

MARY KAY TIMEWISE DAYTIME DEFENDER SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone/octisalate/octocrylene lotion

Mary Kay 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.

Mary Kay TimeWise Daytime Defender Sunscreen Broad Spectrum SPF 30

Active ingredients

Avobenzone 3% (w/w)

Octisalate 4.5% (w/w)

Octocrylene 9% (w/w)

Purpose

Sunscreen

Uses

Helps prevent sunburn.

Warnings

For external use only.

Do not use

on broken skin.

When using this product

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor

if rash occurs.

Keep out of reach of children.

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

Directions

Adults and children over 6 months of age: ■ apply liberally 15 minutes before sun exposure ■ use a water-resistant sunscreen if swimming or sweating ■ reapply at least

every 2 hours ■ 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 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-sleeve shirts, pants, hats and sunglasses ■ children under 6 months: Ask a doctor

Other information

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

Inactive ingredients

water/eau/aqua, propanediol, glycerin, silica, caprylyl methicone, cetareth-25, aluminum starch octenylsuccinate, ammonium acryloyldimethyltaurate/VP copolymer, beeswax/cire d'abeille/cera alba, glyceryl stearate, niacinamide, dimethicone, phenoxyethanol, disodium ethylene dicocamide PEG-15 disulfate, VP/eicosene copolymer, hydroxyacetophenone, opuntia ficus-indica fruit extract, xanthan gum, disodium EDTA, ethylhexylglycerin, saccharomyces cerevisiae extract, sucrose stearate, alcohol, dipropylene glycol, ethyl macadamiate, resveratrol, sodium benzoate, tocopheryl acetate, oligopeptide-1.

Questions?

1-800-627-9529

Principal Display Panel - 29 ml carton

Mary Kay

TimeWise

DAYTIME DEFENDER

SUNSCREEN

BROAD SPECTRUM SPF 30

1 FL. OZ. / 29 mL

DAYTIME DEFENDER
SUNSCREEN
BROAD SPECTRUM SPF 30

PROTECTEUR DE JOUR
AVEC ÉCRAN SOLAIRE
À LARGE SPECTRE FPS 30

217385

**Drug Facts (continued) /
Info-médicament (suite)**

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. /

Lorsque vous utilisez ce produit éviter tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau.

Stop use and ask a doctor if rash occurs. / Cessez d'utiliser et consultez un médecin si une éruption cutanée se développe.

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

Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

Directions / Mode d'emploi
Adults and children over 6 months of age:

■ apply liberally 15 minutes before sun exposure
■ use a water-resistant sunscreen if swimming or sweating

■ reapply at least every 2 hours

■ 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 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-sleeve shirts, pants, hats and sunglasses

■ children under 6 months: Ask a doctor /

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**Drug Facts (continued) /
Info-médicament (suite)**

Adultes et enfants de plus de 6 mois :

- appliquer généreusement 15 minutes avant l'exposition au soleil
- utiliser un écran solaire résistant à l'eau si vous nagez ou transpirez
- réappliquer au moins toutes les 2 heures.

■ Mesures de protection solaire : Passer du temps au soleil augmente votre risque de cancer de la peau et le vieillissement précoce de la peau. Pour diminuer ce risque, utilisez régulièrement un écran solaire avec un SPF à large spectre de 15 ou plus et d'autres mesures de protection solaire comme :

- limiter le temps au soleil, en particulier entre 10 h et 14 h
- porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil

■ enfants de moins de 6 mois : consulter un médecin

**Other information /
Autres renseignements**

- protect the product in this container from excessive heat and direct sun. /
- protéger le produit dans ce contenant de la chaleur excessive et du soleil direct.

**Inactive ingredients /
Ingrédients inactifs**

water/eau/aqua, propanediol, glycerin, silica, caprylyl methicone, ceteareth-25, aluminum starch octenylsuccinate, ammonium acryloyldimethyltaurate/VP copolymer, beeswax/cire d'abeille/cera alba, glyceryl stearate, niacinamide, dimethicone, phenoxethanol, disodium ethylene dicocamide PEG-15 disulfate, VP/eicosene copolymer, hydroxyacetophenone, opuntia ficus-indica fruit extract, xanthan gum, disodium EDTA, ethylhexylglycerin, saccharomyces cerevisiae extract, sucrose stearate, alcohol, dipropylene glycol, ethyl macadamiate, resveratrol, sodium benzoate, tocopheryl acetate, oligopeptide-1.

Questions? 1-800-627-9529

MARY KAY

TIMESWISE

DAYTIME DEFENDER
SUNSCREEN
BROAD SPECTRUM SPF 30

PROTECTEUR DE JOUR
AVEC ÉCRAN SOLAIRE
À LARGE SPECTRE FPS 30

DIN 02533278

1 FL. OZ. / 29 mL

DAYTIME DEFENDER
SUNSCREEN BROAD
SPECTRUM SPF 30

with TimeWise 3D Complex

Suitable for all skin types. Oil- and fragrance-free. Broad Spectrum UVA/UVB Protection. This daily lotion helps reduce signs of premature aging with our proprietary TimeWise 3D complex. An essential step to help defend skin from environmental aggressors, it also includes skin-conditioning prickly pear extract to help strengthen skin's moisture barrier.

PROTECTEUR DE JOUR AVEC ÉCRAN SOLAIRE À LARGE SPECTRE FPS 30 enrichi du Complexe 3D TimeWise

Convient à tous les types de peaux. Sans huile et sans parfum. Protection UVA/UVB à large spectre. Cette lotion quotidienne aide à réduire les signes visibles du vieillissement prématuré de la peau grâce à notre Complexe 3D TimeWise exclusif. Étape essentielle aidant à protéger la peau contre les agresseurs environnementaux, elle renferme aussi de l'extrait de figue de Barbarie revitalisant pour renforcer la barrière d'hydratation cutanée.

**Drug Facts /
Info-médicament**

Active ingredients (w/w) / Ingrédients actifs (p/p)	Purpose / Utilité
Avobenzone 3%	Sunscreen / Ecran solaire
Octisalate 4.5%	
Octocrylene /	
Octocrylene 9%	

Uses / Usages

- Helps prevent sunburn. /
- Aide à prévenir les coups de soleil.

Warnings / Mises en garde

For external use only. /
Pour usage externe seulement.
Do not use on broken skin. /
Ne pas utiliser sur une peau éraillée.

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"(L) XXXX"
"EXP.MM/YYYY"

MARY KAY TIMESWISE DAYTIME DEFENDER SUNSCREEN BROAD SPECTRUM SPF 30

avobenzone/octisalate/octocrylene lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51531-7385

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PRICKLY PEAR FRUIT (UNII: 18V8PAQ629)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
RESVERATROL (UNII: Q369O8926L)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETEARETH-25 (UNII: 8FA93U5T67)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SUCROSE STEARATE (UNII: 274KW0050M)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-7385-1	1 in 1 CARTON	07/20/2023	
1		29.783 g in 1 BOTTLE, PUMP; 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	07/20/2023	

Labeler - Mary Kay Inc. (049994452)

Establishment

Name	Address	ID/FEI	Business Operations
Mary Kay Inc.		103978839	manufacture(51531-7385)

Revised: 9/2023

Mary Kay Inc.