

TOO FACED TINTED BEAUTY BALM SPF-20- titanium dioxide zinc oxide cream
TOO FACED COSMETICS

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 INGREDIENTS

TITANIUM DIOXIDE 5.0%

ZINC OXIDE 5.0%

PURPOSE

SUNSCREEN

USE

- HELPS PREVENT SUNBURN

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE ON DAMAGED OR BROKEN SKIN.

STOP USE AND ASK DOCTOR IF RASH OCCURS.

WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- APPLY LIBERALLY AND SMOOTHLY 15 MINUTES BEFORE SUN EXPOSURE.
- USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING.
- REAPPLY AT LEAST EVERY 2 HOURS.
- CHILDREN UNDER 6 MONTHS: ASK A DOCTOR.
- OPTIONAL: APPLY TO ALL SKIN EXPOSED TO THE SUN.
- **SUN PROTECTION MEASURES.** SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY SKIN AGING. TO DECREASE THIS RISK, REGULARLY USE A SUNSCREEN WITH A BROAD SPECTRUM SPF OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING:
- LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 A.M. - 2 P.M.
- WEAR LONG-SLEEVED SHIRTS, PANTS, HATS AND SUNGLASSES.

OTHER INFORMATION

- YOU MAY REPORT A SERIOUS ADVERSE REACTION TO:
17361 ARMSTRONG AVENUE
IRVINE, CA 92614
- PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUNLIGHT.

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, PROPYLENE GLYCOL, OCTYLDODECYL NEOPENTANOATE, PEG/PPG-18/18 DIMETHICONE, DIMETHICONE, CYCLOHEXASILOXANE, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, ZINC CHLORIDE, LYSINE, PANAX GINSENG ROOT EXTRACT, GINKGO BILOBA

LEAF EXTRACT, ANTHEMIS NOBILIS FLOWER EXTRACT, CAMELLIA OLEIFERA LEAF EXTRACT, PHYTANTRIOL, MAGNESIUM ASCORBYL PHOSPHATE, RETINYL PALMITATE, TOCOPHERYL ACETATE, TOCOPHEROL, TETRAHEXYDECYL ASCORBATE, ALUMINUM HYDROXIDE, STEARIC ACID, TRIETHOXYCAPRYLYLSILOXANE, BORON NITRIDE, GLYCERIN, SODIUM DEHYDROACETATE, PALMITIC ACID, DEXTRIN PALMITATE, SODIUM HYALURONATE, BUTYLENE GLYCOL, PHENOXYETHANOL, METHYLPARABEN, PROPYLPARABEN, MICA, IRON OXIDES.

QUESTIONS?

(949) 553-4431

MON-FRI 9AM-5PM (PST)

*Too
Faced*

TINTED
*Beauty
Balm*



**MULTI-BENEFIT
SKIN CARE MAKEUP**

**BROAD SPECTRUM
SPF 20 SUNSCREEN**

1.50 Fl. Oz.

Active Ingredients: Titanium Dioxide 5% (Sunscreen), Zinc Oxide 5% (Sunscreen)

Dist. by Too Faced Cosmetics, LLC, Irvine, CA 92614 USA

EU: BIORIUS sprl, 2 rue René Descartes, B-7000 Mons, Belgium. Made in USA

© 2012 Too Faced Cosmetics, LLC • All Rights Reserved www.toofaced.com

Achieve a healthy glow & improve skin's overall appearance with our powerful multi-mineral complex

elle

LIGHT-DIFFUSING PIGMENTS TINT AND ADD RADIANCE

ANTI-AGING, MULTI-MINERAL COMPLEX PRIMES & PREVENTS DAMAGE

MOISTURIZES WITH OIL-FREE HYDRATION

HYPO-ALLERGENIC AND SOOTHING FOR ALL SKIN TYPES

BROAD SPECTRUM SPF 20

Dist. by Too Faced Cosmetics, LLC
Irvine, CA 92614 USA
Biorius, Rue de la Croix 10A,
BE-7170 MANAGE, Made in USA
© 2012 Too Faced Cosmetics, LLC
All Rights Reserved
www.toofaced.com

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 5.0%	Sunscreen
Zinc Oxide 5.0%	Sunscreen

Use
• Helps prevent sunburn

Warnings
For external use only.
Do not use on damaged or broken skin.
Stop use and ask doctor if rash occurs.
When using this product keep out of eyes. Rinse with water to remove.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.
- Optional: apply to all skin exposed to the sun.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - Wear long-sleeved shirts, pants, hats and sunglasses.

Other Information
You may report a serious adverse reaction to:
17361 Armstrong Avenue
Irvine, CA 92614

- Protect the product in this container from excessive heat and direct sunlight.

Questions?
(949) 553-4431
MON-FRI 9AM-5PM (PST) ▶

Too Faced

Beauty Balm

TINTED

MULTI-BENEFIT SKIN CARE MAKEUP

BROAD SPECTRUM SPF 20 SUNSCREEN

45 mL / 1.50 FL. Oz.

Drug Facts (continued)

Inactive Ingredients
Water, Cyclopentasiloxane, Propylene Glycol, Octyldodecyl Neopentanoate, PEG/PPG-18/18 Dimethicone, Dimethicone, Cyclohexasiloxane, Magnesium Chloride, Potassium Chloride, Sodium Chloride, Zinc Chloride, Lysine, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Anthemis Nobilis Flower Extract, Camellia Oleifera Leaf Extract, Phytantriol, Magnesium Ascorbyl Phosphate, Retinyl Palmitate, Tocopheryl Acetate, Tocopherol, Tetrahydroxydecyl Ascorbate, Aluminum Hydroxide, Stearic Acid, Triethoxyacetyl silane, Boron Nitride, Glycerin, Sodium Dehydroascorbate, Palmitic Acid, Dextrin Palmitate, Sodium Hyaluronate, Butylene Glycol, Phenoxethanol, Methylparaben, Propylparaben, Mica, Iron Oxides.

TOO FACED TINTED BEAUTY BALM SPF-20

titanium dioxide zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79596-090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	5 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
LYSINE (UNII: K3Z4F929H6)	
PANAX GINSENG ROOT WATER (UNII: P9T4K47OM0)	
GINKGO BILOBA WHOLE (UNII: 660486U60I)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
PHYTANTRIOL (UNII: 8LV107A72W)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
PALMITIC ACID (UNII: 2V16EO95HI)	
ICODextrin (UNII: 2NX48Z0A9G)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MICA (UNII: V8A1AW0880)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79596-090-22	1 in 1 BOX		
1	NDC:79596-090-21	45 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

OTC monograph final	part352	12/14/2012	
---------------------	---------	------------	--

Labeler - TOO FACED COSMETICS (014131481)

Revised: 1/2013

TOO FACED COSMETICS