

**DERMA-E KIDS ACTIVE SUNSCREEN SPF 50- octocrylene, octisalate, avobenzone spray
Topiderm 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.

Derma-E Kids Active Sunscreen Spray SPF 50

Drug Facts

Active Ingredient

Octocrylene 10%, Octisalate 5%,
Avobenzone 3%

Purpose

Sunscreen

Uses

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions),decreases the risk of skin cancer and early skin aging caused by the sun.

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 consult physician

if irritation or rash develops.

Keep out of reach of children.

If product is swallowed, get medical attention or contact poison control center immediately.

Directions

- Apply liberally 15-minutes before sun exposure.
- Reapply: At least every two-hours. Immediately after swimming, sweating or towel drying.
- 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 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.
 - Reapply at least every 2 hours.
 - For children under 6-months, consult a physician.

Other information

- Protect this product from excessive heat and direct sunlight.


Inactive Ingredients

Actinidia Chinensis (Kiwi) Fruit Extract, Aloe Barbadensis Leaf (Aloe Vera) Extract, Ascorbyl Palmitate (Vitamin C), Butyloctyl Salicylate, Carthamus Tinctorius (Safflower) Oil, Cocos Nucifera (Coconut) Oil, Garcinia Mangostana (Mangosteen) Extract, Hydrogenated Methyl Abietate, Linum Usitatissimum (Linseed) Oil, Lycium Barbarum (Goji) Fruit Extract, Parfum (Fragrance), Punica Granatum (Pomegranate) Extract, SD-Alcohol 40B, Tocopheryl Acetate (Vitamin E).

Questions or comments?

Call toll free 1-800-933-9344 or visit **dermae.com**

Package Labeling:



100% VEGAN • SOY-FREE
ECO-ETHICAL
CRUELTY-FREE

DERMA·E


Kids Active Sunscreen Spray

BROAD SPECTRUM SPF 50

Soothing Aloe
Nourishing Fruit Extracts
Antioxidant-Rich Vitamins C & E

spf
50
KIDS

- ✓ Non-Aerosol spray
- ✓ Ultra-sheer & lightweight
- ✓ Quick-drying & non-greasy



80
Minutes
Water
Resistant


6 FL OZ / 177 mL

Protected fun in the sun.

For active kids on-the-go, our water resistant (80 min) sunscreen spray goes on clear to protect young skin. Blended with soothing Aloe and skin-nourishing Kiwi, Mangosteen, Goji Berry and Pomegranate Fruit Extracts, our ultra-sheer sunscreen provides UVA/UVB protection while enriching delicate skin with Vitamins C & E. Our environment-friendly, non-aerosol spray is perfect for easy, even coverage for active kids.

We Suggest:

- Spray 4 inches away from body.
- Do not spray directly on face or neck. Instead, use the DERMA E Sun Defense Mineral Sunscreen SPF 30 Face.



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DERMA-E KIDS ACTIVE SUNSCREEN SPF 50

octocrylene, octisalate, avobenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
KIWI FRUIT (UNII: 71ES77LGJC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
FLAX SEED (UNII: 4110YT348C)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
PUNICA GRANATUM ROOT BARK (UNII: CLV243T1D)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-043-00	177 mL in 1 CAN; Type 0: Not a Combination Product	04/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/10/2019	

Labeler - Topiderm Inc. (049121643)

Revised: 4/2019

Topiderm Inc.