

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product Name
ARNICA MONTANA 3C-30C HPUS
General Use
Relieves muscle pain and stiffness, swelling from injuries, discoloration from bruises *
Product Formulation Name
ARNICA MONTANA 3C-30C HPUS Multidose Tube
DISTRIBUTOR
Boiron Inc 4 Campus Blvd Newtown Square, PA 19073 Emergency Phone: 610-325-7464

2. HAZARDS IDENTIFICATION**GHS CLASSIFICATIONS**

N/A

COMMENTS: This is an OTC Homeopathic product in a low dusting pellet form that is intended to be absorbed sublingually according to dosing on the label. 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Wt. %	CAS
Sucrose	85	57-50-1
Lactose	15	63-42-3

COMMENTS: Homeopathic Active Ingredient:

ARNICA MONTANA 3C-30C HPUS

CAS# 68990-11-4

Percentage of Active Ingredient: 1%

The active ingredient is a dilution of its extract at 3C made in accordance with the Homeopathic Pharmacopeia of the United States. The 3C is a homeopathic serial dilution carried out at a ratio of 1:100 3 times.

The active ingredient is a dilution of its extract at 5C made in accordance with the Homeopathic Pharmacopeia of the United States. The 5C is a homeopathic serial dilution carried out at a ratio of 1:100 5 times.

The active ingredient is a dilution of its extract at 6C made in accordance with the Homeopathic Pharmacopeia of the United States. The 6C is a homeopathic serial dilution carried out at a ratio of 1:100 6 times.

The active ingredient is a dilution of its extract at 8C made in accordance with the Homeopathic Pharmacopeia of the United States. The 8C is a homeopathic serial dilution carried out at a ratio of 1:100 8 times.

The active ingredient is a dilution of its extract at 9C made in accordance with the Homeopathic Pharmacopeia of the United States. The 9C is a homeopathic serial dilution carried out at a ratio of 1:100 9 times.

The active ingredient is a dilution of its extract at 12C made in accordance with the Homeopathic Pharmacopeia of the United States. The 12C is a homeopathic serial dilution carried out at a ratio of 1:100 12 times.

The active ingredient is a dilution of its extract at 13C made in accordance with the Homeopathic Pharmacopeia of the United States. The 13C is a homeopathic serial dilution carried out at a ratio of 1:100 13 times.

The active ingredient is a dilution of its extract at 15C made in accordance with the Homeopathic Pharmacopeia of the United States. The 15C is a homeopathic serial dilution carried out at a ratio of 1:100 15 times.

The active ingredient is a dilution of its extract at 30C made in accordance with the Homeopathic Pharmacopeia of the United States. The 30C is a homeopathic serial dilution carried out at a ratio of 1:100 30 times.

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

COMMENTS: N/A

6. ACCIDENTAL RELEASE MEASURES**COMMENTS:** N/A**7. HANDLING AND STORAGE****STORAGE TEMPERATURE:** N/A**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****EXPOSURE GUIDELINES**

OSHA HAZARDOUS COMPONENTS (29 CFR1910.1200)				
Chemical Name	EXPOSURE LIMITS			
	Type		ppm	mg/m ³
	OSHA PEL	TWA	15	
Sucrose				
	ACGIH TLV	TWA	10	

ENGINEERING CONTROLS: Adequate ventilation and access to eye wash.**PERSONAL PROTECTIVE EQUIPMENT****SKIN:** Gloves.**COMMENTS:** The personal protective equipment described in this section is to be used for occupational exposures.**9. PHYSICAL AND CHEMICAL PROPERTIES****APPEARANCE:** Hard white granules (3.8 millimeters).**SOLUBILITY IN WATER:** Complete**10. STABILITY AND REACTIVITY****REACTIVITY:** Stable.**11. TOXICOLOGICAL INFORMATION****GENERAL COMMENTS:** Sucrose: Widely used in food and pharmaceutical formulations. Sucrose consumption is of concern and should be monitored in patients with diabetes mellitus or other metabolic sugar intolerance.¹ Product contains 212.5 mg sucrose in 5 pellets.

Lactose: A natural sugar found in milk products. It is non-toxic via any route of exposure, however, lactose- intolerant individuals may experience watery diarrhea, abnormal intestinal flow, and colic pains upon ingestion of large amounts of lactose. Adverse reactions to lactose are largely attributed to lactose intolerance, which occurs in people with a deficiency of the intestinal enzyme lactase. In clinical studies between 10 and 20% of lactose intolerant patients showed symptoms of intolerance after ingestion of 3 to 5 grams of lactose.^{2,3} Product contains 37.5 mg of lactose in 5 pellets.

Due to the extremely low concentration of the active ingredient of less than 1 ppm in this preparation, toxic effects resulting from the interaction of the active ingredient with the body are highly unlikely. Despite the lack of risk from chemical exposure to homeopathic potencies, laboratory evidence has shown biological activity associated with homeopathic preparations.⁴ Although the incidence of adverse effects from homeopathic medicines is extremely low, the possibility of unanticipated actions exists. Any adverse effects associated with accidental exposure to this product should be discussed with a physician trained in homeopathy.

12. ECOLOGICAL INFORMATION**COMMENTS:** N/A**13. DISPOSAL CONSIDERATIONS****COMMENTS:** N/A**14. TRANSPORT INFORMATION****COMMENTS:** N/A**15. REGULATORY INFORMATION****GENERAL COMMENTS:** N/A**16. OTHER INFORMATION**

PREPARED BY: Boiron, Inc **Date Revised:** 06/22/2020

REVISION SUMMARY: This SDS replaces the 07/30/2015 SDS. Revised: **Section 2:** GHS CLASSIFICATIONS, COMMENTS, POTENTIAL HEALTH EFFECTS (SKIN, INHALATION, INGESTION). **Section 14:** COMMENTS, DOT (DEPARTMENT OF TRANSPORTATION) - PROPER SHIPPING NAME.

DATA SOURCES: 1. Handbook of Pharmaceutical Excipients. Second Edition 1994. Pages 500-505 (sucrose). American Pharmaceutical Association 2215 Constitution Avenue NW, Washington DC 20037.

2. Lehninger, Albert. 1982. Principles of Biochemistry, Worth Publishers, Inc., New York NY, pages 283-284 (lactose).

3. Martindale The Extra Pharmacopeia 30 Edition 1993 The Pharmaceutical Press, 1 Lambeth High Street, London SE1 7JN, England.

4. Sainte-Laudy J. & Belon P., Analysis of Immunosuppressive Activity of Serial Dilutions of Histamine on Human Basophil Activation by Flow Cytometry (1996), Inflammation Research 45, Supplement 1: 833-834.

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 Workplace Right to Know Act: none known.
- New Jersey "Special Health Hazard" substances >0.01%: none known.
- Pennsylvania "Special Hazardous" substances >0.01%: none known.
- Pennsylvania Workplace Right to Know Act: none known.

SAFETY DATA SHEET



Date Issued : 04/28/2017
SDS No : Arnicare Cream (EDTA Free)
Date Revised : 09/02/2020
Revision No : 4

Arnicare Cream

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Arnicare Cream

GENERAL USE: For relief of muscle aches and stiffness due to minor injuries, overexertion, falls and blows. Reduces pain, swelling and discoloration from bruises.

DISTRIBUTOR

Boiron Inc
 4 Campus Blvd
 Newtown Square, PA 19073
Emergency Phone: 610-325-7464

2. HAZARDS IDENTIFICATION

GHS CLASSIFICATIONS

N/A

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 is not considered hazardous according to the OSHA HazCom 2012 Standard.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Wt. %	CAS
Water	69.9	7732-18-5
Tefose 63	15	9004-99-3
Labrifil M2130 CS	4	12737-91-6
Glycerin	2	56-81-5
Cetyl palminate	1	540-10-3
Sorbic Acid	0.25	110-44-1
1,2 Hexanediol	0.25	6920-22-5
Capryl glycol	0.25	1117-86-8
Carbopol 980 NF	0.2	9003-01-4
Sodium Hydroxide	0.15	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.

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Arnicare Cream

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

COMMENTS: N/A

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 TEMPERATURE: 20°C (68°F) Minimum to 25°C (77°F) Maximum

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE GUIDELINES

OSHA HAZARDOUS COMPONENTS (29 CFR1910.1200)				
Chemical Name	EXPOSURE LIMITS			
	Type		ppm	mg/m ³
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: White cream.

10. STABILITY AND REACTIVITY

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Date Issued : 04/28/2017
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Date Revised : 09/02/2020
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Arnicare Cream

REACTIVITY: Stable.

11. TOXICOLOGICAL INFORMATION

GENERAL COMMENTS: Sodium Hydroxide: Is used as a buffer to neutralize the acidity of the preparation. It is consumed during the manufacturing process.³

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.⁶

Labrafil M2130: Is a mixture of hydrogenated palm kernel glycerides and Polyethylene glycol (PEG) laurate. Manufacturer reports Labrafil is nontoxic by oral route > 2000 mg/kg. Nonirritant via ocular or dermal routes. Palm kernel oil is non-sensitizing. Palm kernel oil is nonmutagenic (Negative Ames test).⁵

SymDiol 68 (1,2-Hexanediol and Caprylyl Glycol): Is used in a wide range of applications in manufacturing cosmetic products. It is a mild irritant to the eyes and skin and a mild inhalation irritant. LC₅₀ dermal, LD₅₀ oral and dermal: nontoxic.⁷

Tefose 63 (PEG stearate): Is a mixture of fatty acid esters and polyethylene glycol. It is nontoxic and nonirritant. Acute toxicity by oral route >= 2002 mg/kg, LD₅₀ in rats: 8.54 g/kg.⁴

Glycerin: Is reported to be nontoxic LD₅₀ > 2000 mg/kg nonirritant and nonmutagenic by the manufacturer. Glycerin is used in a wide variety of pharmaceutical formulations including oral, ophthalmic, parenteral, and topical preparations. Adverse effects are mainly due to the dehydrating effects of glycerin. Oral doses are demulcent and mildly laxative in action. Large doses may produce headache, thirst, nausea, and hyperglycemia. Glycerin is also used orally in doses of 1.0-4.5 g/kg body weight to reduce intraocular pressure. When used as an excipient or food additive, glycerin is generally regarded as a nontoxic and nonirritant material. LD₅₀ (oral rat): 12.6 g/kg.³

Cetyl Palmitate: Is a fatty acid ester reported as nontoxic LD₅₀ > 5000 mg/kg (experimental). Slight skin and eye irritant, however, no labeling required. Not mutagenic (Negative Ames test).³

Sorbic Acid: Skin irritation human: 150mg/1h of contact. Dangerous health effects if inhaled: coughing/irritation to the respiratory tract. Irritant in contact with eyes. Inhalation is not an expected route for this product.³

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

SAFETY DATA SHEET



Date Issued : 04/28/2017
SDS No : Arnicare Cream (EDTA Free)
Date Revised : 09/02/2020
Revision No : 4

Arnicare Cream

COMMENTS: N/A

15. REGULATORY INFORMATION

COMMENTS N/A

16. OTHER INFORMATION

Date Revised: 09/02/2020

REVISION SUMMARY: This SDS replaces the 06/22/2020 SDS. Revised: **Section 11:** GENERAL COMMENTS.

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. Handbook for Pharmaceutical Excipients, Fifth Edition, 2006. American Pharmaceutical Association 2215 Constitution Avenue NW, Washington DC 20037.
4. MSDS Gattefosse - 1-15-2004 Tefose 63.
5. MSDS Gattefosse - 1-15-2004 Labrifil M2130 CS.
6. MSDS Neveon, Inc. 11-16-2001 Carbopol 980 NF Polymer.
7. MSDS Symrise GmbH & Co. KG 07-16-2008 SymDiol 68 1-800-422-1559 or (973) 256-2930.

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).