# HOT STUFF- capsicum oleoresin cream Mueller Sports Medicine 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.

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Hot Stuff®

**Drug Facts** 

## **Active ingredient**

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

# Purpose

Pain Relief

#### Uses

for the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains

#### **Warnings**

#### For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, pack, wrap, hot water bottle or any heating element

#### **When using this product** do not get into eyes

avoid contact with other mucous membranes.

**Discontinue use and ask a doctor 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
- if pregnant or nursing, seek the advice of a health professional before using

#### **Directions**

- Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock
- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other sensitive mucous membranes

- A burning sensation may occur upon initial application but generally disappears with continued use
- For a severe burning discomfort, remove excess product wiht a soft cloth and mineral oil

### **Inactive ingredients**

Water (Aqua), Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Medicago Sativa (Alfalfa) Extract, Arnica Montana Flower Extract, Cymbopogon Schoenanthus Stem/Leaf/Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Celosia Argentea Seed Extract, Euterpe Oleracea Fruit Extract, Mentha Piperita (Peppermint) Oil, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Menthane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Ceteareth-12, Cetyl Palmitate, Emu Oil, Polysorbate 20, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide

# Questions or comments?

Call 1-800-356-9522 or Email us at sportcare@muellersportsmed.com

#### PRINCIPAL DISPLAY PANEL - 106 g Bottle Label

**MUELLER**<sub>®</sub>

Hot Stuff<sup>®</sup> Cream topical analgesic

Warming **Capsaicin** formula delivers comforting, targeting relief

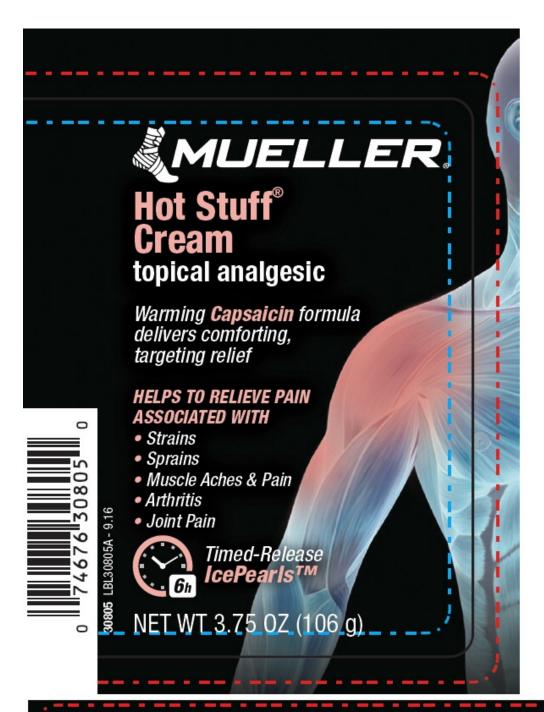
# HELPS TO RELIEVE PAIN ASSOCIATED WITH

- Strains
- Sprains
- Muscle Aches & Pain
- Arthritis
- Joint Pain

6h Timed-Release IcePearls™

30805 LBL30805A - 9.16

NET WT 3.75 OZ (106 g)



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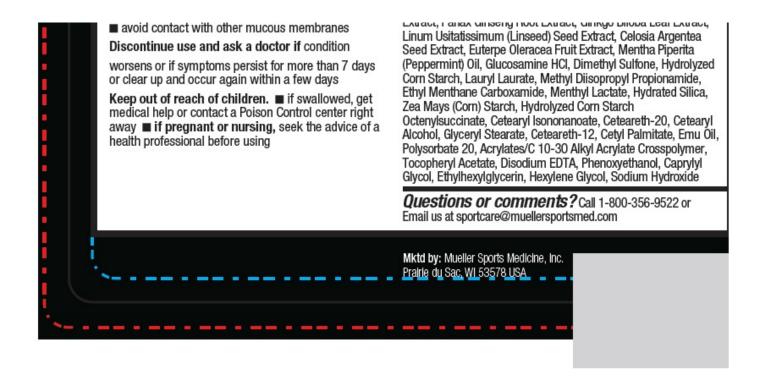
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#### **HOT STUFF**

capsicum oleoresin cream

Product Information	duct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52564-308	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength	
	CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII: UW86K581WY)	CAPSAICIN	0.0265 g in 106 g	

Ingredient Name  WATER (UNII: 059QF0KO0R)  BUTYLENE GLYCOL (UNII: 3XUS85K0RA)  GLYCERIN (UNII: PDC6A3C0OX)  ALOE VERA LEAF (UNII: ZY81Z83H0X)  SUNFLOWER OIL (UNII: 3W1JG795YI)  ALFALFA (UNII: DJO934BRBD)	Inactive Ingredients		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)  GLYCERIN (UNII: PDC6A3C0OX)  ALOE VERA LEAF (UNII: ZY81Z83H0X)  SUNFLOWER OIL (UNII: 3W1JG795YI)	Strength		
GLYCERIN (UNII: PDC6 A3C0 O X)  ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)  SUNFLOWER OIL (UNII: 3W1JG795YI)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) SUNFLO WER O IL (UNII: 3W1JG795YI)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
ALFALFA (UNII: DJO934BRBD)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
ROSEMARY (UNII: IJ67X351P9)			
MENTHA PIPERITA LEAF (UNII: A389O33LX6)			
ASIAN GINSENG (UNII: CUQ3A77YXI)			
GINKGO (UNII: 19FUJ2C58T)			
FLAX SEED (UNII: 4110 YT348 C)			

ACAI (UNII: 46 AM2VJ0 AW)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
GLUCO SAMINE HYDRO CHLO RIDE (UNII: 750 W5330 FY)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
LAURYL LAURATE (UNII: GPW77G0937)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBO XAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
STARCH, CORN (UNII: O8232NY3SJ)	
CETEARYL ISONONANO ATE (UNII: P5001U99NI)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
EMU O IL (UNII: 344821WD61)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52564-308- 02	106 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 16	
2	NDC:52564-308- 01	106 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/25/2014	0 3/0 1/20 18

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part348	06/25/2014		

# **Labeler -** Mueller Sports Medicine LLC (006426316)

Revised: 11/2016 Mueller Sports Medicine LLC