

**MENTHOLATUM NATURAL ICE SPORT SPF 30- avobenzone, dimethicone, octinoxate, octisalate ointment**  
**The Mentholatum Company**

*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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**Drug Facts**

**Active ingredients**

Avobenzone 3%  
Dimethicone 1%  
Octinoxate 7.5%  
Octisalate 5%

**Purpose**

Avobenzone - Sunscreen  
Dimethicone - Skin protectant  
Octinoxate - Sunscreen  
Octisalate - Sunscreen

**Uses**

- helps prevent sunburn
- temporarily protects chapped or cracked lips

**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
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

## **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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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 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
  - children under 6 months: ask a doctor

## **Other information**

- protect this product from excessive heat and direct sun

## **Inactive ingredients**

mineral oil, ozokerite, petrolatum, tricaprln, fragrance, aloe barbadensis leaf extract, cocos nucifera (coconut) oil, cholecalciferol, menthol, retinyl palmitate, tocopheryl acetate, zea mays (corn) oil

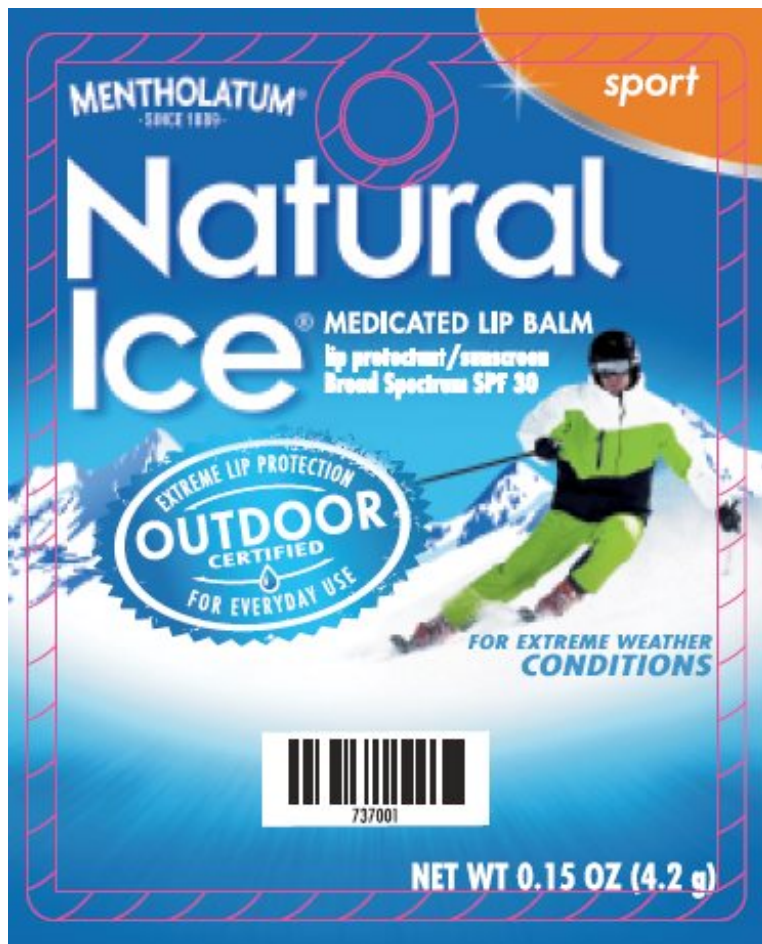
## **Questions?**

**1-877-636-2677**



MON-FRI 9 AM to 5 PM (EST)

mentholatum.com

## **Principal Display Panel**



**Principal Display Panel**

<p><b>Natural Ice<sup>®</sup> SPORT</b></p> <p>Medicated Lip Protectant/Sunscreen SPF 30</p>		<p><b>Mentholatum<sup>®</sup></b></p> <p>Manufactured By: The Mentholatum Co. Orchard Park, NY 14127</p> 									
<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Dimethicone 1%</td> <td>Skin Protectant</td> </tr> <tr> <td>Octinoxate 7.5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p><b>Uses</b> ■ helps prevent sunburn ■ temporarily protects chapped or cracked lips</p> <p><b>Warnings</b> For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p><b>Stop use and ask a doctor if</b> ■ rash occurs ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ apply liberally 15 minutes before sun exposure ■ use a water resistant sunscreen if swimming or sweating ■ reapply at least every 2 hours</p>	Active ingredients	Purpose	Avobenzone 3%	Sunscreen	Dimethicone 1%	Skin Protectant	Octinoxate 7.5%	Sunscreen	Octisalate 5%	Sunscreen	<p><b>Drug Facts (continued)</b></p> <p>■ <b>Sun Protection Measures.</b> 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 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 ■ children under 6 months: ask a doctor</p> <p><b>Other information</b> ■ protect this product from excessive heat and direct sun</p> <p><b>Inactive ingredients</b> mineral oil, ozokerite, petrolatum, tricaprin, fragrance, aloe barbadensis leaf extract, cocos nucifera (coconut) oil, cholecalciferol, menthol, retinyl palmitate, tocopheryl acetate, zea mays (corn) oil</p> <p><b>Questions?</b> 1-877-636-2677 MON-FRI 9 AM to 5 PM (EST) mentholatum.com</p> <p>EB737001 ©2019</p>
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<p>Retain this card for complete information.</p>		 <p>3 10742 01840 0</p>									

# MENTHOLATUM NATURAL ICE SPORT SPF 30

avobenzone, dimethicone, octinoxate, octisalate ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8980
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>TRICAPRIN</b> (UNII: O1PB8EU98M)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>CALCIFEDIOL</b> (UNII: P6YZ13C99Q)	
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10742-8980-1	1 in 1 BLISTER PACK	03/29/2000	04/01/2019
1		4.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-8980-2	4.5 g in 1 TUBE; Type 0: Not a Combination Product	03/29/2000	04/01/2019
3	NDC:10742-8980-3	1 in 1 BLISTER PACK	04/02/2019	
3		4.2 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:10742-8980-4	4.2 g in 1 TUBE; Type 0: Not a Combination Product	04/02/2019	
5	NDC:10742-8980-5	1 in 1 BLISTER PACK	03/29/2000	

5		4.5 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:10742-8980-6	4.5 g in 1 TUBE; Type 0: Not a Combination Product	03/29/2000	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/29/2000	

**Labeler** - The Mentholatum Company (002105757)

**Registrant** - The Mentholatum Company (002105757)

## Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8980)

Revised: 2/2023

The Mentholatum Company