# CORETEX SUN X SPF 30- avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion CoreTex Products

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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#### Sun X SPF 30 Thick

## **Active ingredients**

Avobenzone 1.0%

Homosalate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

## **Purpose**

Sunscreen

Sunscreen

Sunscreen

Sunscreen

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 the eyes
- rinse with water to remove

## Stop use and ask a doctor if

rash occurs

#### Keep out of the 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
- **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 after sun protection measures including:
- limit time in the sun, especially from 10:00 a.m. 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.
- 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

#### Other information

• protect this product from excessive heat or direct sun

## **Inactive ingredients**

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, butylparaben, calendula officinalis flower extract, carbomer, chamomile recutita extract, dimethicone, dimethyl capramide, ethylparaben, fragrance, glyceryl stearate, isobutylparaben, methylparaben, nasturtium officinale extract, peg-100 stearate, phenoxyethanol, propylparaben, symphytum officinale leaf extract, tetrasodium EDTA, triethanolamine, tocopherol, tocopherol acetate, water

#### Questions?

Call 1-877-684-5774

#### **Principal Display Panel**

image of pdp





#### **UVA/UVB** Protection

Contains Aloe Vera Gel & Vitamin E Passed the Lineman's Glove Test (Type 1 Class 2 ANSI/ASTM D 120) PABA Free & Oil Free Non-Greasy

WATER RESISTANT (80 MINUTES)

Sunscreen Lotion 4 FL. OZ. (118 ml)

Active ingredients .	Purpose
vobenzone - 1.0%	Sunscreen
lomosalate - 5.0%	Sunscreen
Octinoxate - 7.5%	Sunscreen
Octisalate - 5.0%	Sunscreer
)xybenzone - 6.0%	Sunscreer

Uses: - helps prevent surburn. - if used as orecome was very skin aging caused by the sun.

\*\*MARNINGS\*\*
For extracted use only.

\*\*Do not use - on damaged or broken skin.

\*\*When using the product - keep out of eyes. - rinse with water to remove.

\*\*Stop use and ask a doctor - if rish occurs.

\*\*Keep out of reach of children - if swallowed get medical help or contact a Poison Control Conter right way.

\*\*Directions - apply liberally for generously and evenly 15 initiates before sun exposure of the product - stop of the sun protection measures including:

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 Inactive Ingradients: scrylebs/CID-30 sily acrylete crosspolymer, slote betadersies jobs even juel sides, butypatambe, carboner, claendad efficientals flower extract, chamomite results immitrational series. (21-21-5 sily bescore), dimethicose, method excessives, chamomite results immitrated particles. (21-21-5 sily bescore), dimethicose, dimethicose, registrated, polycopy silvaria, ingrareza (partini), giving-yi silvaria, kodulylparabe phonosystranol, propipicanola, symphytim efficients (confriey) led sutract, tetracodia CIDIA, socophery, locopiery accessite, particles (society), silvaria, silva



avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-100	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
.ALPHATO COPHEROL (UNII: H4N855PNZ1)			
TROLAMINE (UNII: 903K93S3TK)			
PROPYLPARABEN (UNII: Z8 IX2SC10H)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
ETHYLPARABEN (UNII: 14255EXE39)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)			
C12-20 ALKYL BENZOATE (UNII: Y15I6 XI14C)			
CHAMO MILE (UNII: FGL3685T2X)			
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)			
PEG-100 STEARATE (UNII: YD0 1N1999R)			
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68 VH75CJC)			
NASTURTIUM OFFICINALE (UNII: YH89GMV676)			
COMFREY LEAF (UNII: DG4F8T839X)			
EDETATE SO DIUM (UNII: MP1J8420LU)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
.ALPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			

Product Characteristics		
Color	white (Thick White Lotion)	Score
Shape		Size
Flavor		Imprint Code

Pá	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65753-100- 01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/26/2019			
2	NDC:65753-100- 32	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 01/25/2013				
3	NDC:65753-100- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
4	NDC:65753-100- 33	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
5	NDC:65753-100- 03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
6	NDC:65753-100- 34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
7	NDC:65753-100- 04	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
8	NDC:65753-100- 05	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
9	NDC:65753-100- 07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
10	NDC:65753-100- 09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 01/25/2013				
11	NDC:65753-100- 10	$3785\ mL$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/25/20 13			
12	NDC:65753-100- 37	44 mL in 1 PACKET; Type 0: Not a Combination Product	01/25/2013			
13	NDC:65753-100- 18	65753-100- 1000 in 1 CARTON				
13		44 mL in 1 PACKET; Type 0: Not a Combination Product				
14	NDC:65753-100- 22	25 in 1 CONTAINER	0 1/25/20 13			
14		207 mL in 1 PACKET; Type 0: Not a Combination Product				
15	NDC:65753-100- 23	50 in 1 CONTAINER	0 1/25/20 13			
15		207 mL in 1 PACKET; Type 0: Not a Combination Product				
16	NDC:65753-100- 24	50 in 1 CARTON	01/25/2013			
16		207 mL in 1 PACKET; Type 0: Not a Combination Product				
17	NDC:65753-100- 25	100 in 1 CARTON	01/25/2013			
17		207 mL in 1 PACKET; Type 0: Not a Combination Product				
18	NDC:65753-100- 26	300 in 1 BOX	01/25/2013			
18		207 mL in 1 PACKET; Type 0: Not a Combination Product				
19	NDC:65753-100- 08	1 in 1 BOX	0 1/25/20 13			
19		500 mL in 1 BAG; Type 0: Not a Combination Product				
20	NDC:65753-100- 40	1 in 1 BOX	0 1/0 1/20 17			
20	NDC:65753-100- 35	751 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/25/20 13	

## Labeler - CoreTex Products (061944620)

Establishment				
Name	Address	ID/FEI	Business Operations	
CoreTex Products		061944620	label(65753-100)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source		080354456	manufacture(65753-100)	

Revised: 11/2019 CoreTex Products