PERSONAL CARE COCOA BUTTER- white petrolatum cream Delta Brands & Products LLC

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.

Drug Facts

Active ingredient

Petrolatum (30%)

Purpose

Skin protectant

Uses

■ temporarily protects minor: ■ cuts ■ scrapes ■ burns ■ temporarily protects and helps relieve chapped or cracked skin ■ helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only

When using this product

do not get into eyes

Stop use and ask a doctor if

■ condition worsens ■ symptoms last more than 7 days or clear up and occur again in a few days

Do not use on

■ deep or puncture wounds ■ animal bites ■ serious burns

Keep out of reach of children

■ If swallowed, get medical help or contact a Poison Control Center right away

Directions

apply as needed

Inactive ingredients

water (aqua), mineral oil, glycerin, cetearyl alcohol, cetyl alcohol, stearyl alcohol, glyceryl stearate, fragrance, ploysorbate-80, laureth-20, BHT, methyparaben,propylparaben, dimethicone, theobroma cacao (cocoa) seed butter, tocopheryl acetate



PERSONAL CARE COCOA BUTTER

white petrolatum cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72133-121 Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) PETROLATUM 30 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)				

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) GLYCERIN (UNII: PDC6A3C0OX) MINERAL OIL (UNII: T5L8T28FGP) METHYLPARABEN (UNII: A218C7H19T) PROPYLPARABEN (UNII: Z8IX2SC1OH) BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MINERAL OIL (UNII: T5L8T28FGP) METHYLPARABEN (UNII: A218C7H19T) PROPYLPARABEN (UNII: Z8IX2SC10H) BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
METHYLPARABEN (UNII: A218 C7 H19 T) PRO PYLPARABEN (UNII: Z8 IX2S C10 H) BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K) .ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)
PROPYLPARABEN (UNII: Z8IX2SC10H) BUTYLATED HYDROXYTOLUENE (UNII: 1P9 D0 Z171K) .ALPHATOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0)
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K) .ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)
COCOA BUTTER (UNII: 5120 YT1CRR)
CETYL ALCOHOL (UNII: 936JST6JCN)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
LAURETH-20 (UNII: 6SU0SC83AH)
DIMETHICO NE (UNII: 92RU3N3Y1O)

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:72133-121-45	127 g in 1 TUBE; Type 0: Not a Combination Product	04/09/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	04/09/2018		

Labeler - Delta Brands & Products LLC (080999173)

Revised: 11/2018 Delta Brands & Products LLC