

**SKIN MD- octinoxate, octisalate, homosalate lotion
21st Century Formulations**

**21st Century Formulations - Skin MD Shielding Lotion (44099-011) DELIST 03,
04 & 05.**

Active ingredients

Octinoxate 7%

Octisalate 5%

Homosalate 3%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Decreases the risk of skin cancer and early aging caused by the sun.

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

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.

Spending time in the sun increases your risk of skin cancer and early skin aging.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Water (aqua), Aloe Barbadensis Leaf Extract (Aloe Vera), Cyclopentasiloxane, Dimethicone, Methyl Gluceth-20, Extracts of Arnica Montana Flower (Arnica), Symphytum Officinale Leaf (Camfrey), Chamomilla Recutita (Matricaria Chamomile), Achillea Millefolium (Yarrow), Chondrus Crispus (Carrageenan), Tocopheryl Acetate (Vitamin E), Sorbitan Oleate, 1,2 Hexanediol, Caprylyl Glycol, Butylene Glycol, Aminomethyl Propanol, Phenoxyethanol (preservative), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Bis-Hydroxyethoxypropyl Dimethicone.

Questions?

Call toll free 1-800-540-4790

®2013 Made in USA

21st Century Formulations

Beverly Hills, CA 90210

www.skinmdnatural.com

+SPF15



Shielding Lotion

Sunscreen

Providing super-hydrating non-greasy, relief and serious protection for sensitive skin



Aloe Vera, Comfrey, Yarrow, Chamomile and Arnica

117 ml e 4 oz



Drug Facts	
Active Ingredients	Purpose
Octinoxate 7% Octisalate 5% Homosalate 3%	Sunscreen
Uses	
Helps prevent sunburn.	
Warnings	
Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. 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 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	
Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours.	
Inactive Ingredients:	
Deionized water (Aqua), Aloe Barbadensis Leaf Extract (Aloe Vera), Cyclopentasiloxane, Dimethicone, Methyl Gluceth-20, Arnica Montana Flower Extract (Arnica), Symphytum Officinale Leaf Extract (Comfrey), Chamomilla Recutita (Matricaria) Extract (Chamomile), Achillea Millefolium Extract (Yarrow), Chondrus Crispus (Carrageenan), Tocopheryl Acetate (Vitamin E), Sorbitan Oleate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 1,2 Hexanediol, Caprylyl Glycol, Butylene Glycol, Aminomethyl Propylol, Phenoxyethanol	
Other Information:	
Protect this product from excessive heat and direct sun.	
Questions or comments? Call toll free 1-800-540-6790	
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SKIN MD

octinoxate, octisalate, homosalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44099-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 mg in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
COMFREY LEAF (UNII: DG4F8T839X)	
CHAMOMILE (UNII: FGL3685T2X)	
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
BIS-HYDROXYETHOXYPROPYL DIMETHICONE (37 CST) (UNII: 7K226YI89Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44099-011-01	117 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2008	
2	NDC:44099-011-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2008	
3	NDC:44099-011-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2008	11/30/2025
4	NDC:44099-011-04	100 mL in 1 TUBE; Type 0: Not a Combination Product	07/16/2018	11/30/2025
5	NDC:44099-011-05	200 mL in 1 TUBE; Type 0: Not a Combination Product	07/16/2018	11/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/19/2008	

Labeler - 21st Century Formulations (039644618)