

**SPF 50 SUNSCREEN- avobenzene, homosalate, octisalate, octocrylene, oxybenzone lotion**  
**DEMOULAS SUPER MARKETS, 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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**MARKET BASKET KIDS SPF 50 MOISTURIZING LOTION SUNSCREEN**

**☐Active ingredients**

Avobenzene 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 4.0%

**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 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, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, triethanolamine, sorbitan isostearate, benzyl alcohol, dimethicone, tocopherol (vitamin E), polyglyceryl-3 distearate, fragrance, methylparaben, carbomer, propylparaben, disodium EDTA

***Questions or comments?***

Call toll free 1-800-527-7731

MARKET BASKET KIDS SPF 50 MOISTURIZING LOTION SUNSCREEN

8 FL OZ (237mL)

NDC 53942-003-11



**SPF 50**

**KIDS 50**

- Hypoallergenic
- Water resistant (80 minutes)
- With antioxidants

**8 FL OZ (237 mL)**

**Drug Facts**

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Octisalate 5.0%  
Octocrylene 7.0%  
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**Dist. by Demoulas Supermarket Inc.  
875 East St, Tewksbury, MA 01876**



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# SPF 50 SUNSCREEN

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## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-003
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	130 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
METHYL PARABEN (UNII: A218C7H9T)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942-003-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/15/2016	

**Labeler** - DEMOULAS SUPER MARKETS, INC (007869647)

**Registrant** - FRUIT OF THE EARTH, INC. (079559467)

**Establishment**

Name	Address	ID/FEI	Business Operations
FRUIT OF THE EARTH, INC.		080086802	manufacture(53942-003)

Revised: 3/2020

DEMOULAS SUPER MARKETS, INC