

**1177, 1178 SUNSCREEN- 1177, 1178 sunscreen cream  
Dynarex**

*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.*

-----  
**1177, 1178 Sunscreen**

***Active Ingredients***

Homosalate 6%, Octinoxate 7.5%, Octisalate 5%, Oxygenzone 5%

***Purpose***

Sunscreen

***Uses***

- . Protects from excessive heat and direct sun
- . Helps prevent sunburns
- . Higher SPF gives more sunburn protection
- . For skin highly sensitive to sunburn

***Warnings***

For External Use Only.

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

***Do not use***

On damaged or broken skin

***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 (800-222-1222) right away.

***Directions***

- . Apply liberally 15 minutes before sun exposure
- . Reapply at least every 2 hours
- . Children under 6 months: as a doctor

### Inactive ingredients

Antaron V-220, Butylated Hydroxyanisole, Butylated Hydroxytoluene, Carbopol Ultrez 10, Cetareth 20, Cetyl Alcohol, Dimethicone 350, Edetate Disodium, Glyceryl Stearate SE, Methylparaben, Propylparaben, Purified Water, Sorbitan Monostearate, Sorbitol Solution, Stearic Acid, Trolamine

### Questions?

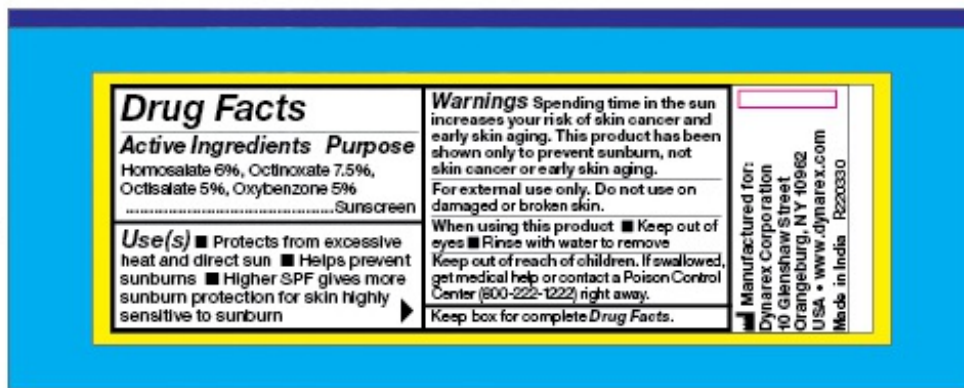
1-888-DYNAREX Monday - Friday, 9AM - 5PM EST

### Label



1177 Sunscreen

### Label



1177, 1178

Sunscreen

<b>1177, 1178 SUNSCREEN</b>			
1177, 1178 sunscreen cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-177
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)		OXYBENZONE	5 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	6 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	5 g in 100 g
<b>Inactive Ingredients</b>			
Ingredient Name			Strength

<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>SORBITOL SOLUTION 70%</b> (UNII: 8KW3E207O2)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>EICOSYL POVIDONE</b> (UNII: XQQ9MKE2BJ)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	FREEFORM	<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:67777-177-01	24 in 1 CASE	05/27/2021	
1	NDC:67777-177-11	25 in 1 BOX		
1		3.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-177-02	1000 in 1 CASE	05/27/2021	
2		3.5 g 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	05/27/2021	

**Labeler** - Dynarex (008124539)