GLOW GO LIP OIL SPF50- avobenzone 30mg/g, homosalate 100mg/g, octocrylene 100mg/g, octisalate 50mg/g, (sunscreens) oil NAKED SUNDAY PTY 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.

NAKED SUNDAYS SPF50+ Glow + Go Lip Oil

ACTIVE INGREDIENTS

AVOBENZONE 3 %
HOMOSALATE 10%
OCTISALATE 5 %
OCTOCRYLENE 10%

PURPOSE

SUNSCREEN

USE

- Helps prevents sunburn
- If used as directed with other sun protection measures (see directions) decreases the risk of skin cancer and early skin ageing caused by the sun.

WARNINGS

FOR EXTERNAL USE ONLY

- Do not use on damaged or broken skin.

keep out of eyes, Rinse with water to remove

Stop use & ask doctor

If rash occurs

If product is swallowed, get medical help or contact a poison control center right away

Directions

- Apply 20 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating

- Re-apply frequently especially after swimming excercising or towel drying
- Re-apply at least every 2 hours
- Children under 6 months of age- 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 inclusing:

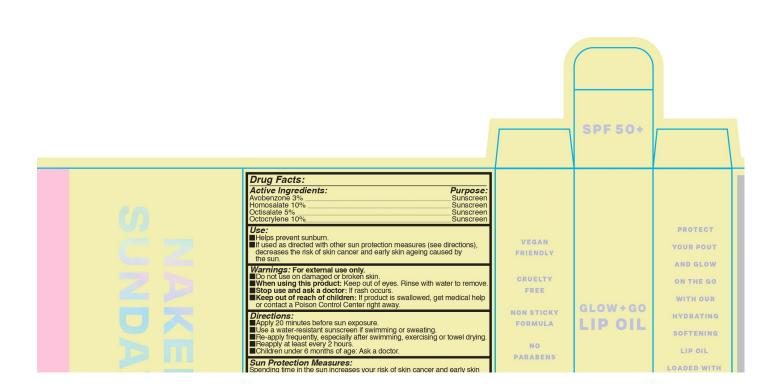
- limit time in the sun, especially from 10:00 AM- 02:00 PM
- Wear long- Sleeved shirts, pants, Hats and sunglasses

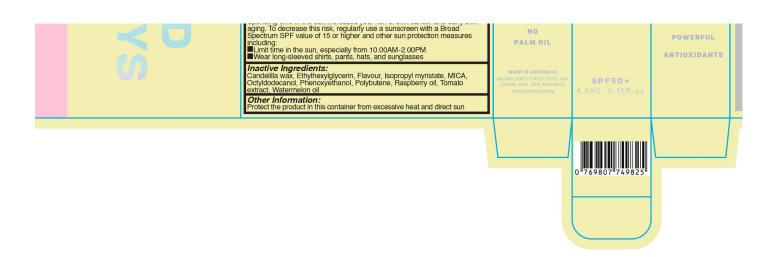
Ingredients

Candelilla wax, Ethylhexylglycerin, Flavour, Isopropyl myristate, MICA, Octyldodecanol, Phenoxyethanol, Polybutene, Raspberry oil, Tomato extract, Watermelon oil

Protect the product in this container from excessive heat & direct sun

Label





Label

GLOW GO LIP OIL SPF50

avobenzone 30mg/g, homosalate 100mg/g, octocrylene 100mg/g, octisalate 50mg/g, (sunscreens) oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81104-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 g in 100 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CANDELILLA WAX (UNII: WL0328HX19)		

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
TOMATO EXTRACT CONTAINING LYCOPENE (UNII: N53I4V2IA6)	
WATERMELON SEED OIL (UNII: L33J06UQTT)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:81104-111- 02	4.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2021	

Labeler - NAKED SUNDAY PTY LTD (746918845)

Establishment				
Name	Address	ID/FEI	Business Operations	
WLD CHILD W A PTY LTD		744660692	manufacture(81104-111) , relabel(81104-111)	

Revised: 9/2021 NAKED SUNDAY PTY LTD