

# ALPHA-H TOTAL ECLIPSE- titanium dioxide, zinc oxide lotion

## Alpha-H

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.

### Alpha-H Total Eclipse

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DocuSign Envelope ID: 7C9CBCD0-5551-4A1E-BE66-977D5EAA387C  
 DocuSign Envelope ID: 27B8A7C96A414D2...  
 Katherine Weller  
 Muhammad Ili  
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 3/1/2023 | 11:39 PM CST  
 2/28/2023 | 10:24 AM CST

6.421

37

37

9.493

135

IP221103A4

**ALPHA-H**

**TOTAL ECLIPSE**  
BROAD SPECTRUM SPF 40  
PRIMING MINERAL  
SUNSCREEN

40 mL / 1.35 fl. oz.

**Drug Facts**

Active Ingredients	Purpose
Titanium Dioxide 2%	Sunscreen
Zinc oxide 1%	

**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 skin rash occurs
- 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
- reapply:
  - use a water-resistant sunscreen if swimming or sweating
  - at least every 2 hours
  - children under 6 months of age: Ask a doctor
- 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**

- protect the product in this container from excessive heat and direct sun

**Inactive ingredients**

Allantoin, Avena Sativa (Oat) Kernel Extract, Bisabolol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Tea) Leaf Extract, Caprylyl Glycol, Ceteth-20, Cetyl Alcohol, Dicaetea Rotunda Oil,

**Drug Facts (Continued)**

Dimethicon/Caprylsilsesquioxane/Silicate Crosspolymer, Dimethicon/Propylsilsesquioxane/Silicate Crosspolymer, Disodium EDTA, Ethylhexyl Isononanoate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hexylene Glycol, Hydrolyzed Sodium Hyaluronate, Iron Oxides (CI 77491, CI 77492, CI 77499), Lecithin, Lysolecithin, Neopentyl Glycol Dihexanoate, Octyldodecyl Neopentanoate, PEG-75 Stearate, Phenoxethanol, Polyester-7, Potassium Sorbate, Pullulan, Pyrus Malus (Apple) Fruit Extract, Rutinaria Lamellosa Oil, Sclerotium Gum, Silica, Sodium Ascorbate, Sodium Citrate, Sodium Hyaluronate, Squalane, Stearath-20, Tocopherol, Tricetate-4 Phosphate, Triaurath-4 Phosphate, Water, Xanthan Gum.

**Questions or comments?**

+1 800 906 7708

You may also report serious side effects to this phone number.

Monday-Thursday.

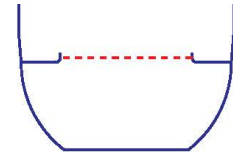
**MANUFACTURED FOR:**  
INTERNATIONAL WATERS PTY.LTD.,  
27 MILLENNIUM CIRCUIT,  
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ACN 071698185.  
ALPHA-H.COM

EMAIL: HELLO@ALPHA-H.COM

MADE IN USA

9 536328 066482



INTEGRATED PACKAGING	
end user :ALPHA H	
item :SPF 40	
code # :	
size :37 x 37 x 135	
ref # :IP221103A4	view :PRINT SIDE
material :.018 SBS	date :02/15/2023
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**COLOURS:**

	<b>PMS 426C</b>
	<b>PMS COOL GREY 11 C</b>
	<b>EMBOSSSED</b>
	<b>SPOT UV</b>

**ALPHA-H TOTAL ECLIPSE**

titanium dioxide, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55528-400
<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	9.7 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	19.4 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>AVENA SATIVA WHOLE</b> (UNII: 5P8D0Z74RG)	
<b>DICRATERIA ROTUNDA OIL</b> (UNII: Z0DWU9R4GM)	
<b>DISODIUM EDTA-COPPER</b> (UNII: 6V475AX06U)	
<b>CAMELLIA SINENSIS WHOLE</b> (UNII: C5M4585ZBZ)	
<b>TRICETEARETH-4 PHOSPHATE</b> (UNII: 69534Y66NO)	
<b>PULLULAN</b> (UNII: 8ZQ0AYU1TT)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	

<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>TRILAURETH-4 PHOSPHATE</b> (UNII: M96W2OLL2V)
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (45000000 MW)</b> (UNII: 9KB5R958PB)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>ETHYLHEXYL ISONONANOATE</b> (UNII: I6KB4GE3K4)
<b>CETETH-20</b> (UNII: I835H2IHHX)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>RUTTNERA LAMELLOSA OIL</b> (UNII: 5XZ38R4SUT)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55528-400-02	1 in 1 CARTON	05/05/2023	
1	NDC:55528-400-01	40 mL in 1 TUBE; 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	05/05/2023	

**Labeler** - Alpha-H (754473957)