

CELESTY SUN PROTECTION SERIES SOLAR PROTECTION CREAM SPF 50- homosalate, avobenzone, octocrylene, octinoxate cream
MABA KOZMETIK LIMITED SIRKETI

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.

Celesty SUN PROTECTION series SOLAR PROTECTION CREAM SPF 50

Drug Facts:

Active Ingredients

Homosalate: 8%

Avobenzone: 2,66%

Octocrylene: 6,98%

Octinoxate: 7,36%

Purpose

Sunscreen

Use

Helps prevent sunburn.

Warnings

For external use only.

Do not use on damaged or broken skin.

When using this product keep out 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 minimum 30 minutes before sun exposure. • Repeat every 4 hours. • Reapply after swimming or sweating.

Other Information

Protect this product from excessive heat and direct sun. May stain some fabrics.

Inactive Ingredients

Water\Aqua\Eau, Cyclopentasiloxane, Butylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Glycerin, Polysorbate 60, Polyhydroxystearic Acid, Allantoin, Dimethicone, Squalene, Bisabolol, Tocopheryl Acetate (Vitamin E), Stearic Acid, Propylene Glycol, Biosaccharide Gum-1, Triethanolamine, Panthenol

(Pro Vitamin B5), Phenoxyethanol, Carbomer, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, Aloe Barbadensis Leaf Juice, Peg-8, Tocopherol (Vitamin E), Ascorbyl Palmitate, Ascorbic Acid, Disodium EDTA, Camallia Sinensis Leaf Extract, BHT, Citric Acid.

shield with

GREEN TEA

ALOE VERA

BISABOLOL

BEAUTY CARE

SOLAR PROTECTION CREAM SPF 50 (DRY/NORMAL SKIN)

Sun protection cream for dry and normal skin types. Enriched with Aloe Vera and Green Tea. Suitable for face and body.

Brace **Beauty**, Embrace **Purity**.

www.celesty.com

Made in TURKEY

MABA KOZMETIK A.S.

ESENTEPE MAH. YUZBASI KAYA ALDOGAN SOK.

ONUR IS MERKEZI NO:12 D:8 ISTANBUL

Distributed by CELESTY LLC

3970 NW 167TH ST. MIAMI GARDENS,

FL 33054 - USA

info@celesty.com

Packaging

INNER PACKAGE LABEL

 SUN PROTECTION series SOLAR PROTECTION CREAM SPF 50	Drug Facts: <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Homosalate: 8%</td><td rowspan="4">Sunscreen</td></tr><tr><td>Avobenzone: 2.66%</td></tr><tr><td>Octocrylene: 6.98%</td></tr><tr><td>Ocinoxate: 7.36%</td></tr></tbody></table> <p>Use Helps prevent sunburn.</p> <p>Warnings 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 swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ Apply minimum 30 minutes before sun exposure. ■ Repeat every 4 hours. ■ Reapply after swimming or sweating.</p> <p>Other Information Protect this product from excessive heat and direct sun. May stain some fabrics.</p> <p>Inactive Ingredients Water/Aqua/Eau, Cyclopentasiloxane, Butylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Glycerin, Polysorbate 60, Polyhydroxystearic Acid, Allantoin Dimethicone, Squalene, Bisabolol, Tocopheryl Acetate (Vitamin E), Stearic Acid, Propylene Glycol, Biosaccharide Gum-1, Triethanolamine, Panthenol (Pro Vitamin B5), Phenoxyethanol, Carbomer, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, Aloe Barbadensis Leaf Juice, Peg-8, Tocopherol (Vitamin E), Ascorbyl Palmitate, Ascorbic Acid, Disodium EDTA, Camallia Sinensis Leaf Extract, BHT, Citric Acid.</p>	Active Ingredients	Purpose	Homosalate: 8%	Sunscreen	Avobenzone: 2.66%	Octocrylene: 6.98%	Ocinoxate: 7.36%
Active Ingredients	Purpose							
Homosalate: 8%	Sunscreen							
Avobenzone: 2.66%								
Octocrylene: 6.98%								
Ocinoxate: 7.36%								
GREEN TEA ALOE VERA BISABOLOL								
 BEAUTY CARE								
75 ml e 2.5 fl.oz.								
	www.celesty.com Made in TURKEY MABA KOZMETIK A.S. ESENTEPE MAH. YUZBASI KAYA ALDOGAN SOK. ONUR IS MERKEZI NO:12 D:8 ISTANBUL Distributed by CELESTY LLC 3970 NW 167 TH ST. MIAMI GARDENS, FL 33054 - USA  info@celesty.com 							

OUTER PACKAGE LABEL



CELESTY SUN PROTECTION SERIES SOLAR PROTECTION CREAM SPF 50

homosalate, avobenzone, octocrylene, octinoxate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:8 1120-110

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.6 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	69.8 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	73.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALLANTOIN (UNII: 344S277G0Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SQUALENE (UNII: 7QWM220FJH)	
LEVOMENOL (UNII: 24WE03BX2T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
TROLAMINE (UNII: 9O3K93S3TK)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:8 1120-110-01	1 in 1 BOX	12/07/2020	
1		75 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/07/2020	

Labeler - MABA KOZMETIK LIMITED SIRKETI(503001418)

Establishment

Name	Address	ID/FEI	Business Operations
MABA KOZMETIK LIMITED SIRKETI		503001418	manufacture(8 1120-110)

Revised: 12/2020

MABA KOZMETIK LIMITED SIRKETI