

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

*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.*

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**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 chinensis (kiwi) extract, aloe barbadensis 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 annuus (sunflower) 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 °F (43 °), Read the Safety Data Sheet for this Product. You may obtain an SDS from our website: [www.coretexproducts.com](http://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 butter

### **SunX 30 Lip Balm**

#### **Other information**

Protect this product from excessive heat and direct sun.

### **Anti-Itch**

#### **Active Ingredients**

Camphor 0.1%

Diphenhydramine hydrochloride 2%

Zinc acetate 1%

### **Anti-Itch**

#### **Purpose**

Extremal 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 by 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](http://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 Outdoor Kit Refill**





**Hand Sanitizer  
Package Label**



**Antibacterial  
HAND SANITIZER**  
AND Waterless Hand Cleaner  
with Moisturizers

Kills Germs  
Without Water

4 FL. OZ. (118 ml)

Drug Facts	
Active Ingredients	Purpose
SD Alcohol 40-B 62.5%	Antimicrobial
<b>Uses:</b> Hand Sanitizer to help reduce bacteria on the skin.	
<b>Warnings:</b> 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.	
<b>Stop use and ask a doctor</b> 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.	
<b>Directions:</b> Put enough product in your palm to cover hands and rub hands together briskly until dry.	
<b>Inactive Ingredients:</b> Actinidia Chinensis (Kiwi) Extract, Aloe Barbadensis Leaf Juice, Ammonomethyl Propanol, Brassica Oleracea Italica (Broccoli) Extract, Cannabis Sativa (Hemp) Seed Extract, Carbomer, Citrullus Vulgans (Watermelon) Fruit Extract, Euterpe Oleracea Fruit Extract, Fragaria Vesca (Strawberry) Fruit Extract, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hippophae Rhamnoides (Sea Buckthorn) Fruit Extract, Lycium Barbarum (Goji) Extract, Myricaria dubia (Camu Camu) Fruit Extract, Propanediol, Propylene Glycol, Punica Granatum Extract, Rubus Rubus (Idaeus Seed Extract), Tocopheryl Acetate (Vitamin E Acetate), Vaccinium Angustifolium (Blueberry) Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Vitis Vinifera (Grape) Seed Extract, Water.	
<b>Other information:</b> Store below 110°F (43°C). Read the Safety Data Sheet for this Product. You may obtain an SDS from our website: <a href="http://www.coretexproducts.com">www.coretexproducts.com</a> or Call: 1-877-684-5774	






Made in USA for CoreTex Products, Inc.  
Bakersfield, CA 93308 | [www.CoreTexProducts.com](http://www.CoreTexProducts.com) | (877) 684-5774

SKUP23666 rev.0819



# Sun X Pouch

<b>DRUG FACTS</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active Ingredients</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene - 1.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate - 5.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Octinoxate - 5.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Octylsalate - 5.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Oxybenzone - 6.0%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p><b>Uses:</b> 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.</p> <p><b>WARNINGS: For external use only.</b></p> <p><b>Do not use on:</b> Damaged or broken skin.</p> <p><b>When using the product:</b> Keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if: Rash occurs.</p> <p>Keep out of reach of children: If swallowed get medical help or contact a Poison Control Center right way.</p> <p><b>Directions:</b> Apply liberally (or generously) and evenly 15 minutes before sun exposure. Children under 6 months of age: Ask a doctor. 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 including: Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Reapply after 80 minutes of swimming or sweating. Immediately after towel drying.</p> <p><b>Inactive Ingredients:</b> Water, Dimethyl Dimethylsiloxane, Dimethylsiloxane, C12-15 Alkyl Benzoate, Aloe Vera Gel, Shea Butter, Lipoic Acid, Tocopherol Acetate, Symphytum Officinale (Comfrey) Leaf Extract, Tocopheryl Acetate, Nardolium Officinale (Watercress) Extract, Chamomile Recens (Matricaria) Extract, Calendula Officinalis Flower Extract, Turbinosone, Propylparaben, Phenylethylalcohol, Glycerol Stearate, Methylparaben, Ethylparaben, Butylparaben, Poly-100 Glycerin, Isobutylparaben, Tetrahydrofurfuryl Ether, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum).</p> <p><b>Other Information:</b> Protect this product from excessive heat and direct sun.</p> <p><b>Questions?</b> Call: 1-877-694-5774</p>   <p>Made in USA for CoreTex Products, Inc. Bakersfield, CA 93308   www.CoreTexProducts.com   (877) 694-5774</p>	Active Ingredients	Purpose	Azobenzene - 1.0%	Sunscreen	Homosalate - 5.0%	Sunscreen	Octinoxate - 5.0%	Sunscreen	Octylsalate - 5.0%	Sunscreen	Oxybenzone - 6.0%	Sunscreen	<b>Sunscreen Lotion Pouch</b>   <b>BROAD SPECTRUM SPF 30+</b>  <b>UVA/UVB Protection</b> <b>Contains Aloe Vera Gel &amp; Vitamin E</b> <b>Passed the Lineman's Glove Test</b> <small>(Type 1 Class 2 ANSI/ASTM D 120)</small> <b>PABA Free &amp; Oil Free</b> <b>Non-Greasy</b>  <b>WATER RESISTANT</b> <small>(80 MINUTES)</small>  Sunscreen Lotion <small>1/4 OZ. (7 GRAMS)</small>  <b>Protect Yourself!</b>
Active Ingredients	Purpose												
Azobenzene - 1.0%	Sunscreen												
Homosalate - 5.0%	Sunscreen												
Octinoxate - 5.0%	Sunscreen												
Octylsalate - 5.0%	Sunscreen												
Oxybenzone - 6.0%	Sunscreen												



Black



PMS 187

Pouch Size: 2.5 x 3.5"

**SunX 30 Multipack with Towelette Label**



## SunX 30 Lip Balm Label

▼ PEEL HERE FOR DRUG FACTS

Made in the USA

**Broad Spectrum SPF 30 Sunscreen**

**Beeswax Lip Balm**

Net Wt. .15 oz.

**Drug Facts**

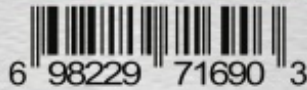
Active Ingredients:	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 7.5%	
Octisalate 5.0%	
Octocrylene 2.5%	
Oxybenzone 6.0%	

**SunX<sup>30+</sup>**  
s u n s c r e e n

**L I P B A L M**



**BROAD SPECTRUM  
SPF 30+**



6 98229 71690 3

**Drug Facts** (continued)

**Uses** • Helps prevent sunburn

**Warnings**

• **For external use only** • **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 with water to remove. **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 • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: **Ask a doctor**

**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 including: • limit time in the sun, especially from 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

**Inactive Ingredients:** Beeswax, coconut oil, castor oil, shea butter, cocoa butter.

**Other Information**

Protect this product from excessive heat and direct sun.

**Dist. by:** CoreTex Products, Inc., Bakersfield, CA 93308 0417

SAFETY  
SEAL

IMPRINT AREA

OVERLAPPED AREA

**Anti-Itch Label**



# Anti-Itch

Dual Action Gel



Itch Relief

**Histamine Blocker**  
Temporarily Relieves  
Pain & Itching  
from Insect Bites  
and Rashes.

6 FL. OZ. (177 ml)

### Drug Facts

Active Ingredients	Purpose
Camphor 10%	External analgesic
Diphenhydramine hydrochloride 2%	Antihistamine
Zinc acetate 1%	Skin protectant

**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.

**Warnings:**  
For external use only.  
**Do not use** • on children, paws, blisters or on an extensive areas of the skin • with any other drugs containing diphenhydramine while using this product.  
**When using the product** • keep out of eyes.  
**Stop use and ask a doctor if** • if condition worsens, or if symptoms 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 a Poison Control Center right away.

**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 by a doctor.  
• **Children under 6 months of age** Ask a doctor.

**Other information** • protect this product from excessive heat and direct sun.

**Inactive ingredients:** citric acid, disodium edta, glycerin, hydroxypropyl methylcellulose, methylparaben, propylene glycol, propylparaben, SD alcohol 40, sodium citrate, water (aqua).

**Questions?** Call: 1-877-684-5774



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



PMS 187



Black

Sting X Label

# Sting X Pouch

PMS 339 C



PMS 3945 C



PMS  
Hexachrome  
Black



<b>Drug Facts</b>	
<b>Active Ingredients.....</b>	<b>Purpose</b>
Benzocaine - 6%	Topical Anesthetic
<b>Use:</b> For temporary pain relief from insect bites and stings.	
<b>Warnings</b>	
<b>For external use only</b>	
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.	
<b>Directions:</b> Apply to affected area not more than 3 to 4 times daily, for adults and children 2 years of age or older.	
<b>Inactive Ingredients:</b> SD Alcohol 40, Water (Aqua), Glycerin, Allantoin.	
Made in USA for CoreTex Products, Inc. Bakersfield, CA 93308 www.CoreTexProducts.com • (877) 684-5774	

H2.5" x W2"

coretex professional outdoor skin protection wallet kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65753-504
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**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 PACKET	44 mL
Part 2	1 POUCH	7 g
Part 3	1480926 APPLICATOR	65753105 mL
Part 4	1 POUCH	1 mL
Part 5	1 POUCH	1.1 mL
Part 6	1 POUCH	3.5 mL

**Part 1 of 6**

**CORETEX SUN X SPF 30**

avobenzene, homosalate, octinoxate, octisalate, oxybenzone lotion

**Product Information**

<b>Item Code (Source)</b>	NDC:65753-100
<b>Route of Administration</b>	TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	



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

### Product Characteristics

<b>Color</b>	white (Thick White Lotion)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 2 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
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 g

## Inactive Ingredients

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

## Packaging

Item

Marketing Start

Marketing End

#	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 3 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
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
<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

## Inactive Ingredients

Ingredient Name	Strength
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

## 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	

## Part 4 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
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.1 g in 100 mL
<b>ZINC ACETATE</b> (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 g in 100 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>METHYLCELLULOSE (1500 CPS)</b> (UNII: P0NTE48364)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL 1-ALLYL ETHER</b> (UNII: QRB8092KPK)	

## 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 5 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
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 g in 100 mL

## Inactive Ingredients

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

## 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 6 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
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)	
CANNABIS SATIVA SEED (UNII: QE567Z26NG)	
PUNICA GRANATUM WHOLE (UNII: O2ZTS50U5E)	
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)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
1,3-PROPANEDIOL BIS(4-AMINO BENZOATE) (UNII: 8860R9ORQR)	

## 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	

## Marketing Information

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

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

Revised: 11/2022

CoreTex Products Inc