

**SONAGE ROUX TINTED DAY CREME WITH SPF 30 SHEER TINTED
MOISTURIZER- zinc oxide lotion
ASA Universal Inc. dba: Sonage**

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.

Sonage - SPF 30 Roux Tinted Day Crème (15-EC-080)

Zinc Oxide - 13.0%

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.

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 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

Rapply at least every 2 hours.

Children under 6 monts: 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. to 2 p.m. Wear long-sleeved shirts, pants, hats, and sun glasses.

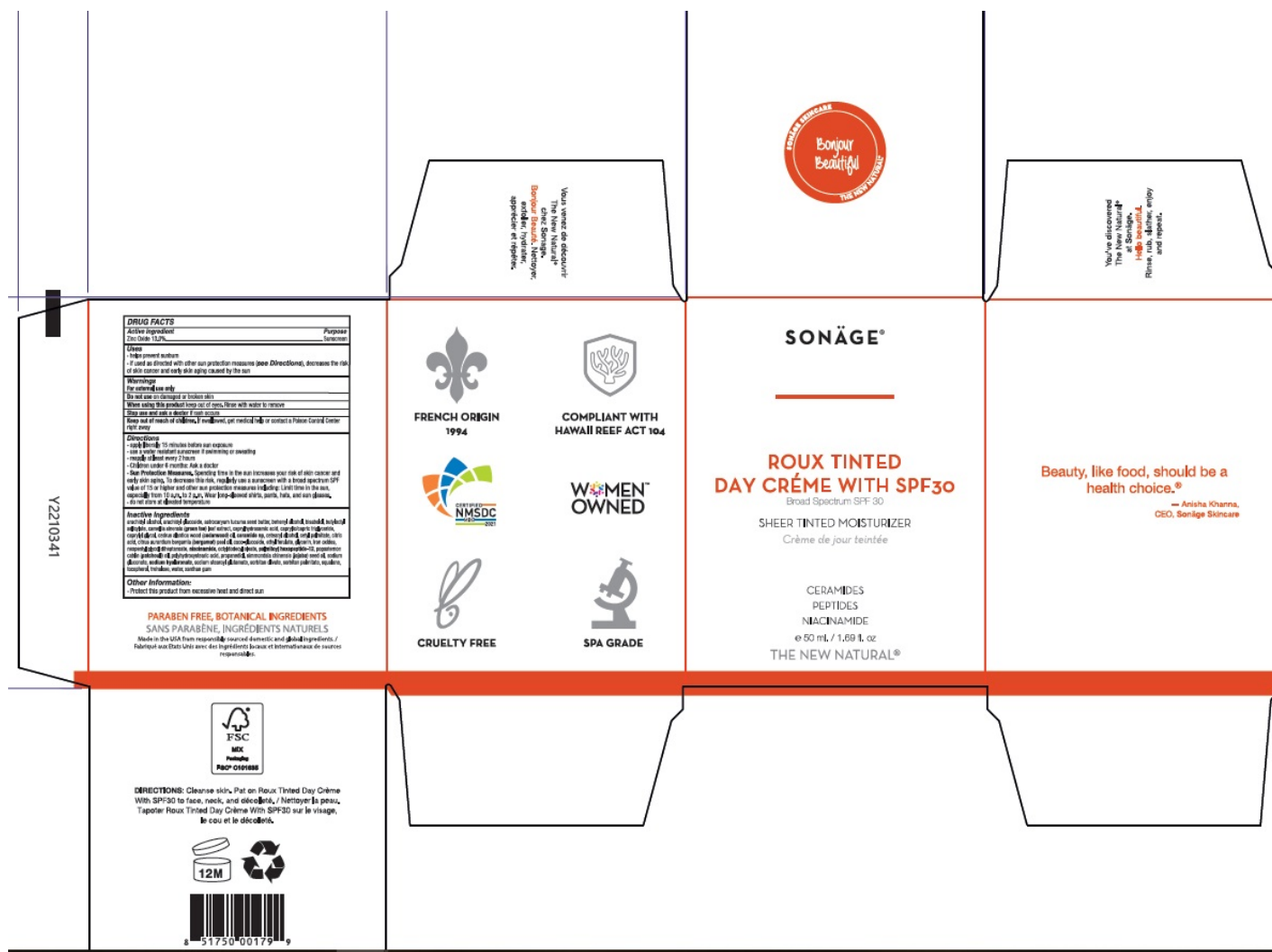
Inactive Ingredients

Arachidyl Alcohol, Arachidyl Glucoside, Astrocaryum Tucuma Seed Butter, Behenyl

Alcohol, Bisabolol, Butyloctyl Salicylate, Camellia Sinensis (Green Tea) Leaf Extract, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cedrus Atlantica Wood (Cedarwood) Oil, Ceramide NP, Cetearyl Alcohol, Cetyl Palmitate, Citric Acid, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Coco-Glucoside, Ethyl Ferulate, Glycerin, Iron Oxides, Neopentyl Glycol Diheptanoate, Niacinamide, Octyldodecyl Oleate, Palmitoyl Hexapeptide-12, Pogostemon Cablin (Patchouli) Oil, Polyhydroxystearic Acid, Propanediol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Gluconate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Sorbitan Oliviate, Sorbitan Palmitate, Squalane, Tocopherol, Trehalose, Water, Xanthan Gum

Other Information

Protect this product from excessive heat and direct sun.



SONAGE ROUX TINTED DAY CREME WITH SPF 30 SHEER TINTED MOISTURIZER

zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69546-313

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TREHALOSE (UNII: B8WCK70T7I)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LEVOMENOL (UNII: 24WE03BX2T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO GLUCOSIDE (UNII: ICS790225B)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PROPANEDIOL (UNII: 5965N8W85T)	
SQUALANE (UNII: GW89575KF9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
DOCOSANOL (UNII: 9G1OE216XY)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CERAMIDE NP (UNII: 4370DF050B)	
ETHYL FERULATE (UNII: 5B8915UELW)	
ASTROCARYUM ACULEATUM SEED OIL (UNII: JUP28JXP3K)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
JOJOBA OIL (UNII: 724GKU717M)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CEDRUS ATLANTICA WOOD OIL (UNII: JEX140NPX8)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)	

POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69546-313-02	1 in 1 CARTON	06/08/2023	
1		50 mL in 1 JAR; 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	06/08/2023	

Labeler - ASA Universal Inc. dba: Sonage (054687895)

Revised: 6/2023

ASA Universal Inc. dba: Sonage