SULFUR- sulfur ointment
Caribe Natural, Inc

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.

Active Ingredient Purpose

Sulfur 10% ..... ointment

Sulfur 10% ointment

Keep out of reach of children.

Sulfur 10% Ointment

Sulfur 10% Ointment

Sulfur 10% Ointment

cetyl/stearyl alcohol, glycerin, glyceryl stearate, methylparaben, mineral oil, paraffin, polyethylenglycol, propylparaben, sorbitan oleate, water

SULFUR
sulfur ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59561-706
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	

POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59561-706-02	57 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/05/2015	

Labeler - Caribe Natural, Inc (624210480)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		101312044	manufacture(59561-706)

Revised: 5/2015 Caribe Natural, Inc