

SAFETY DATA SHEET

CAFFEINE CITRATE INJECTION, USP-60 MG/3 ML



1. IDENTIFICATION

Product Identifier	: Caffeine Citrate Injection, USP-60 mg/3 mL
Recommended use	: Medicinal Product. (Caffeine citrate injection USP is indicated for the short-term treatment of apnea of prematurity in infants between 28 and <33 weeks gestational age). This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician.
Recommended restrictions	: No other uses are advised.
Manufacturer	: <i>Manufactured by:</i> 113-116, IV phase, Jigani Link Road, KIADB, Bommasandra Industrial area, Bangalore- 560099, India. <i>Manufactured for:</i> Armas Pharmaceuticals, Inc. Manalapan, NJ 07726
Emergency contact	: 1-855-839-8195
Active ingredient	: Caffeine (anhydrous)
US	: Caffeine
Chemical name	: 1,3,7-Trimethyl-3,7-dihydro-1H-purine-2,6-dione
Molecular formula	: C ₈ H ₁₀ N ₄ .O ₂
Molecular weight	: 194.19
(CAS) registry number (RN)	: 58-08-2
Therapeutic Category	: Respiratory stimulant

2. HAZARDS IDENTIFICATION

a) Classification:

HMIS Rating

Health Hazard	1
Flammability	0
Physical Hazard	0

NFPA Rating

Health Hazard	1
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Fire Hazard 0
Reactivity Hazard 0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Hazard Statements:</u>	
H315	- Causes skin irritation
H320	- Causes eye irritation
H317	- May cause an allergic skin reaction

(d) Unknown Acute Toxicity: N/A

3. COMPOSITION/INFORMATION ON INGREDIENTS

Material	CAS Number	Quantity
Caffeine (anhydrous)	58-08-2	10.0 mg/ml
Citric Acid monohydrate	5949-29-1	5.000 mg/ml
Trisodium Citrate dihydrate	6132-04-3	8.300 mg/ml
Water for Injection	7732-18-5	Quantity sufficient

4. FIRST-AID MEASURES

Eye Exposure: Immediately flush with plenty of water. Seek medical attention.
Skin Exposure: Immediately remove from skin with dry cloth followed by flushing with plenty of water for at least 15 minutes.
Ingestion: Obtain medical attention immediately if ingested.
Injection: See patient package insert in shipping carton for complete information.
Inhalation: Move exposed subject to fresh air immediately. Obtain medical attention if ill effects occur.
Notes to Physician: See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

- (a) **Extinguishing media :** Use water or an ABC multi-purpose extinguisher for surrounding materials.
- (b) **Hazardous Combustion Products :** Not determined
- (c) **Special Protective Equipment / Precautions:** Caffeine Citrate solution thermally decomposes to form toxic vapors. Vapors can be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.

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6. ACCIDENTAL RELEASE MEASURES

- Spill:** Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
- Release to Air:** If aerosolized, reduce exposure by ventilating area. Clean up spill immediately to prevent evaporation.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

7. HANDLING AND STORAGE

- General Handling:** As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Use in well ventilated area. Wash thoroughly after handling.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limits
Caffeine Citrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Citric Acid monohydrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Trisodium Citrate dihydrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

(b) Engineering Controls

Ventilation: Local exhaust or general ventilation is recommended.

(c) Individual Protection Measures

- Respiratory Protection:** Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / acid gas cartridges.
- Eye Protection:** Wear ANSI approved chemical splash goggles or safety glasses.

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Skin Protection:	When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.
Other Protective Equipment:	Not required
Additional Exposure Precautions:	Not required

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	: Liquid solution.
Color	: Clear, colorless, aqueous solutions
Odor	: No Information.
Odor Threshold	: No Information.
Boiling Point	: Not established.
Melting point	: 235-239°C
Density	: No Information.
Specific Gravity	: No Information.
Specific Volume	: No Information.
Solubility	: Freely soluble in water, Slightly soluble in Ethanol
Vapor Density	: Not established.
Vapor Pressure	: Not established.
Percent Volatile	: Not established.
Evaporation Point	: No Information.
pH	: 6.9
Molecular Formula	: C ₈ H ₁₀ N ₄ .O ₂
Molecular Weight	: 194.19
Viscosity	: No Information.
Coefficient of Water/Oil	: No Information.
Distribution	
Flash Point	: Not established.
Flash Point Method	: Not established.
Auto Ignition Temperature	: Not established.
VOC Content	: No Information.

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10. STABILITY AND REACTIVITY

Reactivity :	Not Reactive
Chemical stability :	Stable
Possibility of hazardous reactions :	Hazardous polymerization will not occur
Conditions to avoid :	Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible materials :	Reactive with oxidizing agents and alkalis.
Hazardous decomposition products :	Acrid and toxic vapors may be released by thermal decomposition.

11. TOXICOLOGICAL INFORMATION

- (a) **Likely Routes of Exposure** Inhalation, eye/skin contact, or ingestion
- (b) **Symptoms related to the physical, chemical and toxicological characteristics** Inhalation of product can irritate the mucous membranes of the respiratory tract. Acute overexposure to this product may result in palpitation, arrhythmia, tachycardia, excitement, insomnia, headache, irritability, confusion, nausea, vomiting, abdominal pain and digestive disturbances. See prescribing information.
- (c) **Delayed and immediate effects and also chronic effects from short and long term exposure** Possible adverse reactions include: fever, tachypnea, tachycardia, increased left ventricular output, jitteriness, fine tremor of the extremities, hypertonia, opisthotonos, tonic-clonic movements, nonpurposeful jaw and lip movements, vomiting, gastrointestinal effects, renal effects, hyperglycemia, elevated blood urea nitrogen, and elevated total leukocyte concentration. Occupational exposure has not been fully investigated.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Caffeine	TD _{Lo}	Intravenous	Cat	2.5 mg/kg
Caffeine	LD	Subcutaneous	Pig	140 mg/kg
Caffeine	LD	Subcutaneous	Guinea pig	200 mg/kg
Caffeine	LD	Intraperitoneal	Guinea pig	220 mg/kg
Caffeine	LD ₅₀	Oral	Guinea pig	230 mg/kg
Caffeine	LD ₅₀	Intravenous	Rabbit	58 mg/kg
Caffeine	LD	Intraperitoneal	Rabbit	150 mg/kg
Caffeine	LD	Intravenous	Cat	80 mg/kg
Caffeine	LD	Subcutaneous	Cat	150 mg/kg
Caffeine	LD	Intraperitoneal	Cat	180 mg/kg

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Caffeine	LD	Oral	Cat	100 mg/kg
Caffeine	LD	Intravenous	Dog	4 mg/kg
Caffeine	LD	Subcutaneous	Dog	100 mg/kg
Caffeine	LD ₅₀	Oral	Dog	140 mg/kg
Caffeine	LD ₅₀	Intravenous	Mouse	62 mg/kg
Caffeine	LD ₅₀	Subcutaneous	Mouse	242 mg/kg
Caffeine	LD ₅₀	Intraperitoneal	Mouse	168 mg/kg
Caffeine	LD ₅₀	Oral	Mouse	127 mg/kg
Caffeine	LD ₅₀	Intravenous	Rat	105 mg/kg
Caffeine	LD ₅₀	Subcutaneous	Rat	170 mg/kg
Caffeine	LD ₅₀	Intraperitoneal	Rat	240 mg/kg
Caffeine	TD _{LO}	Intravenous	Human	7 mg/kg
Caffeine	TD _{LO}	Oral	Human	51 mg/kg
Caffeine	TD _{LO}	Oral	Human	140 mg/kg
Caffeine	LD	Oral	Human	400 mg/kg
Caffeine	LD ₅₀	Oral	Rat	192 mg/kg
Caffeine	TD _{LO}	Oral	Man	13 mg/kg
Caffeine	LD _{LO}	Oral	Woman	1000 mg/kg
Caffeine	LD _{LO}	Oral	Human	192 mg/kg
Caffeine	LD ₅₀	Oral	Rabbit	224 mg/kg
Citric Acid	LD ₅₀	Oral	Mouse	5040 mg/kg
Citric Acid	LD ₅₀	Oral	Rat	3000 mg/kg

(e) Hazardous Chemical Listings

NTP: No IARC: No OSHA: No

12. ECOLOGICAL INFORMATION

Ecotoxicity

CITRIC ACID:

Algae – IC₅₀, 80 mg/L at 72 hrs

Fish – LC₅₀, >100 mg/L

Persistence and degradability

CAFFEINE: HIGH

Estimated bioconcentration factors ranging from 0.52 to 2.25 indicate that caffeine will not bioconcentrate in fish and aquatic organisms. Limited data indicate that caffeine will biodegrade in water under aerobic conditions.

If released to the atmosphere, an estimated rate constant for the gas-phase reaction of caffeine with photochemically produced hydroxyl radicals of 1.52×10^{-10} cu cm/mole-sec translates to

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	an atmospheric half-life of 2.5 hrs CITRIC ACID: LOW Biodegradeable in a waste treatment facility SODIUM CITRATE: LOW Biodegradeable
Bioaccumulative potential	CAFFEINE: LOW Estimated soil adsorption coefficients ranging from 18-22 indicate that it will not adsorb to sediment and suspended organic matter. CITRIC ACID: LOW WATER: LOW
Mobility in soil	CAFFEINE: HIGH If released to soil, estimated soil adsorption coefficients ranging from 18 to 22 indicate that caffeine will display very high mobility. CITRIC ACID: HIGH WATER: HIGH
Other Adverse Effects	No applicable ecological information found.

13. DISPOSAL CONSIDERATION

Waste disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations

14. TRANSPORT INFORMATION

UN Number	Not Regulated
UN Proper Shipping Name	Not Regulated
Transport Hazard Class(es)	Not Regulated
Packing Group	Not Regulated
Environmental Hazards	Not Regulated
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Regulated
Special Precautions	Not Regulated

DOT: Not regulated

ICAO/IATA: Not regulated

IMO: Not regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Micro Labs usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

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U.S. Regulations:

TSCA: Caffeine and Citric Acid are listed in the 8b inventory

CERCLA: Not on this list

SARA 302: Not on this list

SARA 313: Not on this list

California Proposition 65: Not listed

16. OTHER INFORMATION

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

End of Safety Data Sheet