

SAFETY DATA SHEET

Troy Healthcare, LLC

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Section 1: Identification

Product Name: STOPAIN® CLINICAL Migraine & Headache Gel	Manufacturer: Troy Manufacturing, Inc. 130 Lions Drive Hazleton, PA 18201 USA www.stopainclinical.com
Product NDC Number: N/A	
Reorder Number: N970-01	
UPC Code: 7-24909-97001-0	Telephone: (570) 453-5252
Product Use: Topical Analgesic, Homeopathic OTC	Emergency (Chemtrec): (800) 424-9300

Section 2: Hazard Identification

Classification: Flammable Liquid – Category 2
Skin Irritation – Category 2
Eye Irritation – Category 2B
May Cause Drowsiness or Dizziness

Label elements: Danger



Hazard Statement:

- Highly flammable liquid and vapor.
- Causes skin irritation.
- May cause drowsiness or dizziness.
- Harmful if swallowed.
- Causes serious eye irritation.

Precautionary Statements:

- Keep away from heat, sparks, open flames and/or hot surfaces.
- Keep container tightly closed.
- Keep cool.

Prevention:

- Avoid breathing vapors and or spray.
- Wash thoroughly after handling.
- Wash thoroughly after handling.

Response:

- In case of fire: Use appropriate media.
- If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- Call a Poison Center or doctor/physician if you feel unwell.
- If skin irritation occurs get medical advice/attention.

CANADA
According to WHMIS:

Classification: • Flammable Liquid
WHIMS • Other toxic effects

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Label:
WHIMS



- Flammable Liquid
- Other toxic effects

Section 3: Composition/Information on Ingredients

Mixture

Composition Containing Hazardous Components*

Chemical Name	Identifiers	% weight	Recommended Exposure Limits	Classification According to Regulation	Comments
190 Proof Ethanol USP	CAS: 64-17-5	49.5	400ppm TWA	OSHA HCS 2012	
L-menthol (natural)	CAS: 89-78-1	6.0	NA	NA	

*Proprietary ingredients omitted. As packaged Stopain® products are classified as Consumer Commodity ORM-D 1 – Comprehensive Environmental Response, Compensation and liability Act of 1980 requires notification of the national Response Center of release of quantities of hazardous Substances equal or greater than the reportable quantities (RQ) in 40 CFR 302.4. Components present in this product at a level which could require reporting under this statute are:

Section 4: First-Aid Measures

Inhalation: Move victim to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is not breathing.

Skin: In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Wash skin with soap and water. Take off contaminated clothing and wash before reuse. If skin irritation occurs, get medical advice/attention.

Eye: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Ingestion: DO NOT induce vomiting. If person is drowsy or unconscious and vomiting, place on the left side with head down. Seek medical attention.

Most important symptoms and effects, both acute and delayed
Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

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Section 5: Fire-Fighting Measures

EXTINGUISHING MEDIA

Suitable Extinguishing Media: Carbon dioxide, dry chemical and water spray

Unsuitable Extinguishing Media: Avoid the use of streaming water

SPECIAL HAZARDS ARISING FROM MIXTURE

Unusual fire and explosion hazard:

- Flammable: Will ignite by sparks, heat or flames.
- Vapors may form explosive mixture with air.
- Vapors may travel to source of ignition.

Advice to Firefighters: Firefighters should wear self-contained breathing apparatus. Wear protective clothing that is specifically recommended by manufacturer for firefighters. Use water spray to cool containers exposed to fire.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions:

- Wear appropriate protective equipment including respiratory protection as conditions warrant.
- Do not touch or walk through spilled material
- Do not touch damaged containers or spilled material

Emergency Procedures:

- As immediate precautionary measures, isolate spill or leak area (150 feet radius)
- Eliminate all ignition sources in spill or leak area
- Keep unauthorized personnel away
- Stay upwind and ventilate closed spaces before entering
- Avoid run off to waterways and sewers

Methods and Material for Containment and Cleaning up

Containment/Clean-up Measures:

- Stop leak if it can be done without risk.
- All equipment used when handling the product must be grounded.
- Absorb or cover with dry earth, sand or other non-combustible material and transfer to suitable containers.
- Use clean non-sparking tools to collect absorbed material
- For large spills consider a dike far ahead of liquid spill

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Section 7: Handling and Storage

Precautions for Safe Handling

- Handling:**
- Keep away from heat and ignition sources
 - Empty containers contain residue and maybe dangerous
 - Use with adequate ventilation

Conditions for Safe Storage

- Storage:**
- Store in cool/low temperature, well ventilated area
 - Keep container closed when not in use
 - Keep away from heat, ignition sources, oxidizers and acids

Section 8: Exposure Controls/Personal Protection

Exposure Limits/Guidelines					
	Result	ACGIH	Canada	Canada Quebec	NIOSH
190 Proof Ethanol USP	STELs	1000 ppm	1000 ppm	1000 ppm	1000 ppm
	TWAs	1000 ppm	1000 ppm	1000 ppm	1000 ppm
L-menthol (natural)	STELs	NA	NA	NA	NA
	TWAs	NA	NA	NA	NA

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Exposure Controls

Engineering Measures/Controls:

- Adequate ventilation as needed to control exposure.

Personal Protective Equipment:

Pictograms:



Respiratory:

- In case of insufficient ventilation wear suitable respiratory equipment. Follow OSHA 29CFR 1919.134

Eye/Face:

- Wear safety goggles.

Hands:

- Wear protective gloves (neoprene, butyl or nitrile rubber).

Skin/Body:

- Where extensive dermal exposure is expected wear a chemical suit or chemical apron.

General Industrial Hygiene Considerations:

- Handle in accordance with good industrial hygiene practice. Wash thoroughly with soap and water after handling and before eating or drinking. Safety shower and eye wash should be available close to work areas.

Environmental Exposure Controls:

- Follow best practice for site management and disposal of waste. Avoid release to the environment.

Section 9: Physical and Chemical Properties

Property	190 Proof Ethanol USP	L-menthol (natural)
Appearance	Clear colorless liquid	White crystal/powder
Odor	Characteristic alcohol	Mint-like
pH	NA	NA
Melting point	<-100 °C	42-44 °C
Boiling point	78.3 °C	212 °C
Flash point	24.5 °C For Final Composition (Pensky-Martens Closed Cup Tester)	
Evaporation rate ³	3.34 (butyl acetate=1)	NA
Flammability	Flammable liquid	Flammable (powder)
Upper/lower flammability	3.3% - 19%	NA
Vapor pressure (mm Hg)	43.7	.14
Vapor density	1.59 (versus air)	NA
Relative density (g/ml)	.82	.89
Solubility in water	miscible	trace
Solubility in alcohols	miscible	soluble
Partition coefficient octanol/water (log P)	.32	3.4
Auto-ignition temp	363 °C	478 °C
Viscosity	0.0012 Pa s at 20 °C	Solid at 20 °C

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Section 10: Reactivity

Reactivity: No dangerous reaction known with normal use.

Chemical Stability: Stable under normal temperatures and pressures.

Possibility of Hazardous Reactions: Hazardous reactions may occur with oxidizing agents.

Conditions to Avoid: High temperatures, sparks, open flames and electrical circuits.

Hazardous Decomposition Products: In case of fire carbon dioxide, hydrocarbons, fumes, soot and smoke may be produced.

Section 11: Toxicological Information

Component Name	CAS	Data
190 Proof Ethanol USP (49.5% of Formulation)	64-17-5	Acute Toxicity: LD50(H) Oral Rat 15010 mg/kg, LDLo Oral Rat 7000 mg/kg, Irritation: Eye-rbt 100mg MOD-SEV, skin-human 500mg (MLD). Reproductive: Teratogenic rats, mice. Carcinogenic: Classified 1 (Proven for humans.) by IARC.
GHA Properties		Classification (OSHA HCS 2012)
Acute Toxicity		Classification criteria not met.
Aspiration Hazard		No data available.
Carcinogenicity		Oral consumption of ethanol – IARC classification as carcinogenic to humans based on sufficient evidence in humans.
Germ cell mutagenicity		No data available.
Respiratory sensitization		May cause respiratory irritation - lungs
Serious eye damage/irritation		Classification criteria not met.
Skin corrosion/irritation		Skin irritation 2.
Skin sensitization		Classification not met.
STOT-RE		No data available.
STOR-SE		No data available.
Toxicity for reproduction		Classification criteria not met.

Signs and symptoms of exposure

Central nervous system depression, gastrointestinal disturbance including nausea, as well as headache may occur

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Section 12: Ecological Information

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulation: No data available

Mobility in soil: No data available

PBT and vPvB: No data available

Section 13: Disposal Considerations

Product: Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging: Dispose of as unused product.

Section 14: Transport Information

DOT (US): UN number: 1170, Class 3, Packaging group III.
Proper shipping name: Ethanol solutions.
Marine pollutant: No.
Poison inhalation hazard: No.

IMDG: UN number: 1170, Class 3, Packaging group III.
Proper shipping name: Ethanol solution.
Marine pollutant: No.

IATA: UN number: 1170, Class 3, Packaging group III.
Proper shipping name: Ethanol solution
Marine pollutant: No

OSHA Hazards: Flammable liquid, target organ effect, toxicity by inhalation, ingestion, skin absorption, irritant, carcinogen

SARA 302 Components: None included.

SARA 312 Components: None included

SARA 311/312 Hazards: Fire hazard, acute health hazard, chronic health hazard

Massachusetts Right to Know Components

Ethanol
Menthol

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Pennsylvania Right to Know Components

Ethanol
Menthol

New Jersey Right to Know Components

Ethanol
Menthol

California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 15: Regulatory Information (not listed elsewhere)

US TSCA Inventory Status: All components of this product are either on the Toxic Substance Control Act inventory list or exempt.

Canadian DSL Inventory Status: All components of this product are either on the Canadian DSL Inventory Status List or exempt.

Section 16: Other Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Troy Healthcare, LLC shall not be held liable for any damages resulting from handling or from contact with the above product.