# H2O BEAUTY AQUADEFENSE PROTECTIVE MATCHA SPF 40- avobenzone, homosalate, octisalate, octocrylene lotion Bentley Laboratories, LLC

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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# H2O+ Beauty AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40 - 132

# **Drug Facts Active Ingredients**

Avobenzone 3.0% Homosalate 8.0% Octisalate 5.0% Octocrylene 6.0%

# 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 avoid contact with eyes. If contact occurs, flush thoroughly with water
- **Stop use and ask a doctor** if rash occurs

# Keep out of reach of children.

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

## **Directions**

For sunscreen use:

- Apply liberally 15 minutes before sun exposure
- Reapply at least every two hours
- Use a water resistant sunscreen if swimming or sweating
- For children under 6 months, 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 15 or higher and other sun protection measures including:

• Limit time in the sun, especially from 10a.m. - 2p.m.

• Wear long-sleeve shirts, pants, hats and sunglasses.

### Other Information

• Protect the product in this container from excessive heat and direct sun

# **Inactive Ingredients**

Water/Aqua/Eau, Butyloctyl Salicylate, Dimethicone, Butylene Glycol, Aluminum Starch Octenylsuccinate, Styrene/Acrylates Copolymer, Methyl Methacrylate Crosspolymer, Glycerin, Octyldodecyl Neopentanoate, PEG-8 Stearate, Glyceryl Stearate, Citrullus Lanatus (Watermelon) Fruit Extract, Lens Esculanta (Lentil) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Oryza Sativa (Rice) Bran Extract, Camellia Sinensis Leaf Extract, Sodium Hyaluronate, Hydrolyzed Algin, Sodium Lactate, Xanthan Gum, VP/Eicosene Copolymer, PEG-100 stearate, Cetearyl Alcohol, Caprylyl Glycol, Sorbitan Oleate, PEG-8 Laurate, Hexylene Glycol, Disodium EDTA, Citric Acid, Sodium PCA, Sodium Benzoate, Potassium Sorbate, Phenowyethanol, Fragrance/Parfum, Limonene, Buthyphenyl Methylpropional, Linalool, Citral, Citronellol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (090-50103-000)

## **Questions?** Comments?

Call 1-800-242-2284, M-F 9am - 5pm PST

# H2O+™ BEAUTY AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40 product label

H2O+™ BEAUTY AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40

SUN PROTECTION + ENVIROMENTAL STRESSOR SHIELD

50 mL 1.7 U.S. FL oz

## AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40

SHOW ME THE SUN I Our Protective Matcha Moisturizer SPF 40 packs a punch of broad spectrum coverage without any leftover white residue. Featuring Matcha Green Tea and Rice Bran extracts, it protects against the stress of sun exposure and moisture loss and therefore helps ward off the appearance of wrinkles. Its ultra-lightweight texture and fast absorbing finish will knock-your-flops off.

USES I Helps prevent sunburn. If used as directed with other sun measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

DIRECTIONS 1 For sunscreen use: Shake well. Apply liberally 15 minutes before sun exposure. Reapply at least every two hours. For children under 6 months, ask a doctor.

H2O+TM

Distributed by: H2o Plus, LLC

San Francisco, CA. 94104 www.H2OPLUS.COM

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083-50103-002 50103

We plus it up with The result is positively smart.

# WATER

energy, confidence, and advanced technology.

# Octocrylene 6.0%. Homosalate 8.0%... Octisalate 5.0%.....

# **Drug Facts**

# Active Ingredients Avobenzone 3.0%.

# Purpose Sunscreen Sunscreen Sunscreen

protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

with water

• 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 immediately

Reapply at least every two hours
 Use a water resistant sunscreen if swimming or sweating

 Do not use on damaged or broken skin
 When using this product avoid contact with eyes. If contact occurs, flush thoroughly For external use only

Apply liberally 15 minutes before sun exposure

and early

your risk of skin cancer skin aging

Spending time in the sun Sun Protection Measures. For children under 6 months,

ask a doctor

Directions

# H2O+ BEAUTY

# AQUADEFENSE

**PROTECTIVE** MATCHA MOISTURIZER SPF 40

SUN PROTECTION + ENVIRONMENTAL STRESSOR SHIELD

0 mL 1.7 U.S. Fl oz e

# **AQUADEFENSE** PROTECTIVE MATCHA MOISTURIZER SPF 40

SHOW ME THE SUNNY | Our Moisturizer SPF 40 packs a punch of broad spectrum coverage without any leftover white residue. Featuring Matcha Creen Tea and Rice Bran extracts, it off the appearance wrinkles. Its ultra-lightweight texture and fast absorbing finish will knock-your-flops off.

USES | Helps prevent sunburn.
If used as directed (see Directions), decreases the risk of skin cancer and early skin aging caused by

DIRECTIONS | For well. Apply liberally 15 minutes before sun exposure. Reapply at least every two hours. For children under 6 months, ask a doctor.

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083-50103-002 50103

from 10a.m. - 2 p.m.

Wear long-sleeve shirts, pants, hats

and sunglasses

Limit time in the sun, especially

To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF 15 or higher and other sun protection measures including:

Drug Facts

(Continued)

If used as directed with other sun Helps prevent sunburn

Water/Aqua/Eau, Butyloctyl Salicylate, Dimethicone, Butylene (Bycol, Aluminum Starch Octenylsuccinate Styrene/Acrylates Copolymer, Methyl Methacrylate Styrene/Acrylates Copolymer, Methyl Methacrylate

# Inactive Ingredients

Protect the product in this container from excessive heat and direct sun

Other Information

Orosspolymer, Glycerin, Octyldodecyl Neopentanodie, PEG-8 Stearate, Glyceryl Stearate, Citrulius Larratus (Watermekor) Fruit Edmad, Lens Esculerita (Lentil) Fruit Edmad, Prus Malus (Apple) Fruit Edmad, Oryza Satirka (Rice) Bran Edmad, Carmellia Sinensis Leaf Edmad, Sodium Hyalurorete, Hydrolyzad Agin, Sodium Lactate, Xamfinan Gum, VPEGoosene Oppolymer, PEG-100 Stearate, Cetearyl Aborhol, Caprylyll Glycol, Sorbitan Olleate, PEG-8 Laurate, Hesylvare Glycol, Discollum EDTA, Chric Acid, Sodium PCA, Sodium Berzonate, Potassium Sorbate, Prencoyethanol, Fragranca-Partum, Limonene, Butylphenyl Methylpropional, Linalool, Citral, Citronellol, Hydrolysohesyl 3-Cyclohesene Carboxaldehyde (090-50103-000)

Questions? Comments? Call 1-800-242-2284, M-F 9am-5pm PST





AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40

SUN PROTECTION + ENVIRONMENTAL STRESSOR SHIELD

50 mL 1.7 U.S. Fl oz e

### AQUADEFENSE PROTECTIVE MATCHA MOISTURIZER SPF 40

ACTIVE INCREDIENTS | Avabenzone 3.0% Homosalate 8.0% Octisalate 5.0% Octocrylene 6.0%

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.

WARNING | For external use only. Do not use on damaged or broken skin. Avoid contact with eyes. If contact occurs, flush thoroughly with water, 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 immediately.

DIRECTIONS | For sunscreen use: Apply liberally 15 minutes before sun exposure. Reapply at least every two hours. For children under 6 months, ask a doctor.

SHAKE WELL

120+

Distributed by: 8H2O Plus, LLC San Francisco, CA 94104 WWW.H2OPLUS.COM 62016 MADE IN USA

400-50103-001 80103

# H2O BEAUTY AQUADEFENSE PROTECTIVE MATCHA SPF 40

avobenzone, homosalate, octisalate, octocrylene lotion

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54111-132

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety Basis of Strength** Strength **Ingredient Name** AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) AVOBENZONE 1.5 g in 50 mL HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) HOMOSALATE 4 g in 50 mL OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) OCTISALATE 2.5 g in 50 mL OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) **OCTOCRYLENE** 3 g in 50 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ0 O 6 29 4)
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0 NC5MT)
GLYCERIN (UNII: PDC6A3C0OX)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
PEG-8 STEARATE (UNII: 2P9L47VI5E)
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)
WATERMELON (UNII: 231473QB6R)
LENS CULINARIS FRUIT (UNII: ZYZ076G9JH)
APPLE (UNII: B423VGH5S9)
RICE BRAN (UNII: R60 QEP13IC)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)
SODIUM ALGINATE (UNII: C269C4G2ZQ)
SODIUM LACTATE (UNII: TU7HW0W0QT)
XANTHAN GUM (UNII: TTV12P4NEE)
VINYLPYRROLIDONE/EICO SENE COPOLYMER (UNII: 035MV9 S1C3)
PEG-100 STEARATE (UNII: YD01N1999R)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)
SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)
PEG-8 LAURATE (UNII: 762O8IWA10)
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469OTG57A2)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LIMO NENE, (+)- (UNII: GFD7C86Q1W)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
LINALOOL, (+/-)- (UNII: D81QY6188E)
CITRAL (UNII: T7EU0O9VPP)
.BETACITRONELLOL, (R)- (UNII: P01OUT964K)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE (UNII: QUE43B9Z2Q)

ı	Packaging						
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
	1 NDC:54111-132-50	50 mL in 1 TUBE; Type 0: Not a Combination Product	12/06/2016				

<b>Marketing Info</b>	arketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part352	12/06/2016				

# Labeler - Bentley Laboratories, LLC (068351753)

Revised: 12/2018 Bentley Laboratories, LLC