ATOMY SUNSCREEN BEIGE BROAD SPECTRUM SPF 50 PLUS- homosalate, octisalate, titanium dioxide, zinc oxide cream ATOMY CO., LTD.

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.

ACTIVE INGREDIENTS

HOMOSALATE 7.50% OCTISALATE 4.50% TITANIUM DIOXIDE 2.20% ZINC OXIDE 12.70%

INACTIVE INGREDIENTS

Aqua/Water/Eau, Cyclopentasiloxane, Dipropylene Glycol, Disiloxane, Lauryl Peg-10 Tris(Trimethylsiloxy)Silylethyl Dimethicone, Glycerin, Niacinamide, Propylheptyl Caprylate, Portulaca Oleracea Extract, Silica, Dimethicone, Disteardimonium Hectorite, Magnesium Sulfate, Dicaprylyl Carbonate, 1,2-Hexanediol, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Synthetic Fluorphlogopite, Triethoxycaprylylsilane, Aluminum Hydroxide, Stearic Acid, Sorbitan Caprylate, Dimethicone/Peg-10/15 Crosspolymer, Fragrance(Parfum), Iron Oxides(Cl 77492), Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Ethylhexylglycerin, Adenosine, Iron Oxides(Cl 77491), Iron Oxides(Cl 77499), Tocopherol, Camellia Sinensis Leaf Extract, Melissa Officinalis Extract, Centella Asiatica Extract, Perilla Ocymoides Leaf Extract

PURPOSE

Sunscreen

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.

DESCRIPTION

Directions:

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours

- Use a water-resistant sunscreen if swimming or sweating
- 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 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

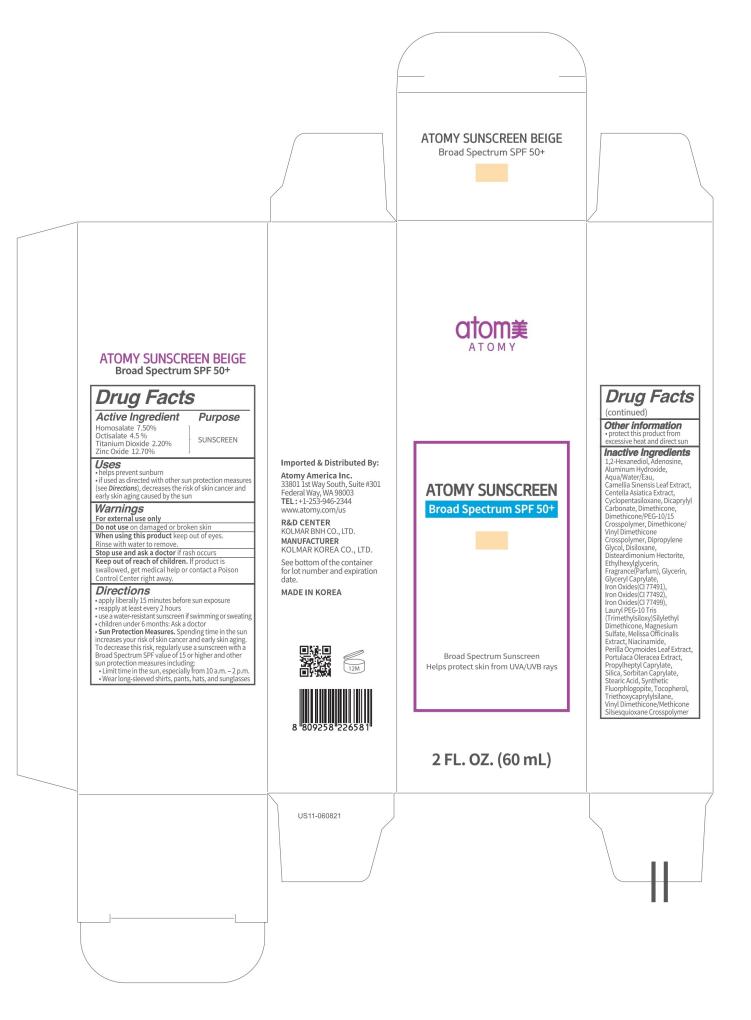
Uses:

- 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

Other Information:

Protect this product from excessive heat and direct sun

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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homosalate, octisalate, titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52257-1420
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.5 g in 60 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.7 g in 60 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.32 g in 60 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	7.62 g in 60 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
Dipropylene Glycol (UNII: E107L85C40)		

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:52257- 1420-1	60 mL in 1 CARTON; Type 0: Not a Combination Product	06/01/2021	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
art352	06/01/2021		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Labeler - ATOMY CO., LTD. (631154601)

Registrant - ATOMY CO., LTD. (631154601)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kolmar Korea Co.,LTD. Gwanjeong Factory		689512611	manufacture(52257-1420)	

Revised: 7/2021 ATOMY CO., LTD.