

**HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM  
SPF 50- titanium dioxide, zinc oxide cream  
Tecnocosmesi S.p.A.**

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**HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM SPF 50**

***Active ingredients***

TITANIUM DIOXIDE 14.2 %

ZINC OXIDE 4.9 %

***Purpose***

Sunscreen

***Uses***

- Tinted compact SPF 50 helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions for use**), decreases the risk of skin cancer and early skin aging caused by the sun.

***Warnings***

**For external use only**

**Do not use**

on damaged or broken skin.

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and consult a health care practitioner**

if rash occurs.

**Keep out of reach of children.**

If product is swallowed, get medical help or contact a Poison Control Center right away.

***Directions for use***

- Apply liberally/generously and evenly 15 minutes before sun exposure.
- Reapply:

- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours.
- Children under 6 months: Consult a health care practitioner.
- **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. to 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses.

### **Inactive Ingredients**

DIMETHICONE, HYDROGENATED POLYISOBUTENE, PHENYL TRIMETHICONE, ISODECYL NEOPENTANOATE, SQUALANE, TALC, ETHYLHEXYL HYDROXYSTEARATE, SYNTHETIC WAX , POLYMETHYL METHACRYLATE, SILICA, WATER/EAU, POLYGLYCERLYL-3 DIISOSTEARATE, ALUMINA, STEARIC ACID, BEESWAX, CAPRYLIC/CAPRIC TRIGLYCERIDE, MICROCRYSTALLINE WAX, PHENOXYETHANOL, TOCOPHERYL GLUCOSIDE, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE, TITANIUM DIOXIDE (CI77891), IRON OXIDES (CI77492), (CI77491), (CI77499)

### ***Other information***

Protect this product from excessive heat and direct sun

Questions ?

1-866-41-AVENE

(28363) (USA)

1-877-441-2011 (CAN)

### **PACKAGE LABEL - HIGH PROTECTION TINTED COMPACT HONEY**

HAUTE PROTECTION

HIGH PROTECTION

COMPACT TEINTÉ - TINTED COMPACT

DORE - HONEY and SABLE - BEIGE

RÉSISTANT À L'EAU

WATER RESISTANT

40 minutes

UVB UVA

FPS

SPF

LARGE SPECTRE

BROAD SPECTRUM

50

Peaux intolérantes - For intolerant skin

NON COMÉDOGÈNE - N'OBSTRUE PAS LES PORES

LABORATOIRES DERMATOLOGIQUES AVÈNE - PARIS

10g e NET WT. 0.3 OZ.

NPN 80085664



# HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM SPF 50

titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66888-051
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.42 g in 10 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.49 g in 10 g

## Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>HYDROGENATED POLYISOBUTENE 8</b> (UNII: 7YR4ZFS62E)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ETHYLHEXYL HYDROXYSTEARATE</b> (UNII: B7I80BWW5E)	
<b>SYNTHETIC WAX (1800 MW)</b> (UNII: 248P1AUJ90)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TOCOPHERYL GLUCOSIDE</b> (UNII: 9CKD1JE38R)	
<b>TRIBEHENIN</b> (UNII: 8OC9U7TQZ0)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66888-051-01	1 in 1 CARTON	03/16/2021	
1		10 g in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/16/2021	

**Labeler** - Tecnicosmesi S.p.A. (435445218)

**Registrant** - Tecnicosmesi S.p.A. (435445218)

## Establishment

Name	Address	ID/FEI	Business Operations
Tecnicosmesi S.p.A.		435445218	manufacture(66888-051)

