

DR.ORACLE AIR FIT DEFENSE SOOTHING SUNSCREEN- homosalate, octyl salicylate, titanium dioxide, zinc oxide cream
Oracle Cosmetic Co., Ltd.

Dr.Oracle AIR FIT DEFENSE SOOTHING SUNSCREEN

Active ingredients

Homosalate 7.5 %

Octyl salicylate 4.5 %

Titanium dioxide 2.2 %

Zinc oxide 12.7 %

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 skin 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

Keep out of reach of children

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

Directions

- apply liberally 15 minutes before sun exposure. **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
- children under 6 months of age: Ask a doctor
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

Other information

- protect the product from excessive heat and direct sun
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Water, Cyclopentasiloxane, Coco-Caprylate/Caprates, Dipropylene Glycol, Lauryl PEG-10 Tris(trimethylsiloxy)silyl ethyl Dimethicone, Glycerin, Niacinamide, Butyloctyl Salicylate, Methyl Methacrylate Crosspolymer, Dist- eardimonium Hectorite, Magnesium Sulfate, Vinyl Dimethicone/Methicone Silsesquioxane Cross- polymer, Dimethicone, 1,2-Hexanediol, Triethoxycaprylylsilane, Stearic Acid, Aluminum Hydroxide, Sorbitan Caprylate, Dimethicone/PEG- 10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Ethylhexylglycerin, Sodium Citrate, Tocopherol

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.35 g in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.1 g in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3.75 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN MONOCAPRYLATE (UNII: 1VTA8DCP5Q)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACINAMIDE (UNII: 25X51I8RD4)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71883-050-02	1 in 1 BOX	09/26/2024	
1	NDC:71883-050-01	50 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 Drug	M020	09/26/2024	

Labeler - Oracle Cosmetic Co., Ltd. (688258270)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd		963271745	manufacture(71883-050)

Revised: 2/2026

Oracle Cosmetic Co., Ltd.