

**HAK KWAI PAIN RELIEVING- methyl salicylate and camphor oil**  
**MADISON ONE ACME INC**

*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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**Active ingredient** Camphor 5% Methyl salicylate 50%

**Purpose**

External analgesic  
External analgesic

**Uses**

For the temporary relief of minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- bruises
- sprains

**Warnings**

**For external use only**

**Do not use**

- on wounds
- on irritated or damaged skin

**Ask a doctor or pharmacist before use if you have**

- any concerns about using this product

**When using this product**

- do not use otherwise than as directed
- avoid contact with the eyes or mucous membranes
- do not bandage tightly
- ☐ ■ do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)

**Stop use and ask a doctor if**

- condition worsens
- ☐ ■ symptoms persist for more than 7 days
- ☐ ■ symptoms clear up and occur again within a few days
- ☐ ■ excessive irritation of the skin develops
- nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
- you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)
- when using for pain of arthritis:
  - pain persists for more than 10 days

- redness is present
- in conditions affecting children under 12 years of age

**Report any unexpected side effects** from the use of this product to the FDA MedWatch Program

**Keep out of reach of children** to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- adults and children 3 years of age and older: apply several drops and rub into the affected area not more than 3 to 4 times daily
- children under 3 years of age: consult your physician

***Other information***

- keep container tightly closed
- store protected from light at 15 ° to 30 C (59 to 86 F)

***Inactive ingredients*** Clove oil, cinnamon oil, citronella oil, and thyme oil.

***Questions or comments?*** (888) 221-3496 M-F 9 am to 5 pm

- you may also report serious side effects to this phone number

HAK KWAI PAIN RELIEVING OIL

Methyl Salicylate and Camphor

NDC 55614-710-01

EXTERNAL ANALGESIC

1.69 FL OZ (50 ML)

黑鬼油 紙盒

1.69FL OZ (50ML) Box

Size: 53 (W) x 27.5 (D) x 140.5 (H) mm

11/18/2020



**Drug Facts (Continued) 藥品資料 (續)**

**Inactive Ingredients 非活性成分** Clove oil, chironomol oil, citronella oil, eucalyptus oil, geraniol, ginger oil, lavender oil, menthol, peppermint oil, rosemary oil, sage oil, tea tree oil, thyme oil, ylang-ylang oil.

**Questions or comments? 問題或建議?** (888) 221-3486  
 M-F 9 am to 5 pm 星期一至五, 上午九時至下午五時  
 You may also report serious side effects to this phone number  
 您還可向本藥廠報告嚴重的副作用

U.S. Distributor 美國總代理:  
**SOL STICE MEDICINE COMPANY**  
 美國蘇氏藥業有限公司  
 215 W. Ann St., Los Angeles, CA 90012  
 Toll Free: 1-888-221-3486  
 www.solsticemed.com  
 PRODUCT OF CHINA

**Drug Facts 藥品資料**

**Active ingredients 有效成份 Purpose 用途**  
 Methyl Salicylate 水楊酸甲酯 50% External analgesic 外用止痛藥  
 Camphor 樟腦 5% External analgesic 外用止痛藥

**Uses 作用**  
 For the temporary relief of minor aches and pains of muscles and joints due to:  
 暫時緩解因下列症狀引起的肌肉和關節輕微疼痛:  
 ■ simple backache 一般腰背疼痛 ■ arthritis 關節炎  
 ■ strains 扭傷 ■ bruises 瘀傷 ■ sprains 扭傷

**Warnings 警告**  
 For external use only 本品僅供外用  
**Do not use 不要用於**  
 ■ on wounds 傷口  
 ■ on irritated or damaged skin 過敏或破損的皮膚  
 Ask a doctor or pharmacist before use if you have  
 如果有以下情況, 在使用前請諮詢醫生或藥劑師  
 ■ any concerns about using this product 對使用本產品有任何顧慮

**When using this product 在使用本品時**  
 ■ do not use otherwise than as directed 請遵醫囑使用  
 ■ avoid contact with the eyes or mucous membranes 避免接觸眼睛或黏膜  
 ■ do not bandage tightly 切勿貼過緊  
 ■ do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns) 不要以加熱墊、熱水瓶或加熱燈的形式對患處施加熱量 (這樣做會增加嚴重灼傷的風險)

**Stop use and ask a doctor if 如果出現下列情況應停止使用本品並請教醫生**  
 ■ condition worsens 情況加重  
 ■ symptoms persist for more than 7 days 症狀持續七天以上  
 ■ symptoms clear up and occur again within a few days 症狀消失幾天後又再出現  
 ■ excessive irritation for the skin develops 皮膚出現過敏  
 ■ nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs 噁心、嘔吐、腹部不適、腹瀉或出現皮疹  
 ■ you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation) 使用後您感到實際疼痛或起水泡灼痛 (感覺溫暖或涼快是正常的)  
 ■ when using for pain of arthritis 用於關節炎止痛時:  
 ■ pain persists for more than 10 days 疼痛持續超過十天  
 ■ redness is present 皮膚發紅  
 ■ in conditions affecting children under 12 years of age 影響12歲以下兒童的症狀

**Drug Facts (Continued) 藥品資料 (續)**

Report any unanticipated side effects from the use of this product to the FDA MedWatch Program  
 向FDA MedWatch 計劃報告您使用本產品所產生的任何意外副作用  
 Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away. 保存在兒童無法拿到的地方防止意外中毒。如果吞下, 請立即就醫或聯絡毒物控制中心。

**Drug Facts (Continued) 藥品資料 (續)**

**Directions 用法**  
 ■ adults and children 3 years of age and older: apply several drops and rub into the skin 3 to 4 times a day. 成人及3歲或以上兒童: 每日塗抹3至4次。  
 ■ children under 3 years of age: consult your physician. 3歲以下兒童: 向醫生諮詢。

**Other information 其它資訊**  
 ■ Keep container tightly closed. 保存容器緊蓋。  
 ■ store at 15° to 30° C (59° to 86° F) 請存儲於15至30度 (華氏59 - 86度)

NDC 55614-710-01

**HAK KWAI PAIN RELIEVING OIL**  
 External Analgesic

**林標 蘇氏 藥業 有限公司**  
**YU LAM**

**黑鬼油**

1.69 FL. OZ (50mL) (毫升)



methyl salicylate and camphor oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:556 14-710
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	50 g in 100 mL
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CLOVE OIL</b> (UNII: 578389D6D0)	
<b>CINNAMON OIL</b> (UNII: E5GY4I6YCZ)	
<b>CITRONELLA OIL</b> (UNII: QYO8Q067D0)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:556 14-710-01	1 in 1 BOX	11/27/2020	
1		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/27/2020	

**Labeler** - MADISON ONE ACME INC (096196758)

### Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(556 14-710)

Revised: 12/2020

MADISON ONE ACME INC