

**CORTEX SUNX 50 THICK- avobenzone, homosalate, octisalate,
octocrylene lotion
CoreTex Products Inc**

**CoreTex SunX 50 Thick
65753-604
and Multipack
65753-602**

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 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 barbedensis 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?

Call: 1-877-684-5774

65753-603-09

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
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	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 and lasts

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Directions:

- apply liberally 15 minutes before sun exposure
- Reapply:
 - after 80 minutes of swimming or sweating
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 - 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, phenoxypentanol, 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:

65753-602-24

ACTIVE FORMULA



SunX⁵⁰

Multi-Purpose Foil Pack

SunX⁵⁰
sunscreen lotion pouch



**BROAD SPECTRUM
SPF 50**

SunX
utility towelette



**DRY & SUPER
ABSORBENT**

**NON-GREASY
OXYBENZONE FREE
PARABEN FREE**

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



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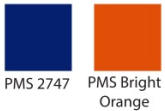
Pull Tray Open To Dispense

SKU#61661 rev.1222

65753-602-22,-23,-26,and -31



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



65753-603-22,-23,-24,-25,-26

Sun X 50 Pouch

Drug Facts	
Active Ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen
Uses:	
<ul style="list-style-type: none"> helps prevent sunburn. higher SPF gives more sunburn protection. reduces SPF after 60 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:	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure Reapply: <ul style="list-style-type: none"> 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:	
<ul style="list-style-type: none"> 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, phenoxypentanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocoferol acetate, water.	
Questions and comments? Call: 1-877-684-5774	
Made in USA for CoreTex Products, Inc. Erwin, TN 37650 www.CoreTexProducts.com (877) 684-5774	

ACTIVE FORMULA



SunX50

sunscreen lotion

NON-GREASY
OXYBENZONE FREE
PARABEN FREE

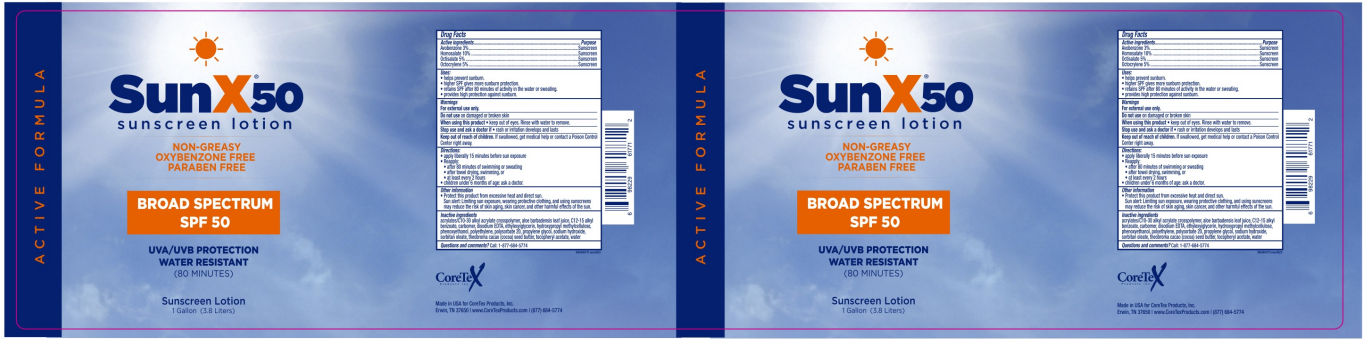
**BROAD SPECTRUM
SPF 50**

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

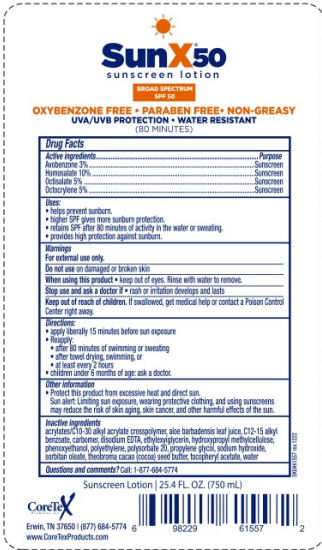
Sunscreen Lotion Pouch
1/4 OZ. (7 GRAMS)

Protect Yourself!

Pouch Size: 2.5 x 3.5"



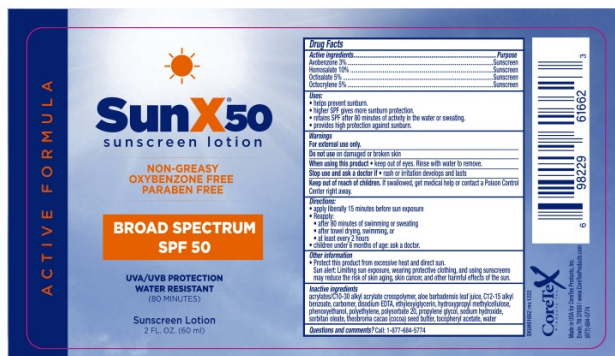
65753-603-35



#468
4.25 x 2.25"

Ink Colors: Black, PMS 187

65753-603-02



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



PMS 2747



PMS Bright Orange

65753-603-01



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65753-603-33



Front



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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	
Active ingredients	Purpose
Azobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen
Uses:	
<ul style="list-style-type: none"> • 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 and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions:	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • Reapply: <ul style="list-style-type: none"> • 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:	
<ul style="list-style-type: none"> • 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/C10-18 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, tocoopheryl acetate, water.	
Questions and comments? Call: 1-877-684-5774	



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65753-603-05



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



65753-603-04

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:	
<ul style="list-style-type: none"> • 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 and lasts.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions:	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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:	
<ul style="list-style-type: none"> • 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, carbonic acid, disodium EDTA, ethylhexylglycerin, hydroxypropyl methylcellulose, phenylpropanediol, polyethylene, polypropylene 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopherol acetate, water	
Questions and comments? Call 1-877-864-5774	



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CoreTex Products



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Erwin, TN 37650 | www.CoreTexProducts.com | (877) 864-5774

65753-603-34

Front

Back



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

65753-603-32

Front



Back



65753-603-39



Pouch Size: 2.5 x 3.5"

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CORTEX SUNX 50 THICK

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

WATER (UNII: 059QF0KO0R)
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S)
POLYSORBATE 20 (UNII: 7T1F30V5YH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-602-22	25 in 1 CONTAINER	03/09/2023	
1		7 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:65753-602-23	25 in 1 CONTAINER	03/09/2023	
2		7 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:65753-602-24	50 in 1 CONTAINER	03/09/2023	
3		7 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:65753-602-26	150 in 1 CARTON	03/09/2023	
4		7 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:65753-602-31	300 in 1 CARTON	03/09/2023	
5		7 g 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	03/09/2023	

CORTEX SUNX 50 THICK			
avobenzone, homosalate, octisalate, octocrylene lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-603

Route of Administration TOPICAL**Active Ingredient/Active Moiety**

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

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0KO0R)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-603-22	25 in 1 CONTAINER	03/09/2023	
1	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:65753-603-23	25 in 1 CONTAINER	03/09/2023	02/06/2025
2	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:65753-603-24	50 in 1 CONTAINER	03/09/2023	
3	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:65753-603-26	150 in 1 CARTON	03/09/2023	02/06/2025
4	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:65753-603-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	

6	NDC:65753-603-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
7	NDC:65753-603-35	762 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
8	NDC:65753-603-09	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
9	NDC:65753-603-10	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
10	NDC:65753-603-25	100 in 1 CONTAINER	03/09/2023	
10	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
11	NDC:65753-603-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
12	NDC:65753-603-32	44 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
13	NDC:65753-603-33	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
14	NDC:65753-603-04	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
15	NDC:65753-603-05	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
16	NDC:65753-603-07	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
17	NDC:65753-603-34	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2023	
18	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product	03/09/2023	
19	NDC:65753-603-43	50 in 1 CONTAINER	03/09/2023	
19	NDC:65753-603-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
20	NDC:65753-603-46	300 in 1 CARTON	03/09/2023	
20	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	03/09/2023	

Labeler - CoreTex Products Inc (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products Inc		061944620	pack(65753-602, 65753-603)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(65753-603, 65753-602)

