NATURES GATE KIDS SPF 50- homosalate, octinoxate, octisalate, and zinc oxide lotion
Levlad, LLC

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.

Nature's Gate® Kids SPF 50

Drug Facts

Active ingredients

Homosalate 10%
Octinoxate 7.5%
Octisalate 5%
Zinc oxide 10%

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 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 and evenly 15 minutes before sun exposure
- reapply:
  - after 40 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

Inactive ingredients

aloe barbadensis leaf juice, benzyl alcohol, calendula officinalis flower extract, caprylhydroxamic acid, chamomilla recutita (matricaria) flower extract, coco-caprylate, copernicia cerifera (carnauba) wax, glycerin, magnesium sulfate, phytic acid, polyglyceryl-2 dipolyhydroxystearate, polyglyceryl-4 isostearate, rosmarinus officinalis (rosemary) leaf extract, sodium chloride, tocopheryl acetate, water.

Questions or comments?

1 (800) 327-2012
Monday – Friday 8 a.m. – 5 p.m. PST

Distributed by Nature's Gate

PRINCIPAL DISPLAY PANEL - 118 mL Tube Label

NATURE'S GATE®

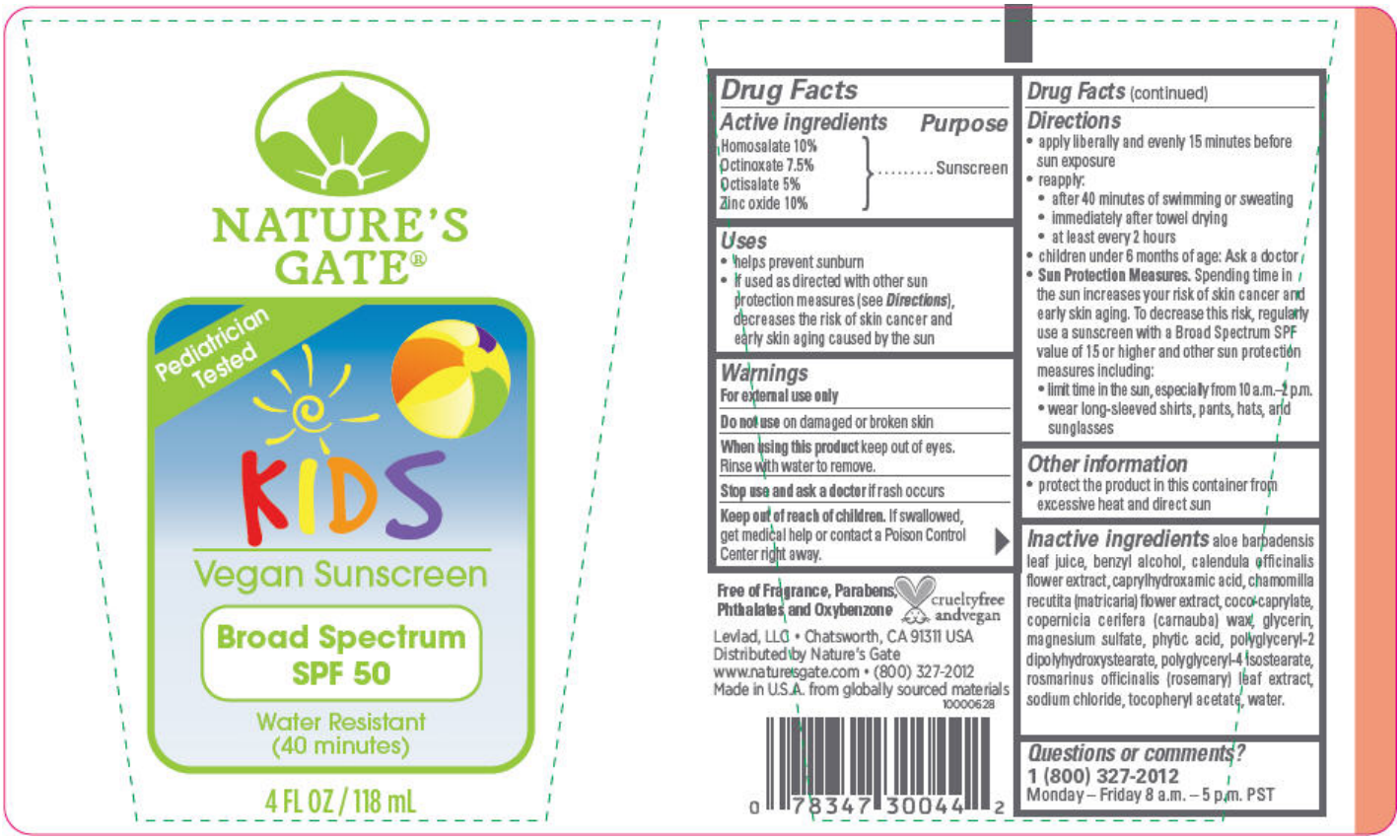
Pediatrician Tested

KIDS
Vegan Sunscreen

Broad Spectrum SPF 50

Water Resistant (40 minutes)

4 FL OZ / 118 mL



NATURES GATE KIDS SPF 50

homosalate, octinoxate, octisalate, and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61380-166
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CHAMOMILE (UNII: FGL3685T2X)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
FYTIC ACID (UNII: 7IGF0S7R8I)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ROSEMARY (UNII: IJ67X351P9)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61380-166-27	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/14/2017	

Labeler - Levlad, LLC (076245109)

Establishment

Name	Address	ID/FEI	Business Operations
Levlad, LLC		076245109	MANUFACTURE(61380-166) , ANALYSIS(61380-166) , LABEL(61380-166) , PACK(61380-166)

Revised: 6/2017 Levlad, LLC