PAIN RELIEF LIQUID- menthol liquid
Great Lakes Wholesale, Marking, and Sales, 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.

Menthol 16%

Topical analgesic

temporariy relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

For external use only

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight

Flammable

- keep away from fire or flame

stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again witin a few days sy

If pregnant or breast-feeding, ask a health professional before use.

If swallowed, get medical help, or contact a Poison control Center right away

Adults and children over 12 years;

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 3-4 times daily
- IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

children 12 years or younger: ask a doctor

acrylates/C10-30 alkyl acrylate crosspolymer, capsaicin, glycerin, isopropyl myristate, propylene glycol, SD alcohol 40 (3

0%), water (245-256)

Personal Care Solutions

Maximum Strength

Pain Relief Liquid

with no mess roll-on applicator

Long lasting pain relief

- Powerful, fast acting formula
- Deep Penetrating Quick Drying
- Roller Ball Keeps Hands Clean

2.5 fl. oz. (73 ml)

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- repeat as necessary, but no more than 3-4 times daily.

PAIN RELIEF LIQUID

menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64092-402
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.16 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CAPSAICIN (UNII: S07O44R1ZM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-402-02	73 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	12/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/05/2016	

Labeler - Great Lakes Wholesale, Marking, and Sales, Inc. (361925498)

Registrant - Illinois Industrial Tool, Inc (628032898)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Dedi Medical Device Co., Ltd.		421353662	manufacture(64092-402)

Revised: 12/2016 Great Lakes Wholesale, Marking, and Sales, Inc.