>Active Ingredient</i>	<i>Purpose</i>
Zinc Oxide (CI 77947) - 7.8%	Sunscreen
Ocinoxate - 7.5%	Sunscreen
Ocilsalate - 4.0%	Sunscreen

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**Warnings** For external use only.

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**See Carton for complete information**

FACE / VISAGE

**SUN**

total protector  
color 30  
dual-purpose  
daily protection  
**dark tint**

écran protection  
maximum 30 teinté  
protection de jour  
multi-usage  
**teinté foncée**

75ml (2.5oz.)

Distributed by BIOCEUTIX  
San Francisco, CA 94108, U.S.A.  
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## SUN TOTAL PROTECTOR COLOR 30 DARK TINT

sun total protector color 30 dark tint cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66078-505
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<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:66078-505-25	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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