#### MEIJER KIDS BROAD SPECTRUM SPF 50 MINERAL BASED SUNSCREENoctinoxate, octisalate, zinc oxide lotion MEIJER DISTRIBUTION 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.

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#### MEIJER KIDS BROAD SPECTRUM SPF 50 MINERAL-BASED SUNSCREEN LOTION

#### Active ingredients

Octinoxate 7.5%, Octisalate 5.0%, Zinc Oxide 14.5%

#### **Purpose**

Sunscreen

#### Uses

- helps prevent sunburn
- if used as directed with othersun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging casued 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 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 liberally 15 minutes before sun exposure

- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: 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.-2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

#### Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

#### Inactive ingredients

water, propylene glycol, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, cyclopentasiloxane, cetyl PEG/PPG-10/1 dimethicone, OEG-12 dimethicone crosspolymer, triethoxycaprylylsilane, aloe barbadensis leaf juice, ethylhexyl palmitate, diazolidinyl urea, methylparaben, propylparaben, sodium chloride

#### Label

Meijer® Baby Sunscreen Lotion SPF 50 delivers broad-spectrum UVA/UVB protection with the hypoallergenic, tear-free and fragrance-free formula. We care about baby's' sensitive skin so we have formulated this lotion to moisturize as it protects. Water resistant up to 80 minutes for protection you can trust.

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Questions or comments? Call toll free 1-800-527-7731

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PID 3828347





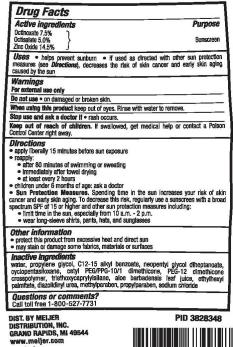
sunscreen otion

> **Broad Spectrum** SPF 50 Sunscreen

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MINERAL-BASED

Metjer® Kids Sunscreen Lotion SPF 50 delivers broad-spectrum UVA/UVB protection with the hypoallergenic, tear-free and fragrance-free formula. We care about kids' sensitive skin so we have formulated this lotion to moisturize as it protects. Water resistant up to 80 minutes for protection you can trust.





## MEIJER KIDS BROAD SPECTRUM SPF 50 MINERAL BASED SUNSCREEN

octinoxate, octisalate, zinc oxide lotion

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-362 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	145 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	

#### **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41250-362- 71	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2018		

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	11/06/2018			

## Labeler - MEIJER DISTRIBUTION INC (006959555)

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