# DHC BRIGHTENING SUNSCREEN- titanium dioxide and zinc oxide lotion DHC USA Incorporated

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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### **DHC Brightening Sunscreen**

#### **Drug Facts**

#### **Active Ingredients**

Titanium dioxide 8%

Zinc oxide 13%

### **Purpose**

Sunscreen

#### Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), 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 ask a doctor if rash occurs

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

#### **Directions**

- shake well before use
- apply evenly 15 minutes before sun exposure
- reapply:
  - at least every 2 hours
  - use a water resistant sunscreen if swimming or sweating
- **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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

#### **Inactive Ingredients**

cyclopentasiloxane, water, talc, dimethicone, PEG-10 dimethicone, triethylhexanoin, glycerin, alumina, nylon-12, olea europaea (olive) fruit oil, butylene glycol, PEG-9 polydimethylsiloxyethyl dimethicone, methicone, phenoxyethanol, hydrogen dimethicone, alpha-arbutin, pentylene glycol, aloe barbandensis leaf juice, pentasodium pentetate, tocopherol, tricalcium phosphate, ascorbyl tetraisopalmitate, olea europaea (olive) leaf extract, citric acid, magnolia obovate extract, silica, silver

#### Other Information

protect this product from excessive heat and direct sun

# Questions or Comments? 800-DHC-CARE (342-2273)

DHCcare.com

Distributed by DHC USA Inc. Mechanicsburg, PA 17050

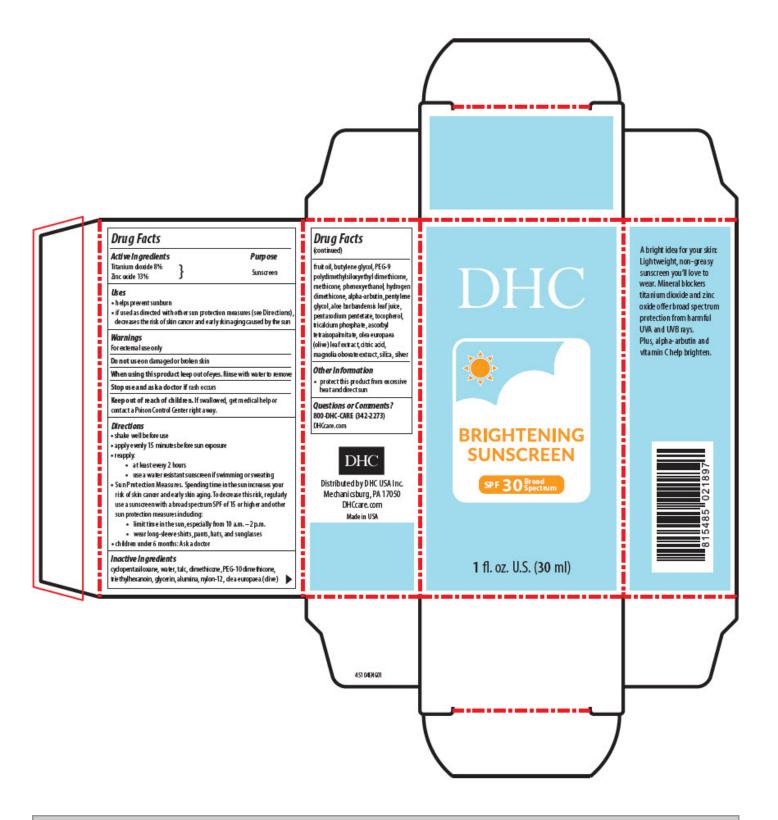
#### PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box

DHC

BRIGHTENING SUNSCREEN

SPF 30 Broad Spectrum

1 fl. oz. U.S. (30 ml)



## **DHC BRIGHTENING SUNSCREEN**

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63433-452
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	80 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	130 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
Water (UNII: 059QF0KO0R)	
Talc (UNII: 7SEV7J4R1U)	
Dimethicone (UNII: 92RU3N3Y10)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
Triethylhexanoin (UNII: 7K3W1BIU6K)	
Glycerin (UNII: PDC6A3C0OX)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
<b>Nylon-12</b> (UNII: 446U8J075B)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
Butylene glycol (UNII: 3XUS85K0RA)	
PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: TYP81E471F)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
ALPHA-ARBUTIN (UNII: 72VUP07IT5)	
Pentylene Glycol (UNII: 50C1307PZG)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Pentasodium Pentetate (UNII: 961TOZ5L7T)	
Tocopherol (UNII: R0ZB2556P8)	
Tricalcium Phosphate (UNII: K4C08XP666)	
Ascorbyl Tetraisopalmitate (UNII: 47143LT58A)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Silver (UNII: 3M4G523W1G)	

F	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63433- 452-30	1 in 1 BOX	03/01/2020	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2020	

# **Labeler - DHC USA Incorporated (004087554)**

# **Registrant -** ABBE Laboratories, Inc. (781745286)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
ABBE Laboratories, Inc.		781745286	MANUFACTURE(63433-452)	

Revised: 2/2022 DHC USA Incorporated