

**RAW HEAT- menthol liquid**  
**Raw Health International, 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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**Drug Facts**

**Active Ingredient**

Menthol 3.5%

**Purpose**

Pain Reliever

**Uses**

Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.

**Warnings**

For external use only. Flammable. Keep away from open flame or extreme heat.

Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.

When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly.

Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application.

Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.

**Directions**

For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.

**Inactive Ingredients**

Aloe Barbadosensis (Aloe) Leaf Gel, SDA 38B, Glycerin, Xanthan Gum, Gaultheria Procumbens (Wintergreen) Leaf Oil, Cinnamomum Cassia (Cassia) Oil, Dehydroxyxanthan Gum, Cinnamomum Camphora (Camphor) Bark Oil, Organic Chamomilla Recutita (Matricaria), Organic Symphytum Officinale (Comfrey)

**RAW Health International, LLC**

91 Ft. Couch Road-Pittsburgh, PA 15241

[www.rawhealthintl.com](http://www.rawhealthintl.com)

Ph: 1-888-RAW-HLTH

**Questions or comments:**

Email us at: [info@rawhealthintl.com](mailto:info@rawhealthintl.com)

MSRP \$14.99

**PRINCIPAL DISPLAY PANEL – 3 oz. bottle**

**RAW**

RAW HEALTH INTERNATIONAL

HEAT

The All-Natural  
Warming Pain Reliever

Muscle Strains,  
Joint Sprains, Neck/Back Aches,  
Pains and Much More...

3 fl OZ / 89 mL

[www.rawhealthintl.com](http://www.rawhealthintl.com)

Also Try RAW-ICE for cooling pain relief

<b>Drug Facts</b>	
<b>Active Ingredient</b> Menthol 3.5%	<b>Purpose</b> Pain Reliever
<b>Uses</b> Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.	
<b>Warnings</b> For external use only. Flammable. Keep away from open flame or extreme heat. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away. When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.	
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MSRP \$14.99



Containers are BPA Free Made in the USA No Animal Testing 100% Recyclable Container



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Warming Pain Reliever**

**Muscle Strains,  
Joint Sprains, Neck/Back Aches,  
Pains and Much More...**

3 fl OZ / 89 mL

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# RAW HEAT

menthol liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55413-250 1
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	34.86 g in 1 L

## Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z83H0 X)	
glycerin (UNII: PDC6 A3C0 O X)	
xanthan gum (UNII: TTV12P4NEE)	
methyl salicylate (UNII: LAV5U5022Y)	
chinese cinnamon oil (UNII: A4WO0626T5)	
camphor oil (UNII: 751ZZ8 Y727)	
matricaria recutita (UNII: G0R4UB12ZZ)	
symphytum uplandicum leaf (UNII: D05HXK6 R3G)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55413-250 1-1	0.089 L in 1 BOTTLE		
2	NDC:55413-250 1-2	0.118 L in 1 BOTTLE		
3	NDC:55413-250 1-3	0.004 L in 1 PACKET		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2013	

**Labeler** - Raw Health International, LLC (014982454)

**Registrant** - Safetec of America, Inc. (874965262)

## Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(55413-2501)

