

**CORETEX SUN X 50- avobenzone, homosalate, octisalate, octocrylene lotion**  
**CoreTex Products Inc**

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**Sun X 50**  
**65753-603**

***Active ingredients***

Avobenzone...3%

Homosalate...10%

Octisalate...5%

Octocrylene...5%

***Purpose***

Sunscreen

Sunscreen

Sunscreen

Sunscreen

***Uses:***

- helps prevent sunburn.
- higher SPF gives more sunburn protection.
- retains SPF after 80 minutes of activity in the water or sweating.
- provides high protection against sunburn

***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 or irritation develops or lasts

**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
- after towel drying, swimming, or
- at least every 2 hours
  
- children under 6 months of age: Ask a doctor.

**Other information**

- protect this product from excessive heat and direct sun.

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients**

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, ethylexyglycerin, hydroxypropyl methylcellulose phenoxyethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water

**Questions?**

Call 1-877-684-5774

**-603-34**

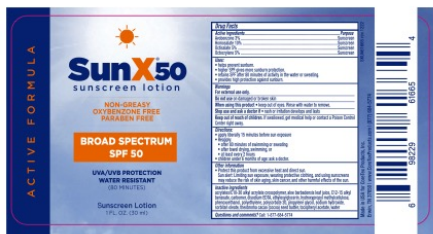
Front

Back



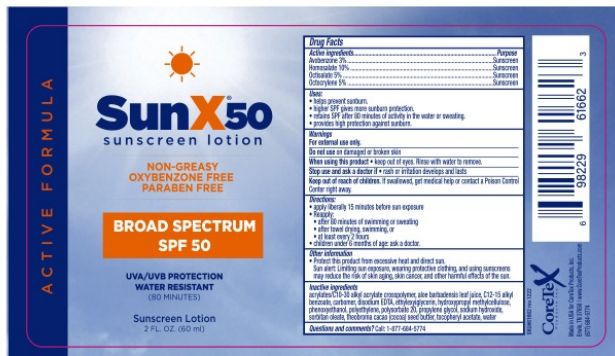
Accent Tag#:  
 SunX 50 size: 4oz tottle  
 Label: Special Shape  
 Ink Colors:

-603-01



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-603-02



SunX 50 size: 2oz  
 Label: 2.5x4.5 with a Corner Radius .1250  
 Ink Colors:



PMS 2747



PMS Bright  
 Orange

-603-03



SunX 50 size: 4oz  
 Label: 3.25x5.125 with a Corner Radius .1250  
 Ink Colors:



**-603-04**

ACTIVE FORMULA



# SunX50

sunscreen lotion

NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE

**BROAD SPECTRUM  
SPF 50**

UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)

Sunscreen Lotion  
6 FL. OZ. (177 ml)

**Drug Facts**

Active Ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen

**Uses:**

- helps prevent sunburn.
- higher SPF gives more sunburn protection
- reduces SPF after 80 minutes of activity in the water or sweating.
- provides high protection against sunburn.

**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 or irritation develops and lasts

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
  - after towel drying, swimming, or
  - if used every 2 hours
- children under 6 months of age: ask a doctor.

**Other information:**

- Protect this product from excessive heat and direct sun.
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients:**  
acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, decahydron EPO, ethylhexylglycerin, hydroxypropyl methylcellulose, phenoxyethanol, polyethylene, potassium 20, propylene glycol, sodium hydroxide, sorbitan sesquioleate, theobroma cacao (cocoa) seed butter, tocopherol acetate, water

Questions and comments? Call: 1-877-684-5774

CoreTex



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Made in USA for CoreTex Products, Inc.  
Erwin, TN 37650 | www.CoreTexProducts.com | (877) 684-5774

**-603-05**



SunX 50 size: 8oz  
Label: 6x4 with a Corner Radius .1250  
Ink Colors:



-603-07



ACTIVE FORMULA



# SunX50

sunscreen lotion

NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE

**BROAD SPECTRUM  
SPF 50**

**UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)**

Sunscreen Lotion  
16 FL. OZ. (473 ml)

Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen
<b>Uses:</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn.</li> <li>higher SPF gives more sunburn protection.</li> <li>retains SPF after 80 minutes of activity in the water or sweating.</li> <li>provides high protection against sunburn.</li> </ul>	
<b>Warnings:</b>	
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 or irritation develops and lasts.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>Reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>after towel drying, swimming, or</li> <li>at least every 2 hours</li> </ul> </li> <li>children under 6 months of age: ask a doctor.</li> </ul>	
<b>Other information:</b>	
<ul style="list-style-type: none"> <li>Protect this product from excessive heat and direct sun.</li> <li>Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.</li> </ul>	
<b>Inactive ingredients:</b>	
acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, diethylene glycol, hydroxypropyl methylcellulose, phenoxethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water	
Questions and comments? Call: 1-877-684-5774	



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-603-09

ACTIVE FORMULA



# SunX50

sunscreen lotion

**NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE**

**BROAD SPECTRUM  
SPF 50**

**UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)**

Sunscreen Lotion  
32 FL. OZ. (946 ml)

**Drug Facts**

Active ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen

**Uses:**

- helps prevent sunburn.
- higher SPF gives more sunburn protection.
- releaves SPF after 80 minutes of activity in the water or sweating.
- provides high protection against sunburn.

**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 or irritation develops and lasts  
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
  - after towel drying, swimming, or
  - at least every 2 hours
- children under 6 months of age; ask a doctor.

**Other information**

Protect this product from excessive heat and direct sun.  
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients:**  
acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, ethylhexylglycerin, hydroxypropyl methylcellulose, phenoxyethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water

Questions and comments? Call: 1-877-684-5774






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Made in USA for CoreTex Products, Inc.  
Erwin, TN 37650 | www.CoreTexProducts.com | (877) 684-5774

Accent Tag#: SunX 50 size: 32oz  
 Label: 8.1875x6.25 with a Corner Radius .3125  
 Ink Colors:

-603-10

ACTIVE FORMULA



# SunX50

sunscreen lotion

**NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE**

**BROAD SPECTRUM  
SPF 50**

**UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)**

Sunscreen Lotion  
1 Gallon (128 Ounces)

**Drug Facts**

Active ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen

**Uses:**

- helps prevent sunburn.
- higher SPF gives more sunburn protection.
- releaves SPF after 80 minutes of activity in the water or sweating.
- provides high protection against sunburn.

**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 or irritation develops and lasts  
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
  - after towel drying, swimming, or
  - at least every 2 hours
- children under 6 months of age; ask a doctor.


**Other information**

Protect this product from excessive heat and direct sun.  
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

**Inactive ingredients:**  
acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, ethylhexylglycerin, hydroxypropyl methylcellulose, phenoxyethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water

Questions and comments? Call: 1-877-684-5774





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Made in USA for CoreTex Products, Inc.  
Erwin, TN 37650 | www.CoreTexProducts.com | (877) 684-5774

-603-22-23-26-39

# Sun X 50 Pouch

<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate 10%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 3%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>• helps prevent sunburn.</li> <li>• Higher SPF gives more sunburn protection.</li> <li>• renews SPF after 80 minutes of activity in the water or sweating.</li> <li>• provides high protection against sunburn.</li> </ul> <p><b>Warnings:</b></p> <p>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>Stop use and ask a doctor if • rash or irritation develops and lasts.</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></p> <ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• Reapply:             <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• after towel drying, swimming, or</li> <li>• if tanned every 2 hours</li> <li>• children under 6 months of age: ask a doctor.</li> </ul> </li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• Protect this product from excessive heat and direct sun.</li> <li>• Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.</li> </ul> <p><b>Inactive ingredients</b></p> <p>acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, ethylhexylglycerin, hydrogenated methylcellulose, phenylethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water</p> <p>Questions and comments? call: 1-877-684-5774</p>		Active ingredients	Purpose	Azobenzene 3%	Sunscreen	Homosalate 10%	Sunscreen	Octisalate 5%	Sunscreen	Octocrylene 3%	Sunscreen	<p><b>ACTIVE FORMULA</b></p>  <p><b>SunX50</b> sunscreen lotion</p> <p><b>NON-GREASY OXYBENZONE FREE PARABEN FREE</b></p> <p><b>BROAD SPECTRUM SPF 50</b></p> <p><b>UVA/UVB PROTECTION WATER RESISTANT (80 MINUTES)</b></p> <p>Sunscreen Lotion Pouch 1/4 OZ. (7 GRAMS)</p> <p><b>Protect Yourself!</b></p>
Active ingredients	Purpose											
Azobenzene 3%	Sunscreen											
Homosalate 10%	Sunscreen											
Octisalate 5%	Sunscreen											
Octocrylene 3%	Sunscreen											
<p>Made in USA for Cor-Tek Products, Inc. Drew, TN 37620 www.Cor-TekProducts.com (877) 684-5774</p> 												

Pouch Size: 2.5 x 3.5"

ACTIVE FORMULA



# SunX<sup>®</sup>50

sunscreen lotion

NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE

**BROAD SPECTRUM  
SPF 50**

**UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)**



Made in USA for CoreTex Products, Inc.  
Erwin, TN 37650  
[www.CoreTexProducts.com](http://www.CoreTexProducts.com)  
(877) 684-5774



**Pull Tray Open To Dispense**

50 Pouches - SKU#61663 rev.1222

**-603-25**

ACTIVE FORMULA



# SunX<sup>®</sup>50

sunscreen lotion

NON-GREASY  
OXYBENZONE FREE  
PARABEN FREE

**BROAD SPECTRUM  
SPF 50**

**UVA/UVB PROTECTION  
WATER RESISTANT  
(80 MINUTES)**



Made in USA for CoreTex Products, Inc.  
Erwin, TN 37650  
www.CoreTexProducts.com  
(877) 684-5774



**Pull Tray Open To Dispense**

100 Pouches - SKU#61674 rev.1222

-603-32

Front

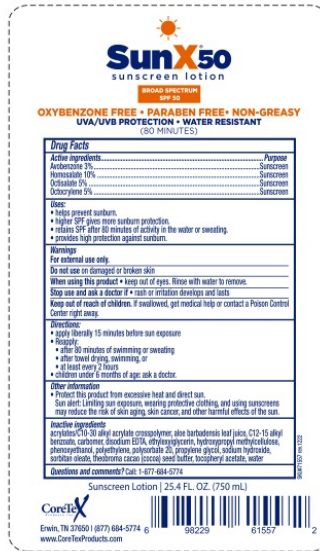


Back



-603-33





#468  
4.25 x 2.25"

Ink Colors: Black, PMS 187

## CORETEX SUN X 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65753-603
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ACRYLATES CROSSPOLYMER-6</b> (UNII: 4GXD0Q3OS3)	



<b>METHYLCELLULOSE, UNSPECIFIED</b> (UNII: Z944H5SN0H)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>MEDIUM DENSITY POLYETHYLENE</b> (UNII: 3W404QE89S)
<b>THEOBROMA CACAO WHOLE</b> (UNII: EB048G1S9J)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PEG-6 SORBITAN OLEATE</b> (UNII: 5807V09UCI)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>WATER</b> (UNII: 059QF0K00R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>DISODIUM EDTA-COPPER</b> (UNII: 6V475AX06U)

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65753-603-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
2	NDC:65753-603-32	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
3	NDC:65753-603-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
4	NDC:65753-603-33	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
5	NDC:65753-603-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
6	NDC:65753-603-34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
7	NDC:65753-603-04	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
8	NDC:65753-603-05	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
9	NDC:65753-603-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
10	NDC:65753-603-09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
11	NDC:65753-603-10	3788 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/03/2023	
12	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product	01/03/2023	
13	NDC:65753-603-22	25 in 1 CONTAINER	01/03/2023	
13	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
14	NDC:65753-603-23	25 in 1 CONTAINER	01/03/2023	
14	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
15	NDC:65753-603-24	50 in 1 CONTAINER	01/03/2023	
15	NDC:65753-	7 mL in 1 POUCH; Type 0: Not a Combination Product		

15	603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
16	NDC:65753-603-25	100 in 1 CONTAINER	01/03/2023	
16	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
17	NDC:65753-603-26	300 in 1 CARTON	01/03/2023	
17	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/03/2023	

**Labeler** - CoreTex Products Inc (061944620)

## Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products Inc		061944620	pack(65753-603)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(65753-603)

Revised: 11/2023

CoreTex Products Inc