

MARK GLOSSWORKS LIP GLOSS- octinoxate, avobenzone, octisalate lipstick
Avon Products, Inc

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 ingredient

Octinoxate 1.0%.....

Avobenzone 0.5%.....

Octisalate 0.5%.....

Purpose

.....Sunscreen

.....Sunscreen

.....Sunscreen

Uses

- helps prevent sunburn

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
- children under 6 months of age: ask a doctor
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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

Other information

- protect the product in this container from excessive heat and direct sun

Inactive Ingredients:

ETHYLHEXYL ISONONANOATE, HYDROGENATED STYRENE/BUTADIENE COPOLYMER, HYDROGENATED POLYISOBUTENE, SILICA Silylate, CAPRYLIC/CAPRIC TRIGLYCERIDE, DICALCIUM PHOSPHATE, PARFUM/FRAGRANCE, STEARALKONIUM HECTORITE, PROPYLENE CARBONATE, SILICA, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE
SPARKLE SHADES MAY ALSO CONTAIN: TIN OXIDE, CALCIUM ALUMINUM BOROSILICATE MAY CONTAIN: MICA/CI 77019, TITANIUM DIOXIDE/CI 7789, IRON

OXIDES, RED 7 LAKE/CI 15850, RED 30 LAKE/CI 73360, YELLOW 5 LAKE/CI 19140, BLUE 1 LAKE/CI 42090

Questions or Comments?

Call toll free **1-800-FOR-AVON** or **1-800-265-AVON** in Canada

glossworks

LIP GLOSS
GLOSS LÈVRES

Broad Spectrum SPF 15 sunscreen
Écran solaire à large spectre FPS 15
3 g NET WT 0.10 OZ
DIN 02392771

mark.

INDULGE YOUR TOTAL LIP FIXATION WITH THIS MUST-HAVE GLOSS THAT SHINES AND PROTECTS WITH SPF 15.
COMBLEZ TOTALEMENT VOS LÈVRES GRÂCE À CE GLOSS INDISPENSABLE QUI LES LUSTRE ET LES PROTÈGE D'UN FPS 15.

Drug Facts	
Active ingredients	Purpose
Octinoxate 1.0%.....	Sunscreen
Avobenzone 0.5%.....	Sunscreen
Octisalate 0.5%.....	Sunscreen

Drug Facts (continued)
Uses <ul style="list-style-type: none">• helps prevent sunburn
Warnings <p>For external use only. Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p>

Drug Facts (continued)	Lift to continue/ Soulever pour continuer
Directions <ul style="list-style-type: none">• apply liberally 15 minutes before sun exposure • children under 6 months of age: ask a doctor • reapply at least every 2 hours• use a water resistant sunscreen if swimming or sweating• 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:<ul style="list-style-type: none">• limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses	

Drug Facts (continued)
Other information <ul style="list-style-type: none">• protect the product in this container from excessive heat and direct sun
Inactive ingredients: Ethylhexyl Isononanoate, Hydrogenated Styrene/Butadiene Copolymer, Hydrogenated Polyisobutene, Silica Silylate, Caprylic/Capric Triglyceride, Dicalcium Phosphate, Parfum/Fragrance, Stearalkonium Hectorite, Propylene Carbonate, Silica, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate. Sparkle Shades May Also Contain: Tin Oxide, Calcium Aluminum Borosilicate. May Contain: Mica/CI 77019, Titanium Dioxide/CI 77891, Iron Oxides, Red 7 Lake/CI 15850, Red 30 Lake/CI 73360, Yellow 5 Lake/CI 19140, Blue 1 Lake/CI 42090.

Drug Facts (continued)
Questions or Comments? <p>Call toll free 1-800-FOR-AVON or 1-800-265-AVON in Canada</p>

MARK GLOSSWORKS LIP GLOSS

octinoxate, avobenzone, octisalate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0298
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	5 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0298-2	1 in 1 CARTON		
1	NDC:10096-0298-1	3 g in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/29/2013	

Labeler - Avon Products, Inc (001468693)

Establishment

Name	Address	ID/FEI	Business Operations
Intercos America, Inc		883457061	manufacture(10096-0298)

Revised: 3/2013

Avon Products, Inc