# AGELESS SOLAR DEFENSE (SPF 30)- octinoxate, octisalate, oxybenzone, avobenzone cream Divine 369 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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#### **AGELESS SOLAR DEFENSE (SPF 30)**

#### **Drug Facts**

#### Active ingredients

Octinoxate 7.5%
Octisalate 5.0%
Oxybenzone 4.0%
Avobenzone 3.0%

#### **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.

# Stop use and contact your doctor if

• rash occurs.

### Keep out of reach of children.

- If swallowed, get medical help, or contact a poison control center right away.
- Do not apply too closely to the eye area. Rinse with water to remove.

#### **Directions**

- Apply liberally to face and body at least 15 minutes before sun exposure or two minutes before applying makeup.
- Reapply:

- After 80 minutes of swimming or sweating
- Immediately after towel drying.
- At least every 2 hours.
- Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and 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 specially, from 10 a.m. 2 p.m.
- Wear long sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

#### Other information

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

#### Inactive ingredients

Water (Aqua), Isopropyl Palmitate, Isoeicosane, Potassium Cetyl Phosphate, Glycerin, Ethylhexyl Methoxycrylene, Silica, Cetyl Dimethicone, Hydroxyethylacrylate/sodium acryloyldimethyl taurate copolymer, Dimethicone, Polyglyceryl-3 Diisostearate, Cetearyl Alcohol, Polysorbate 60, Isohexadecane, Hydroxyethylcellulose, Phenoxyethanol, Glyceryl Stearate, PEG-100 Stearate, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Butylene Glycol, Punica Granatum (Pomegranate) Extarct, Camellia Oleifera Leaf Extract

#### Questions or Comments?

Contact us at: contact@audiaskincare.com

Monday - Friday (9am - 5pm PST)

Dist-by Divine 369 LLC. San Francisco CA, 94124

www.audiaskincare.com

### Package Labeling:



# **AGELESS SOLAR DEFENSE (SPF 30)**

octinoxate, octisalate, oxybenzone, avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82084-0011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	40 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

ISOEICOSANE (UNII: AR294KAG3T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POMEGRANATE (UNII: 56687D1Z4D)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:82084- 0011-0	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2021	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part352	07/15/2021		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

# **Labeler -** Divine 369 LLC (081571821)

Revised: 1/2023 Divine 369 LLC