CORETEX PROFESSIONAL OUTDOOR SKIN PROTECTION WALLET- coretex professional outdoor skin protection wallet
CoreTex Products

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

CoreTex Professional Outdoor Skin Protection Wallet and Refill Wallet

Hand Sanitizer
Active Ingredients

SD Alcohol 40-B 62.5%

Hand Sanitizer
Purpose

Antimicrobial

Hand Sanitizer
Uses

Hand Sanitizer to help reduce bacteria on the skin.

Hand Sanitizer
Warnings

Flammable. Keep away from heat or flame.

For external use only.

When using this product

do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get help or contact a Poison Control Center right away.

Hand Sanitizer
Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Hand Sanitizer
Inactive Ingredients

actinidia chinesis (kiwi) extract, aloe barbadenis leaf juice, aminomethyl propanol, brassica oleracea italica (broccoli) extract, cannabis sativa (hemp) seed extract, carbomer citrullus vulgaris (watermelon) fruit extract, euterpe oleracea fruit extract, fragaria vesca (strawberry) fruit extract, glycerin, helianthus annus (sunfloer) seed oil, hippophae rhamnoides (sea buckthorn) fruit extract, lycium barbarum (goji)

extract, myrciaria dubia (camu camu) fruit extract, propanediol, propylene glycol, punica granatum extract, rubus idaeus seed extract, tocopherol acetate (vitamin E acetate), vaccinium angustifolium (blueberry) extract, vaccinium macrocarpon (cranberry) fruit extract, vitis vinifera (grape) seed extra, water

Hand Sanitizer
Other Information

Store below 110 ºF (43 º), Read the Safety Data Sheet for this Product. You may obtain an SDS from our website: www.coretexproducts.com or Call: 1-877-684-5774

SunX 30
Active Ingredients

Avobenzone 1.0%

Homosalate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

SunX 30
Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Sunscreen

SunX 30
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.

SunX 30
Warnings

For external use only

SunX 30
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

SunX 30
Keep out of reach of children

If swallowed get medical help or contact a Poison Control center right away.

SunX 30
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

SunX 30
Other Information

- protect this product from excessive heat or direct sun

SunX 30
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

SunX 30
Questions?

Call: 1-877-684-5774

SunX 30 Lip Balm
Active Ingredients

Avobenzone…3.0%

Homosalate…7.5%

Octisalate…5.0%

Octocrylene…2.5%

Oxybenzone…6.0%

SunX 30 Lip Balm

Purpose

Sunscreen

SunX 30 Lip Balm
Uses

Helps prevent sunburn.

SunX 30 Lip Balm
Warnings

For external use only.

Do not use

Do not use on damaged or broken skin.

Stop use and ask a doctor if
- rash occurs

When using this product
- keep out of eyes. Rinse to remove.

SunX 30 Lip Balm
Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

SunX 30 Lip Balm
Directions
- apply liberally 15 minutes before sun exposure
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: **Ask a doctor**

SunX 30 Lip Balm
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 other sun protection measures:
- limit time in the sun, especially from 10a.m.-2p.m.
- wear long sleeved shirts, pants, hats, and sunglasses.

SunX 30 Lip Balm
Inactive Ingredients

Beeswax, castor oil, cocoa butter, coconut oil, shea utter

SunX 30Lip Balm
Other information

Protect this productfrom excessive heat and direct sun.

Anti-Itch
Active Ingredients

Camphor 0.1%

Diphenhydramine hydrochloride 2%

Zinc acetate 1%

Anti-Itch
Purpose

Extrenal analgesic

Antihistamine

Skin protectant

Anti-Itch
Uses

- For the temporary relief of itching and pain associated with minor skin irritations and rashes due to insect bites, poison ivy, poison oak, poison sumac.
- dries the oozing and weeping of poison ivy, poison oak, poison sumac.

Anti-Itch
Warnings

For external use only

Do Not Use

- on chicken pox, blisters or on extensive areas of the skin
- with any drugs containing diphenhydramine while using this product.

When using this product

- keep out of eyes.

Stop use and ask a doctor if

- conditions worsen or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Anti-Itch
Keep out of reach of children

If swallowed get medical help or contact Poison Control center right away.

Anti-Itch
Directions

- Adults and children 12 years of age and older, apply to affected area not more than 3 to 4 times daily, or as directed bu a doctor.

Anti-Itch

Other Information

- protect this product from excessive heat and direct sun.

Anti-Itch
Inactive Ingredients

citric acid, diazolidinyl urea, glycerin, hydroxypropyl methylcellulose, methylparaben, propylene glycol, propylparaben, SD alcohol 40, sodium citrate, water (aqua).

Anti-Itch
Questions?

Call: 1-877-684-5774

Sting X
Active Ingredients

Benzocaine 6%

Sting X
Purpose

Topical Analgesic

Sting X
Use

For temporary pain relief from insect bites and stings

Sting X
Warnings

For external use only

Do not use

- in or near eyes
- over large areas of the body
- over raw or blistered areas

Sting X
Stop use and ask a doctor if

- conditions worsen or persist for more than 7 days or clear up and occur again within a few days

Sting X
Keep out of reach of children.

If swallowed get medical help or contact Poison Control center right away.

Sting X
Directions

Apply to affected area not more than 3 to 4 times daily, for adults and children 2 years of age or older.

Sting X
Inactive Ingredients

SD alcohol 40, water (aqua), glycerin, allantoin

Sting X
Other Information

Made in USA for CoreTex Products, Inc.

Bakersfield, CA 93308

www.CoreTexProducts.com (877)684-5774

Outdoor Professional Kit and Refill Kit Contents

1 ea – Sun X SPF 30 Broad Spectrum Lotion Pouch

1 ea – Sun X SPF 30 Broad Spectrum Multi-Pack Pouch w/Towelette
1 ea – Sun X SPF 30 Lip Balm
2 ea – Bug X 30 Insect Repellent Towelette
2 ea – Ivy X Pre-Contact Barrier Towelette
2 ea – Ivy X Post-Contact Cleanser Towelette
2 ea – Burn X Lite Cooling Gel Pouch
1 ea – Anti-Itch Gel Pouch
1 ea – Sting X Pain Relief Pad
1 ea – Hand Sanitizer Gel Pouch

Professional Outdoor Kit Label

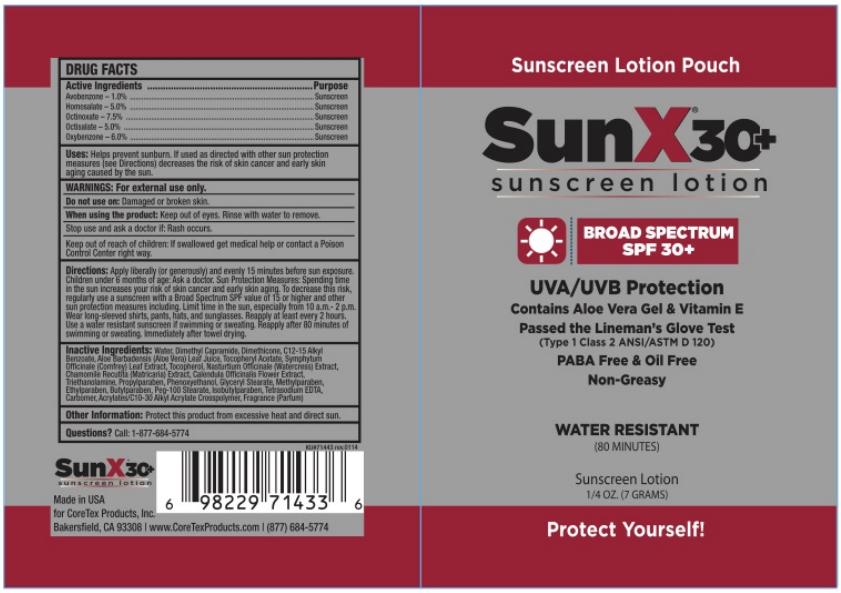
Professional Outdoorkit Refill

Hand Sanitizer
Package Label

PMS 287 PMS 187 BLACK

SunX 30 Label

Sun X Pouch



Black

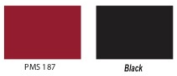
PMS 187

Pouch Size: 2.5 x 3.5"

SunX 30 Multipack with Towelette Label

SunX 30 Lip Balm Label

Anti-Itch Label



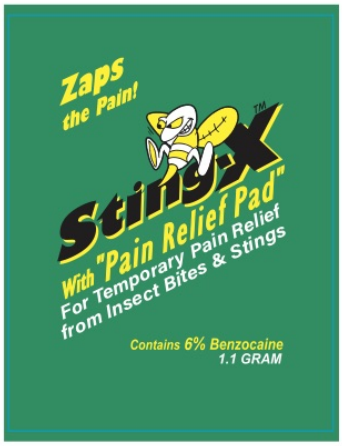
Sting X Label

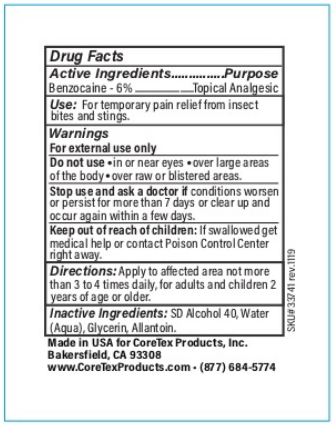
Sting X Pouch

PMS 339 C

PMS 3945 C

PMS Hexachrome Black





Drug Facts

Active Ingredients*.....*Purpose

Benzocaine - 6% .....Topical Analgesic

Use: For temporary pain relief from insect bites and stings.

Warnings

For external use only

Do not use • in or near eyes • over large areas of the body • over raw or blistered areas.

Stop use and ask a doctor if conditions worsen or persist for 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 Poison Control Center right away.

Directions: Apply to affected area not more than 3 to 4 times daily, for adults and children 2 years of age or older.

Inactive Ingredients: SD Alcohol 40, Water (Aqua), Glycerin, Allantoin.

Made in USA for CoreTex Products, Inc.
Bakersfield, CA 93308
www.CoreTexProducts.com • (877) 684-5774

SKU# 33741 rev.1119

H2.5" x W2"

CORETEX PROFESSIONAL OUTDOOR SKIN PROTECTION WALLET

coretex professional outdoor skin protection wallet kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65753-504

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65753-504-36	1 in 1 KIT; Type 0: Not a Combination Product	11/27/2019	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 POUCH	1 mL
Part 2	1 POUCH	1.1 mL
Part 3	1 POUCH	3.5 mL
Part 4	1 PACKET	44 mL
Part 5	1 POUCH	7 g
Part 6	1480926 APPLICATOR	65753105 mL

Part 1 of 6

CORETEX ANTI-ITCH GEL

camphor, diphenhydramine, zinc acetate gel

Product Information	
Item Code (Source)	NDC:65753-400
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.1 g in 100 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL 1-ALLYL ETHER (UNII: QRB8092KPK)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLCELLULOSE (1500 CPS) (UNII: P0NTE48364)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 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 not final	part348	11/25/2019	

Part 2 of 6

STINGX

benzocaine swab

Product Information

Item Code (Source)	NDC:65753-350
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1.1 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 not final	part348	11/25/2019	

Part 3 of 6

CORETEX ANTIBACTERIAL HAND SANITIZER

sd alcohol liquid

Product Information

Item Code (Source)	NDC:65753-200
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGARIA VESCA FRUIT (UNII: CG6IX3GCMU)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
CITRULLUS COLOCYNTHIS FRUIT (UNII: 0E49E3V9U6)	
RUBUS IDAEUS SEED (UNII: M3CL7US2ZG)	
GLYCERIN (UNII: PDC6A3C0OX)	
HELIANTHUS ANNUUS SEEDCAKE (UNII: 482WYF7XLC)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
MYRCIARIA DUBIA FRUIT (UNII: YSW4EM1EKP)	
VACCINIUM MACROCARPON WHOLE (UNII: D11KO7O2DX)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
1,3-PROPANEDIOL BIS(4-AMINOBENZOATE) (UNII: 8860R9ORQR)	
CANNABIS SATIVA SEED (UNII: QE567Z26NG)	
PUNICA GRANATUM WHOLE (UNII: O2ZTS50U5E)	
EUTERPE OLERACEA WHOLE (UNII: Y57H6218HP)	
HIPPOPHAE RHAMNOIDES FRUIT JUICE (UNII: UC3P08EB3Y)	
PROPYLENE GLYCOL 1-BUTYRATE (UNII: PUV901J64H)	
VACCINIUM ANGUSTIFOLIUM WHOLE (UNII: R3538BZ1BW)	
ACTINIDIA CHINENSIS WHOLE (UNII: 8HTD3WU8LH)	
BRASSICA OLERACEA VAR. ITALICA WHOLE (UNII: DW4954EP53)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.5 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 not final	part333E	11/25/2019	

Part 4 of 6

CORETEX SUN X SPF 30

avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information	
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
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
PEG-100 STEARATE (UNII: YD01N1999R)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
COMFREY LEAF (UNII: DG4F8T839X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
CHAMOMILE (UNII: FGL3685T2X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

Product Characteristics

Color	white (Thick White Lotion)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-100-37	44 mL in 1 PACKET; 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	01/25/2013	

Part 5 of 6

SUN X MULTI-PACK SPF 30 THICK

avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Item Code (Source)	NDC:65753-102
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 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
PEG-100 STEARATE (UNII: YD01N1999R)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
COMFREY LEAF (UNII: DG4F8T839X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
CHAMOMILE (UNII: FGL3685T2X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		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 not final	part352	01/01/2017	

Part 6 of 6

SUN XSPF 30 BROAD SPECTRUM SUNSCREEN LIP BALM

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lipstick

Product Information

Item Code (Source)	NDC:65753-105
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCONUT OIL (UNII: Q9L0O73W7L)	
WHITE WAX (UNII: 7G1J5DA97F)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		44.4 mL in 1 APPLICATOR; 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	01/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/27/2019	

Labeler - CoreTex Products (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises		017701475	manufacture(65753-350, 65753-400)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products		061944620	label(65753-504, 65753-200, 65753-105, 65753-102, 65753-100, 65753-350, 65753-400)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		080354456	manufacture(65753-100, 65753-102)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose		083819404	manufacture(65753-105)

Establishment

Name	Address	ID/FEI	Business Operations
HealthSpecialty		794053863	manufacture(65753-200)