HYDRATING LIP BALM SPF 15 SUNSCREEN ASAP- avobenzone, homosalate, octocrylene, octis alate gel

AUSTRALIAN SKIN PRODUCTS PTY LTD

Purpose

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

hydrating lip balm SPF 15 Sunscreen

8	
Avobenzone 3.5%	Sunscreen
Homosalate 5.0%	Sunscreen
Octocrylene 5.0%	Sunscreen
Octisalate 5.0%	Sunscreen

Uses: Helps prevent sunburn and chapped lips. 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.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs.

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

Directions

Apply Liberally to lips as often as desired

Apply liberally 15 minutes before sun exposure

Reapply: at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

Sun Protectection measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly

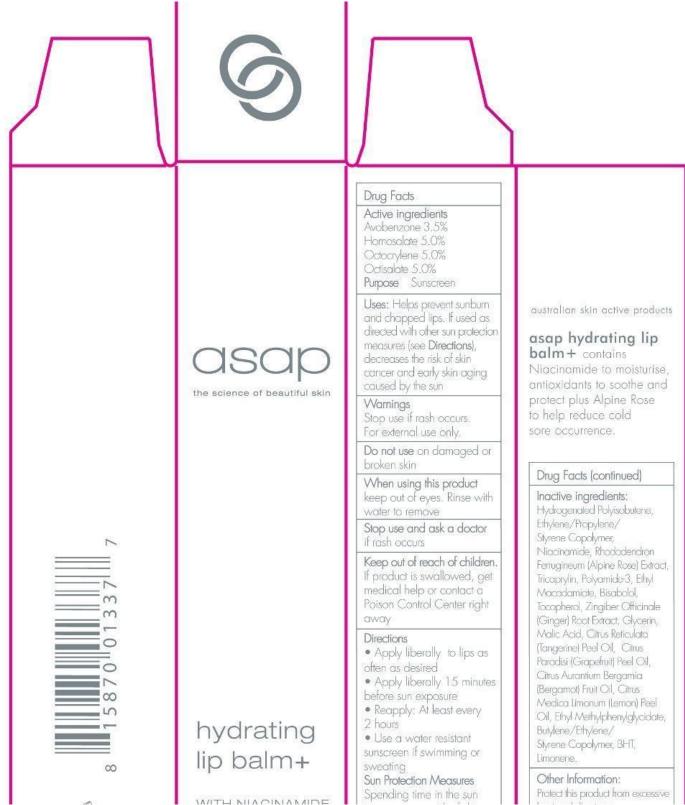
use a sunscreen with a broad spectrum SPF 15 or higher and other skin protection measures including:

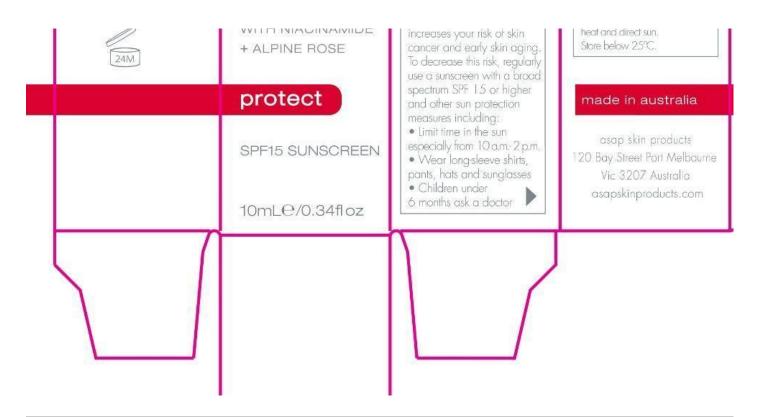
- Limit time in the sun especially from 10 a.m. -2 p.m.
- Wear long-sleeve shirts, pants, and sunglasses
- Children under 6 months ask a doctor

Hydrogenated Polysiobutene, Ethylene/Propylene/Styrene Copolymer, Nicinamide, Rohododendron Ferruineum (Alpine Rose) Extract, Tricaprylin, Polyamide-3, Ethyl Macadamiate, Bisabolol, Tocopherol, Zingiber Officinale (Ginger) Root Extract, Glycerin, Malic Acid, Citrus Reticulata (Tangerine) Peel Oil, Citrus Paradisi (Grapefruit) Peel Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Medica Limonium (Lemon) peel Oil, Ethyl Methylphenylglycidate, Butylene/Ethylene/Styrene Copolymer, BHT,limonene.

asap
the science of beautiful
hydrating lip balm+
with niacinamide +Alpine Rose
protect
SPF 15 SUNSCREEN

10mL/0.34floz





HYDRATING LIP BALM SPF 15 SUNSCREEN ASAP

avobenzone, homosalate, octocrylene, octisalate gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76261-127
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.5 g in 100 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 g in 100 mL		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5.0 g in 100 mL		
OCTISALATE (UNII: 4X49 Y0 59 6 W) (OCTIS ALATE - UNII: 4X49 Y0 59 6 W)	OCTISALATE	5.0 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
HYDRO GENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)		
NIACINAMIDE (UNII: 25X51I8 RD4)		
TRICAPRYLIN (UNII: 6P92858988)		
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)		
.ALPHABISABOLOL, (+)- (UNII: 105S6I733Z)		
TOCOPHEROL (UNII: R0ZB2556P8)		
GINGER (UNII: C5529G5JPQ)		
MALIC ACID (UNII: 817L1N4CKP)		
MANDARIN O IL (UNII: NJO720F72R)		
GRAPEFRUIT OIL (UNII: YR377U58W9)		

BERGAMOT OIL (UNII: 39W1PKE3JI)		
LEMON OIL (UNII: 19 GRO 8 2 4 LL)		
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76261-127-02	1 in 1 CARTON		
1	NDC:76261-127-01	10 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/07/2014	

Labeler - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

Registrant - AUSTRALIAN SKIN PRODUCTS PTY LTD (752403019)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natural Beauty Care Pty Ltd		749369716	manufacture(76261-127)	

Revised: 8/2014 AUSTRALIAN SKIN PRODUCTS PTY LTD