### BIOFREEZE- menthol spray Performance Health LLC Reference Label Set Id: 44348c53-b600-4189-a797-379523b87480

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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#### **Biofreeze Pain Relieving Spray**

#### **Drug Facts**

Active Ingredients:

Menthol USP 10%

Purpose

**Cooling Pain Reliever** 

#### Uses:

Temporary relief from minor aches and pains of sore muscles and joints associated with: -arthritis - backache - strains - sprains

#### Warnings:

For external use only

Flammable: Keep away from excessive heat or open flame

## Ask a doctor before use if you have:

sensitive skin

## When Using This Product:

-Avoid contact with the eyes or mucous membranes - Do not apply to wounds or damages skin -Do not use with other ointments, creams, sprays or liniments -Do not apply to irritated skin or if excessive irritation develops -Do not bandage - Wash hands after use with cool water -Do not use with heating pad or device

#### Stop Use And Ask A Doctor If:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur

## If pregnant or breastfeeding:

Ask a health professional before use.

## Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

## Directions

Adults / Children 12 years and older: Apply on to affected area up to 4 times daily

Children under 12 years of age: Consult a physician

#### **Other Information:**

Store in a cool dry place with lid closed tightly

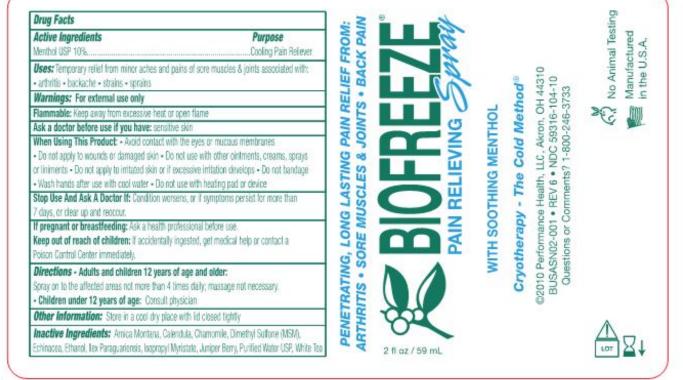
#### **Inactive Ingredients:**

Arnica Montana, Calendula, Chamomile, Dimethyl Sulfone (MSM), Echinacea, Ethanol, Lex Paraguarenis, Isopropyl Myristate, Juniper Berry, Purified Water USP, White Tea

## **Questions or Comments?**

1-800-246-3733

### BIOFREEZE - menthol spray (59316-104-10)



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## BIOFREEZE - menthol spray (59316-104-30)

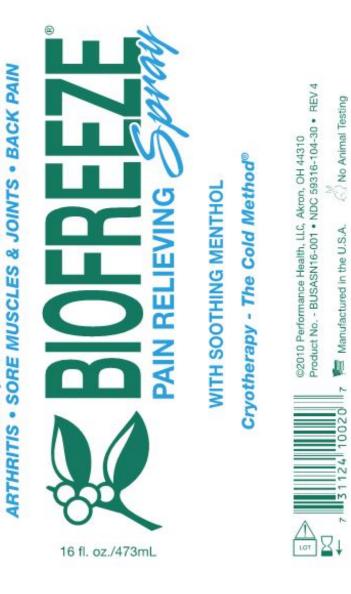
Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients & Athletes Under Their Care

Active Ingredients Menthol USP 10%	Purpose Cooling Pain Reliever
Uses: Temporary relief from mi sore muscles & joints associated strains • sprains	
Warnings: For external u	se only
Flammable: Keep away from ex	cessive heat or open flame
Ask a doctor before use if yo	u have: sensitive skin
When Using This Product: • mucous membranes • Do not app • Do not use with other ointments • Do not apply to irritated skin or • Do not bandage • Wash hands • Do not use with heating pad or	oly to wounds or damaged skin s, creams, sprays or liniments if excessive irritation develops after use with cool water
Stop Use And Ask A Doctor I symptoms persist for more than a If pregnant or breastfeeding: a Keep out of reach of children medical help or contact a Poison	7 days, or clear up and reoccur Ask a health professional before use. 1: If accidentally ingested, get
	Idren 12 years of age and older more than 4 times daily; massage
Children under 12 years of	age: Consult physician
Other Information: Store in	a cool dry place with lid closed tightly
Inactive Ingredients: / Chamomile, Dimethyl Sulfone, Ech	Arnica Montana, Calendula, inacea, Ethanol, ILEX Paraguarenis,

PENETRATING, LONG LASTING PAIN RELIEF FROM:

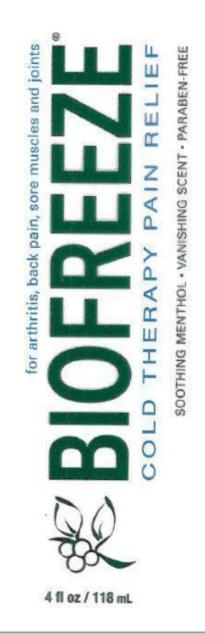
59316-104-25 Package Label

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Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients, & Athletes Under Their Care

00	Drug Facts		
SPRAY	Active Ingredients Merihol USP 10%	Perpase Cooling Pain Relever	
APPLY FROM	<b>Uses:</b> Temporary relief from minor aches and poins i	ol sone muscles & joints associated with	
ANY ANGLE	• artintis • backache • sixans • sprains Warminges: For external use only		
EVEN SPRAYS UPSIDE DOWN	Flammable: Kees away from excessive heat or oper Contents Under Pressure. Do Not Puncture Or In Do Not Store At Temperature Above 120° F		
	Ask a doctor before use if you have: sensitive sk	in	
NO ASPHILIN OR SALICYLATE	When Using This Product:  Avoid contact with th Do not apply to wounds or itemaged skin  Do not apply to initiated skin o Eo not banklage  Wash hands after use with coal or device	l use with office ointments, creams, r il ersessive intlation develops	
018	Stop Use And Ask A Dector If: Condition worsens, 7 days, or clear up and rescaue.	or it symptoms pensist for more then	
31124 10018	If pregnant or breastfeeding: Ack a health profess Keep out of reach of children: I accidentally inges Poison Control Center immediately.		
311 12149 REV	Officertifients * Adults and children 12 years of age and older: Spray on to the affected areas not more than 4 times dely; massage not necessary. Children under 12 years of age: Consult physician		
	Other Information: Store is a cool dry place with 4d closed signify		
© 2012 Parlormence Henth, LLC 1245 Rome Avenue Akron, OH 44310 www.biofrecze.com	ct, Calenchola Officinariis Prower Extract, yf Sulkine (ANSLA), Echinacea Angustitclia I topropyl Myristata, Jumperus Extract		
D07 2P M5665	Questions or Comments? 1-809-246-3733		
LOT ALA	💍 No Animal Testing 🛛 🗯	Manufactured in the U.S.A.	



**BIOFREEZE** 

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Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-104	
Route of Administration	TOPICAL			
A T . ]! ./A .! 3.	• .			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Streng	th Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	100 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
ARNICA MONTANA (UNII: O80TY208ZW)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
CHAMO MILE (UNII: FGL3685T2X)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)				
ALCOHOL (UNII: 3K9958V90M)				
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
JUNIPERUS COMMUNIS WHOLE (UNII: 464910T5N9)				
WATER (UNII: 059QF0KO0R)				

#### Packaging

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#	Item Code		Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59316-104- 10	59 mL Produc	. in 1 BOTTLE, SPRAY; Type 0: Not a Combination ct	08/25/2016		
2	NDC:59316-104- 20	118 ml Produc	L in 1 BOTTLE, SPRAY; Type 0: Not a Combination ct	08/25/2016		
3	NDC:59316-104- 30	473 m Produc	L in 1 BOTTLE, SPRAY; Type 0: Not a Combination ct	08/25/2016		
4	NDC:59316-104- 25	118 ml Produc	L in 1 BOTTLE, SPRAY; Type 0: Not a Combination ct	11/29/2012	12/31/2018	
Marketing Information						
	Marketing Categ	gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
0	TC monograph not	final	part348	11/0 1/20 10		

# Labeler - Performance Health LLC (794324061)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Span Packaging Services LLC dba Multi-Pack Solutions		117101131	manufacture(59316-104)

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Span Packaging services LLC		557434805	manufacture(59316-104)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence, LLC.		825646862	manufacture(59316-104)