1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Arnicare Gel
GENERAL USE: Pain relief - muscle pain and stiffness, swelling from injuries, and bruises.
PRODUCT FORMULATION NAME: Arnicare Gel
DISTRIBUTOR
Boiron Inc
4 Campus Blvd
Newtown Square, PA 19073
Emergency Phone: 610-325-7464

2. HAZARDS IDENTIFICATION

GHS CLASSIFICATIONS
Flammable Liquids, Category 3
GHS LABEL

Flame
SIGNAL WORD: WARNING
HAZARD STATEMENTS
H226: Flammable liquid and vapour.
POTENTIAL HEALTH EFFECTS
SKIN: Not expected to be irritating.
COMMENTS: This is an OTC Homeopathic product in topical form that is intended to be used according to the directions on the label. It is intended for external use only.
This product in its final, packaged form presents minimal risk from occupational exposure. Health effects information is based on potential hazards of components.
This product is not considered hazardous according to the OSHA HazCom 2012 Standard.
Arnicare gel contains approximately 20% ethanol but it also contains at least 70% water. This product does not sustain combustion.
This product is exempt from special flammable storage requirements per 29 CFR 1910.106(d)(2)(iii)(b) Table H-12.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Wt.%	CAS
Water	71.93	7732-18-5
Ethanol	20	64-17-5
Carbopol 980 NF	0.9	9003-01-4
Sodium Hydroxide	0.17	1310-73-2

COMMENTS: Homeopathic Active Ingredient:
Arnica Montana 1X HPUS [CAS# 68990-11-4]: 7%

The active ingredient is a class C tincture (1 part by weight of dry plant material in 9 parts of water + ethanol) made in accordance with the Homeopathic Pharmacopeia of the United States.

4. FIRST AID MEASURES

EYES: Immediately flush eyes with plenty of 1% (one percent) physiological saline solution for five minutes while holding eyelids open and see a physician. Saline flush is the treatment of choice. If no saline is easily available, flush eyes with plenty of clean water for 15 minutes and see a physician.
SKIN: If irritation occurs, discontinue treatment and consult a physician. Wash the affected area with plenty of soap and water.
INGESTION: In cases of accidental ingestion of large amounts, call Poison Control Center and consult a physician. Any treatment should be symptomatic and determined by a physician.
INHALATION: In cases of inhalation exposure treat if necessary, any treatment should be symptomatic and determined by a physician.

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA: Use standard class ABC fire extinguisher.

6. ACCIDENTAL RELEASE MEASURES

COMMENTS: Disposal of collected product, residues, and cleanup materials may be governmentally regulated. Observe all applicable local, state, and federal waste management regulations. Use the appropriate personal protective equipment as described in Section 8. Mop up, wipe up, or soak up with absorbent materials, use appropriate solvents, wash with mild/caustic detergent, and contain for salvage or disposal.

7. HANDLING AND STORAGE

STORAGE: Store in a cool, dry place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE GUIDELINES

OSHA HAZARDOUS COMPONENTS (29 CFR1910.1200)				
	EXPOSURE LIMITS			
Chemical Name	**Type**		**ppm**	**mg/m³**
Ethanol	**OSHA PEL**	**TWA**	1000	1900
		STEL	NL	NL
	ACGIH TLV	**TWA**	1000	1880
		STEL	NL	NL
	Supplier OEL	**TWA**	NL	NL
		STEL	NL	NL
Sodium Hydroxide	**OSHA PEL**	**TWA**	NL	NL
		STEL	NL	C 2
	ACGIH TLV	**TWA**	NL	NL
		STEL	NL	C 2
	Supplier OEL	**TWA**	NL	NL
		STEL	NL	NL

ENGINEERING CONTROLS: Adequate ventilation and access to eye wash.
PERSONAL PROTECTIVE EQUIPMENT
EYES AND FACE: Safety goggles or face shield where appropriate.
SKIN: Gloves.
COMMENTS: The personal protective equipment described in this section is to be used for occupational exposures.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, yellowish gel.
FLASH POINT AND METHOD: 56.5 (+/-)°C Closed cup measurement.

10. STABILITY AND REACTIVITY

REACTIVITY: Stable.

11. TOXICOLOGICAL INFORMATION

GENERAL COMMENTS: Ethanol: Acute ingestion can cause depression of the central nervous system, nausea, vomiting, and diarrhea. Liquid or vapor may cause eye irritation. May cause irritation and defatting of skin on prolonged contact.[4]

Sodium Hydroxide: Is used as a buffer to neutralize the acidity of the preparation and is consumed during the manufacturing process.[5]

Carbopol 980 USP: Carbopol resins are solid (powder) materials that are virtually always processed in a liquid mixture, as in this product. Carbopol is primarily an acrylic polymer (98-100%) with a small amount of acrylic acid (0.01-0.4%). Toxicity due to Carbopol toxicity is primarily associated with inhalation of Carbopol dust; this exposure pathway is not applicable to this product. No evidence of irritation or sensitization during human patch testing has been found. It is not classified as a carcinogen. There is no evidence concerning mutagenicity or teratogenicity.[3]

Disodium Edetate: Is used widely in topical, oral, and parentieral pharmaceutical formulations; it is used extensively in cosmetic and food products. Disodium edetate is poorly absorbed from the gastrointestinal tract and are associated with few adverse effects when used as excipients in pharmaceutical formulations.[5]

Arnica Montana 1X HPUS: The internal use of Arnica is not recommended as the plant is considered poisonous. Gastroenteritis, vomiting, dyspnea, and cardiac arrest may occur with high oral dosages. Severe mucus membrane irritation may occur. Digestive organs and the heart are targeted by the ingestion of Arnica. Numerous cases of allergy and contact dermatitis related to Arnica have been described. Clinical reports have proven the high-sensitizing capacity of the plant. People allergic to Arnica or plants in the daisy family may display a skin rash with burning sensation and sometimes blisters.[1,2]

12. ECOLOGICAL INFORMATION

COMMENTS: N/A

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHOD: Disposal of collected product, residues and cleanup materials may be governmentally regulated. Observe all state and federal disposal regulations.

14. TRANSPORT INFORMATION

DOT (DEPARTMENT OF TRANSPORTATION)
PROPER SHIPPING NAME: N/A
OTHER SHIPPING INFORMATION: Not restricted. Due to the low ethanol content and high water content of Arnicare Gel, this product is classified as an aqueous solution. According to federal regulations, this product is exempt from transportation restrictions and is not classified as a hazardous waste material as it does not sustain combustion.

15. REGULATORY INFORMATION

GENERAL COMMENTS: Due to the low ethanol content and high water content of Arnicare Gel, this product is classified as an aqueous solution. According to federal regulations, this product is exempt from transportation restrictions and is not classified as a hazardous waste material as it does not sustain combustion.
This product is exempt from special flammable storage requirements per 29 CFR 1910.106(d)(2)(iii)(b) Table H-12.

16. OTHER INFORMATION

Date Revised: 04/21/2020
REVISION SUMMARY: This SDS replaces the 06/19/2015 SDS.
DATA SOURCES:
1. Duke, James. 1985. Handbook of Medicinal Herbs, CRC Press, Boca Raton, FL, page 64 (Arnica Montana).

2. Physician Desk Reference for Herbal Medicines, 3rd Edition (2004). Thomson PDR. Page 43.3. MSDS Neveon, Inc. 11-16-2001 Carbopol 980 NF Polymer.

3. MSDS Neveon, Inc. 11-16-2001 Carbopol 980 NF Polymer.

4. MSDS Alcohol USP supplied by Quantum Chemical Corporation, USI Division, 11500 North Lake Drive, Cincinnati, OH 45244, (513) 530-6917 or (715) 479-2873.

5. Handbook for Pharmaceutical Excipients, Fifth Edition, 2006. American Pharmaceutical Association 2215 Constitution Avenue NW, Washington DC 20037.

MANUFACTURER DISCLAIMER:
While we do not specifically analyze these products, or the raw materials used in their manufacture, for substances on various state hazardous substances lists, to the best of our knowledge no such substances are present, or known to be present at reportable amounts, except those specifically listed below:
- California Proposition 65 "substances known to the State of California to cause cancer, birth defects or other reproductive harm: none.
- Massachusetts Substance List "Toxic or Hazardous" substances >1.0%: none known.
- New Jersey "Environmentally Hazardous" substances >1.0%: none known.
- New Jersey "Special Health Hazard" substances >0.01%: none known.
- New Jersey Workplace Right to Know Act: acrylic polymer (CAS# 9003-01-4);polyethylene oxide monoallyl ether (CAS# 027274313); polyethylene glycol (CAS# 025322683).
- Pennsylvania "Special Hazardous" substances >0.01%: none known.
- Pennsylvania Right to Know Act: acrylic polymer (CAS# 9003-01-4); dimethyl, polyethylene oxide monoallyl ether (CAS# 027274313); polyethylene glycol (CAS# 025322683).