CORETEX SUN X SPF 30 NEW- avobenzone, homosalate, octisalate, octocrylene lotion
CoreTex Products Inc

Sun X SPF 30 Thick New formulation
65753-110

Active ingredients

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

Octocylene 5%

Purpose

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 product is 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 sweatingchildren under 6 months of age: Ask a doctor
  - immediately after towel drying
  - 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 10:00 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.
- children under 6 months: Ask a doctor

Other information

- Protect this product from excessive heat or direct sun.

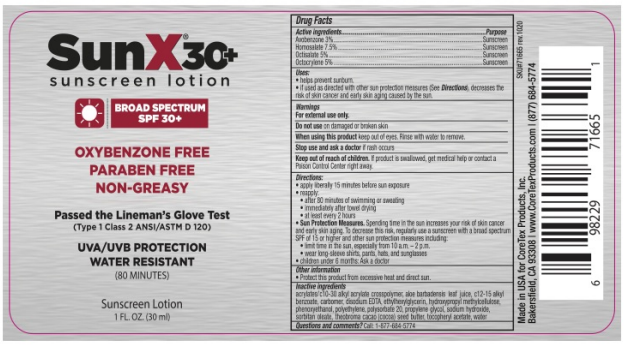
Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, 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, tocopherol acetate, water

Questions and comments?

Call: 1-877-684-5774

Principal Display Panel



CORETEX SUN X SPF 30 NEW

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65753-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
PROPYLENE GLYCOL PROPYL ETHER (UNII: 92KA3PYX0S)	
MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-110-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
2	NDC:65753-110-32	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
3	NDC:65753-110-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
4	NDC:65753-110-33	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
5	NDC:65753-110-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
6	NDC:65753-110-34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
7	NDC:65753-110-04	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
8	NDC:65753-110-05	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
9	NDC:65753-110-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
10	NDC:65753-110-09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
11	NDC:65753-110-10	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2021	
12	NDC:65753-110-37	44 mL in 1 PACKET; Type 0: Not a Combination Product	01/07/2021	
13	NDC:65753-110-18	1000 in 1 CARTON	01/07/2021	
13		44 mL in 1 PACKET; Type 0: Not a Combination Product		
14	NDC:65753-110-22	25 in 1 CONTAINER	01/07/2021	
14		7 mL in 1 PACKET; Type 0: Not a Combination Product		
15	NDC:65753-110-23	50 in 1 CONTAINER	01/07/2021	
15		7 mL in 1 PACKET; Type 0: Not a Combination Product		

16	NDC:65753-110-24	50 in 1 CARTON	01/07/2021	
16		7 mL in 1 PACKET; Type 0: Not a Combination Product		
17	NDC:65753-110-25	100 in 1 CARTON	01/07/2021	
17		7 mL in 1 PACKET; Type 0: Not a Combination Product		
18	NDC:65753-110-26	300 in 1 BOX	01/07/2021	
18		7 mL in 1 PACKET; Type 0: Not a Combination Product		
19	NDC:65753-110-08	1 in 1 BOX	01/07/2021	
19		500 mL in 1 BAG; Type 0: Not a Combination Product		
20	NDC:65753-110-40	1 in 1 BOX	01/07/2021	11/21/2022
20		751 mL in 1 BOTTLE; Type 0: Not a Combination Product		
21	NDC:65753-110-35	751 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/07/2021	

Labeler - CoreTex Products Inc (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products Inc		061944620	pack(65753-110)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(65753-110)

Revised: 10/2023 CoreTex Products Inc