MOISTURIZER- avobenzone, oxybenzone, octisalate, homosalate, octocrylene cream
OXYGEN DEVELOPMENT, 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.

AWAKE HELLO, SUNSHINE MOISTURIZER BROAD SPECTRUM SPF 30 SUNSCREEN

Active Ingredients

Homosalate 10.00%, Oxybenzone 5.00%, Octisalate 5.00%, Avobenzone 3.00%, Octocrylene 1.00%.

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.

Stop use

Stop use and ask doctor if rash occurs.

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of the 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.
- 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. - 2p.m.

-Wear long-sleeved shirts, pants, hats and sunglasses

Other Information

- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse reaction to: Awake Beauty c/o Reprot Reaction, LLC, P.O. Box 22, Plainsboro, New Jersey 08536-0222.

Inactive Ingredients

Water, Glyceryl Stearate, Glycerin, Propanediol, Cetearyl Alcohol, Squalane, Stearic Acid,

C12-15 Alkyl Benzoate, Butylene Glycol, Dimethicone, Polyester-8, Polysorbate 60, Potassium Cetyl Phosphate, Helianthus Annuus (Sunflower) Seed Oil/Helianthus Annuus Seed Oil, Citrus Aurantium Dulcis (Orange) Oil, Phenoxyethanol, Sclerotium Gum, Phenylethyl Resorcinol, Tribehenin, Dimethiconol, Caprylyl Glycol, Chlorphenesin, Allantoin, Tocopheryl Acetate, Disodium EDTA, Sodium Hydroxide, Ceramide NG, PEG-10 Phytosterol, Sodium PCA, Glycine Soja (Soybean) Oil, Hydrogenated Lecithin, Oligopeptide-68, Sodium Oleate, Linalool, Citral, Sodium Carbonate, Limonene, Citronellol, Geraniol, Tocopherol, Palmitoyl Hexapeptide-12, Farnesol, Mica, Titanium Dioxide, Iron Oxides.

Awake	
SUB-BRAND: AWAKE	FILE NAME: HELLO SUNSHINE SPF
COMPENENT: SECONDARY FOLDING CARTON	SHADE: N/A
DATE OPENED: 5/22/18	DATE REVISED: 7/31/18
REASON FOR CHANGE: PRODUCTION	
COLORS	
K 170C WHITE SILVER FOIL SHINY	

P024161

SIZE:64*65*63(mm)
0.365mm

Awake
Drug Facts (continued)
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.
• 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
• Protect the product in this container from excessive heat and direct sunlight.
• You may report a serious adverse reaction to: Awake Beauty c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, New Jersey 08536-0222.
Drug Facts (continued)
Inactive Ingredients
Water, glyceryl stearate, glycerin, propanediol, cetearyl alcohol, squalene, stearic acid, C12-15 alkyl benzoate, butylene glycol, dimethicone, polyester-8, polysorbate 60, potassium cetyl phosphate, helianthus annuus (sunflower) seed oil, citrus aurantium dulcis (orange) oil, phenoxyethanol, sclerotium gum, phenylethyl resorcinol, tribehenin, dimethiconol, caprylyl glycol, chlorphenesin, allantoin, tocopheryl acetate, disodium EDTA, sodium hydroxide, ceramide NG, PEG-10 phytosterol, sodium PCA, glycine soja (soybean) oil, hydrogenated lecithin, oligopeptide-68, sodium oleate, linalool, citral, sodium carbonate, limonene, tocopherol, palmitoyl hexapeptide-12, mica, titanium dioxide, iron oxides. OX100AWFZ000022.
www.awakebeauty.com
Awake
Hello, Sunshine
moisturizer
Broad Spectrum SPF 30
sunscreen
net 50 mL / 1.70 Fl. Oz.
Drug Facts
Active Ingredients
Homosalate 10.00%, Oxybenzone 5.00%, Octisalate 5.00%, Avobenzone 3.00%, Octocrylene 1.00%
Purpose
Sunscreen
Uses
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Stop use and ask doctor if rash occurs.
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Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

50ml, 61354-050-01

10ml, 61354-050-02

Awake	
SUB-BRAND: AWAKE	FILE NAME: 0004AW-4 TS HELLO SUNSHINE
COMPONENT: SEC FC	SHADE: N/A
DATE OPENED: 5/14/19	DATE REVISED:
REASON FOR CHANGE:	
COLORS	
SILVER FOIL SHINY, WHITE OPAQUE, 170C OPAQUE, 183C OPAQUE, CMYK	FINISH: MATTE LAMINATE

P024696-F

SIZE:47.5*48.5*41(mm)
0.365mm

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(2) 2019.03.07
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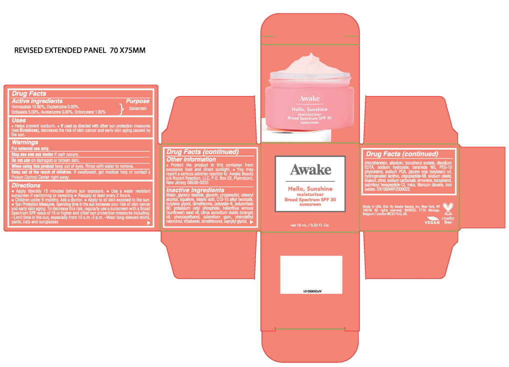
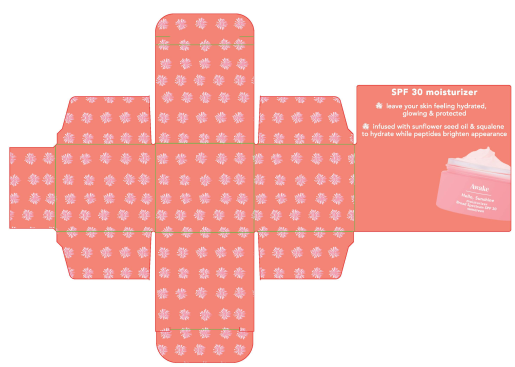
(3) 2019.03.18 -×§ï¥ßµP
(4) 2019.03.19 ¥[¦©¤M
(5) 2019.04.23 -×§ï¤Ø¤o

REVISED EXTENDED PANEL 70 X75MM





MOISTURIZER avobenzone, oxybenzone, octisalate, homosalate, octocrylene cream			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-050

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mg
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mg
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 100 mg
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1 mg in 100 mg
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SQUALANE (UNII: GW89575KF9)	
PHENYLETHYL RESORCINOL (UNII: G37UFG162O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-050-01	50 mg in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	02/22/2021	
2	NDC:61354-050-02	10 mg in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	02/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2021	

Labeler - OXYGEN DEVELOPMENT, LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
OXYGEN DEVELOPMENT, LLC		137098492	manufacture(61354-050)

Revised: 2/2021 OXYGEN DEVELOPMENT, LLC