

**SPF 50 UVA/UVB- ensulizole, oxybenzone, avobenzone, octocrylene cream
MULTALER ET CIE S.A.S.**

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.

DRUG FACTS

Active ingredients Purpose

Ensulizole 3% {

Oxybenzone 5% { Sunscreen

Avobenzone 3% {

Octocrylene 8% {

SOLAR CARE

SPF 50 UVA/UVB

BROAD SPECTRUM

CREME SOLAIRE

Haute Protection

aux 3 thés

SUNSCREEN CREAM

High protection

with 3 teas

Crème solaire aux 3 thés.

Haute protection SPF 50.

Sunscreen cream with 3 teas.

High protection SPF 50

Crema solar con 3 tés.

Alta proteccion SPF 50.

Sonnencreme mit dreierlei Tee.

Hoher Schutz SPF 50.

Crema solare con 3 tè.

Alta Protezione SPF 50.

Zonnen crème met 3 theesorten.

Hoge Bescherming SPF 50.

Crème solaire à base de 3 chas.

Alta protecção SPF 50.

Aide à prévenir les coups de soleil.

Appliquer généreusement avant toute exposition. Renouveler fréquemment et généreusement l'application pour maintenir la protection, surtout après avoir transpiré, avoir nagé ou s'être essuyé. Pour les enfants de moins de 6 mois, consulter un médecin.

Avertissement : Pour usage externe seulement. Éviter tout contact avec les yeux. En cas de contact, rincer abondamment. Cesser d'utiliser et consulter un médecin en cas d'irritations ou d'éruptions cutanées. Tenir hors de la portée des enfants. En cas d'absorption, consulter un médecin ou le centre anti-poisons.

Recommandations : Éviter de trop vous exposer aux heures les plus chaudes de la journée. Ne restez pas trop longtemps au soleil. même si vous utilisez un produit de protection solaire. Protégez-vous avec un chapeau, un t-shirt et des lunettes de soleil. N'exposez pas les bébés et les jeunes enfants directement au soleil. La surexposition au soleil est une menace sérieuse pour la santé.

CONTIENT BENZOPHENONE-3

CONTAINS BENZOPHENONE-3

NON COMEDOGENE

NON COMEDOGENIC

TOLERANCE TESTEE SOUS CONTROLE DERMATOLOGIQUE

TOLERANCE TESTED BY DERMATOLOGISTS

Uses • helps prevent sunburn.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes.

Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Children under 6 months : 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-2p.m
- wear long-sleeved shirts, pants, and sunglasses.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

AQUA/WATER/EAU,
C12-15 ALKYL BENZOATE ,
GLYCERYL STEARATE,

PPG-12/SMDI COPOLYMER,
 GLYCERIN ,
 PEG-100 STEARATE,
 TROMETHAMINE,
 MAGNESIUM ALUMINUM SILICATE,
 PROPYLENE GLYCOL,
 PRUNUS ARMENIACA (APRICOT) KERNEL OIL,
 SORBITAN STEARATE,
 CAPRYLYL GLYCOL,
 BISABOLOL,
 DIMETHICONE,
 CHLORPHENESIN,
 XANTHAN GUM,
 SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE
 COPOLYMER,
 TOCOPHERYL ACETATE ,
 PANTHENOL,
 CAPRYLHYDROXAMIC ACID,
 CAMELLIA SINENSIS LEAF EXTRACT,
 ISOHEXADECANE,
 TETRASODIUM EDTA,
 RETINYL PALMITATE,
 DIPOTASSIUM GLYCYRRHIZATE,
 MALTODEXTRIN,
 POLYSORBATE 80,
 ASPALATHUS LINEARIS LEAF EXTRACT ,
 HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL,
 PANTOLACTONE,
 TOCOPHEROL.





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Ingredients Aqua/water/eau, c12-15 alkyl benzoate, octocrylene, glyceryl stearate, benzophenone-3 /oxybenzone, ppg-12/smdi copolymer, glycerin, butyl methoxydibenzoylmethane/avobenzone, phenylbenzimidazole sulfonic acid/ensulizole, peg-100 stearate, tromethamine, magnesium aluminum silicate, propylene glycol, prunus armeniaca (apricot) kernel oil, sorbitan stearate, caprylyl glycol, bisabolol, dimethicone, chlorphenesin, xanthan gum, sodium acrylate/ sodium acryloyldimethyl taurate copolymer, tocopheryl acetate, panthenol, caprylhydroxamic acid, camellia sinensis leaf extract, isohexadecane, tetrasodium edta, retinyl palmitate, dipotassium glycyrrhizate, maltodextrin, polysorbate 80, aspalathus linearis leaf extract, helianthus annuus (sunflower) seed oil, pantolactone, tocopherol.

Other information

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50ml-solaires26502 USA Fr.ap RC SOLAIR 4 GRIS Vernis Mat trace

APPROUVÉ

EDELMANN

CAO : AZ26239_A
VALIDATION : 11/10/2011
CLIENT : MULTALER
LIGNE : SOIN
PRODUIT : TUBE 50 ML
FORMAT : 41 X 41 X 130

SPF 50 UVA/UVB

ensulizole, oxybenzone, avobenzone, octocrylene cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51191-3015

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WW9CM0067Z)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROMETHAMINE (UNII: 023C2WHX2V)	
PANTOLACTONE, (+/-)- (UNII: IID733HD2M)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51191-3015-1	50 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/15/2013	

Labeler - MULTALER ET CIE S.A.S. (509613345)

Registrant - MULTALER ET CIE S.A.S. (509613345)

Establishment

Name	Address	ID/FEI	Business Operations
MULTALER ET CIE S.A.S.		509613345	manufacture(51191-3015) , label(51191-3015)

Revised: 5/2021

MULTALER ET CIE S.A.S.