

AKWA DAYSTAR SHADE SPF 40- homosalate, zinc oxide, octisalate lotion
4-Life Research USA, 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.

aKwa Daystar Shade SPF 40 Moisturizing Sunscreen

ACTIVE INGREDIENTS

Homosalate 10%

Zinc Oxide 9.425%

Octisalate 4.50%

Purpose

sunscreen

Uses

Helps prevent sunburn

If used as directed with other sun protection neasures (see **DIRECTIONS**), decreases the rist 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 product is swallowed, get medical help or contact a Poison control Center right away.

Directions

- Apply generously and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours during sun exposure.
- 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 valu of 15 or higher and other sun protection measures, including:
 - Limit time in the sun, especially from 10:00 am - 2:00 pm.
 - Wear long-sleeved shirts, pants, hats and sunglasses.
 - Children under 6 months of age: Ask a doctor.

INACTIVE INGREDIENTS

Water, butyloctyl salicylate, coco-caprylate/caprate, glycerin, glyceryl stearate, PEG-100 stearate, dimethicone, C14-22 Alkane, Isododecane, Caprylic/Capric triglyceride, acrylates/polytrimethylsiloxymethacrylate copolymer, hydroxyapatite, C12-20 alkyl glucoside, cetearyl glucoside, tocopherol, tocopheryl acetate, tetrahexyldecyl ascorbate, triolein, linoleic acid, oleic acid, palmitic acid, stearic acid, bisabolol, phtosteryl canola glycerides, lecithin, xanthan gum, citric acid, biosaccharide gum-4, phenyl trimethicone, caprylyl glycol, polyglyceryl-3 polyricinoleate, disteardimonium hectorite, isostearic acid, disodium EDTA, 1,2-hexanediol, benzyl alcohol, benzoic acid, vinyl dimethicone/methicone silsesquioxane crosspolymer, ammonium acryloyldimethyltaurate/VP copolymer, propylene carbonate, fragrance, sodium olivoyl glutamate, glucose, farnesol, cetyl alcohol, stearyl alcohol, ethylhexylglycerin, phenoxyethanol, and propylene glycol.



Drug Facts

Active Ingredients	Purpose
Hemlock 10.00%	Sunscreen
Zinc Oxide 3.425%	Sunscreen
Oxide 4.5%	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.

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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 product is swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- Apply generously and evenly 15 minutes before sun exposure.
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- Use a water-resistant sunscreen if swimming or sweating.
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 - Wear long-sleeved shirts, pants, hats, and sunglasses.
 - Children under 6 months of age: Ask a doctor.


Other Information

- Product has product from excessive heat and direct sun.
- Product may stain some fabrics.

Made in the USA with quality ingredients from around the world
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A PRODUCT OF
4Life

Manufactured for:
BioMedical Research Laboratories, LLC
7850 South 300 West
Sandy, UT 84070
Item: N25152
12111905




Drug Facts (continued)

INACTIVE INGREDIENTS:
Water, butyloctyl salicylate, coco-caprylate/caprate, glycerin, glyceryl stearate, PEG-100 stearate, dimethicone, C14-22 alkane, Isododecane, Caprylic/Capric triglyceride, acrylates/polytrimethylsiloxymethacrylate copolymer, hydroxyapatite, C12-20 alkyl glucoside, cetearyl glucoside, tocopherol, tocopheryl acetate, tetrahexyldecyl ascorbate, triolein, linoleic acid, oleic acid, palmitic acid, stearic acid, bisabolol, phtosteryl canola glycerides, lecithin, xanthan gum, citric acid, biosaccharide gum-4, phenyl trimethicone, caprylyl glycol, polyglyceryl-3 polyricinoleate, disteardimonium hectorite, isostearic acid, disodium EDTA, 1,2-hexanediol, benzyl alcohol, benzoic acid, vinyl dimethicone/methicone silsesquioxane crosspolymer, ammonium acryloyldimethyltaurate/VP copolymer, propylene carbonate, fragrance, sodium olivoyl glutamate, glucose, farnesol, cetyl alcohol, stearyl alcohol, ethylhexylglycerin, phenoxyethanol, and propylene glycol.

Questions or comments?
Call toll free 888-454-4374

El sol nos da vida y luz, pero cuando se trata de tu piel, demasiada exposición puede ser perjudicial. Esta crema hidratante combina FPS 40 con ingredientes fortificantes y ricos en nutrientes para proteger y regenerar la piel. Si se siguen las indicaciones de uso y se combina con otras medidas de protección contra el sol, se disminuye el riesgo de cáncer en la piel y el envejecimiento prematuro de la piel causado por el sol.

- Libre de crueldad—nunca son probados en animales
- Libre de parabenos, sulfatos y ftalatos
- Libre de gluten
- Fórmula vegana



akwä™

DAYSTAR SHADE™
SPF 40
Moisturizing Sunscreen

REAL STEP 6

2 fl oz (60 ml)

Other Uses: As the last step of your morning skincare regimen, apply desired amount to your fingertips and evenly distribute across your face, neck, chest, and the tops of your hands to achieve uniform coverage. Follow with makeup as desired and reapply throughout the day as needed.

The sun brings us life and light, but when it comes to your skin, too much of a good thing can be damaging. This moisturizer combines broad spectrum SPF 40 with fortifying, nutrient-rich ingredients to protect and replenish. If used as directed with other sun protection measures, it decreases the risk of skin cancer and early skin aging caused by the sun.

- Cruelty-free—never tested on animals
- Paraben-free, sulfate-free, and phthalate-free
- Gluten-free
- Vegan formula

SHIELD • SHADE • REBEL

AKWA DAYSTAR SHADE SPF 40

homosalate, zinc oxide, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54997-410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9.425 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
C14-22 ALCOHOLS (UNII: B1K89384R)	
ISODODECANE (UNII: A8289P68Y2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CANOLA OIL (UNII: 331KBJ17RK)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

OLEIC ACID (UNII: 2UMI9U37CP)	
PALMITIC ACID (UNII: 2V16EO95H1)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
LEVOMENOL (UNII: 24WE03BX2T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERYL TRIOLEATE (UNII: O05EC62663)	
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54997-410-02	1 in 1 CARTON	06/02/2020	
1	NDC:54997-410-01	60 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	M020	06/02/2020	

Labeler - 4-Life Reasearch USA, LLC (618510226)

Registrant - Northwest Cosmetic Laboratories, LLC dba Elevation Labs, Idaho (929572014)

Establishment

Name	Address	ID/FEI	Business Operations
Northwest Cosmetic Laboratories, LLC dba Elevation Labs, Idaho		929572014	manufacture(54997-410) , pack(54997-410)

Revised: 11/2022

4-Life Reasearch USA, LLC