ANALGESIC- menthol spray Safetec of America, Inc.

61010-8201. Pain Relief Spray

Active Ingredients

USP Menthol 7%

Purpose

Topical Analgesic

Uses

Temporary relief of minor aches and pains of muscles and joints.

Warnings

For external use only.

Flammable.

Keep away from flame.

Keep out of reach of children.

If swallowed get medical help or contact a poison control center right away. Avoid contact with eyes.

Do not apply to open wounds or damaged skin. Do not bandage tightly.

Consult a doctor if excessive skin irritation occurs, or if you are prone to allergic reactions to salicylates, including aspirin. If condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, discontinue use of this product and consult a doctor.

Directions

For adults and children 2 years of age and older: Shake well and apply to affected area not more than 3-4 times daily. Will not stain clothing. For children under 2 years of age, consult a doctor.

Other Information

Store at room temperature.

Inactive Ingredients

Water, Isopropyl Alcohol, Glycerol, Eucalyptus Leaf Oil, Wintergreen Leaf Oil, Peppermint Oil, Coconut Oil.

Principal Display Panel - Pain Relief Spray Bottle Label

NDC 61010-XXXX-X

Safetec

PAIN RELIEF SPRAY

MEDICATED FAST-ACTING

For temporary relief of minor aches and pains

2 fl. oz. (59.1 ml)

NDC 61010-XXXX-X	Drug Facts				
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MEDICATED • FAST-ACTING For temporary relief of minor aches and pains	Manufactured by SAFETEC OF AMERICA, Inc. Buffalo, NY 14215 800-456-7077 www.safetec.com Reorder No. 58000				
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Inactive Ingredients Water, Isopropyl Alcohol, Glycerol, Eucalyptus Leaf Oil, Wintergreen Leaf Oil, Peppermint Oil, Coconut Oil.

menthol spray							
Product Info	rmation						
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:61010-8201		
Route of Admin	istration	TOPICAL					
Active Ingred	ient/Active	Moiety					
	Ingredient Name Basis of Stre			Basis of Streng	gth Streng	gth	
MENTHOL (UNII: L	7T10EIP3A) (MEN	ITHOL - UNII:L7T10EIP3A)		MENTHOL	70 mg in	1 L	
Inactive Ingre	edients						
		Ingredient Name			Strength		
WATER (UNII: 0590	QF0KO0R)						
ISOPROPYL ALCOHOL (UNII: ND2M416302)							
GLYCERIN (UNII: PDC6A3C0OX)							
EUCALYPTUS OIL (UNII: 2R04ONI662)							
METHYL SALICYL							
PEPPERMINT OIL		•					
IU) LIO TUNODO	NII: Q9L0073W7L	_)					
Packaging							
# Item Code	Pa	ackage Description		Marketing Start Date	Marketing Date	End	
	0.059 L in 1 BO Combination Pro	TTLE, SPRAY; Type 0: Not a oduct	à	09/01/2018			
Marketing	Informat	ion					
Marketing Category	Applicat	tion Number or Monog Citation	graph	Marketing Start Date	Marketing Date	End	
OTC Monograph Dr	ug M017		(09/01/2018			

Labeler - Safetec of America, Inc. (874965262)

Establishment									
Name	Address	ID/FEI	Business Operations						
Safetec of America, Inc		874965262	manufacture(61010-8201)						

Revised: 2/2024

Safetec of America, Inc.