




MATERIAL SAFETY DATA SHEET

CAFFEINE CITRATE INJECTION USP 60MG/3ML

1. IDENTIFICATION			
Material Identification	:	Caffeine Citrate Injection USP 60mg/3ml	
Active ingredient	:	3,7- dihydro -1 p3 ,7-trimethyl-1H - purine-2,6-dione	
Molecular Formula	:	C ₁₄ H ₁₈ N ₄ O ₉	Molecular Weight : 386.31 g/mol
CAS Number	:	58-08-2	
Product Use	:	Central Nervous System Stimulant	
Manufactured by	:	Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	Manufactured for : Armas Pharmaceuticals Inc. ("Distributor") 151 Route 33 East, Suite 203, Manalapan, NJ 07726
Emergency Contact	:	+91-80-27839033	

2. HAZARDS IDENTIFICATION	
Label Elements	
Signal	: Warning 
Physical and Health hazards	: 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.
Classification of the substance	: Acute toxicity (oral) Category 4 Serious eye damage/eye irritation Category 2A Serious eye damage/eye irritation Category 2B Skin corrosion/irritation Category 2 Skin sensitization Category 1
Hazard statements	: H302: Harmful if swallowed H315: Causes skin irritation H317: May Cause an allergic skin reaction H320: Causes eye irritation
Precautionary statements	: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P264 - Wash thoroughly after handling P270 - Do not eat, drink or smoke when using this product P272 - Contaminated work clothing must not be allowed out of the workplace P280 - Wear protective gloves/protective clothing/eye protection/face protection



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	:	<p>P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell</p> <p>P302+P352 - If on skin: Wash with plenty of water</p> <p>P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P330 - Rinse mouth</p> <p>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention</p> <p>P337+P313 - If eye irritation persists: Get medical advice/attention</p> <p>P362+P364 - Take off contaminated clothing and wash it before reuse</p> <p>P363 - Wash contaminated clothing before reuse</p> <p>P501- Dispose of contents/container in accordance with local/regional/National / international regulations.</p>
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Hazard(s) not otherwise classified (HNOC)	:	None known.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Material	%
Caffeine anhydrous USP	42.92
Citric Acid monohydrate USP (Inj. Gr.)	21.46
Tri Sodium citrate dihydrate USP (Inj. Gr.)	35.62

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eyes Contact	:	Immediately flush eyes with plenty of water for at least 15 to 20 min. Remove contact lenses, if present and easy to do so. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact	:	Remove contaminated clothing. Drench affected area with water at least 15 min. Wash skin with plenty of water for at least 15 to 20 minutes. Get medical attention if irritation develops or persists.
Ingestion	:	If conscious, flush out mouth with water immediately. Call a physician or poison control center immediately. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.
Inhalation	:	If inhaled, move person to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
General information	:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. In the event of accidental injection, immediately call a poison center and seek medical attention.



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5. FIRE FIGHTING MEASURES

Extinguishing media	:	In case of fire, use Water spray. Dry chemical powder. Foam. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
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General Information

As in any fire, wear a self-contained breathing apparatus in pressure-demand, (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and Eyes. Do not use water jet as an extinguisher, as this will spread the fire. Do not breathe the fumes. Move containers from fire area if you can do so without risk. During a fire, may form combustible dust concentrations in air.

6. ACCIDENTAL RELEASE MEASURES

This product may be collected by carefully scooping into a pan, paper towel or other absorbent material. Transfer into suitable containers for recovery or disposal. Wear appropriate protective clothing.

Personal precautions, protective equipment and emergency procedures	:	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves). Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
Environmental precautions	:	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
Methods and material for containment and cleaning up	:	Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharge. Use non-sparking tools and explosion-proof equipment. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust or particulates using a vacuum cleaner with a HEPA filter. Prevent product from entering drains. Stop the flow of material, if this is without risk. Large Spills: Shovel the material into waste container. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.



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7. HANDLING AND STORAGE

Precautions for safe handling	:	Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Protect from light. Avoid dust formation. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
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Conditions for safe storage, including any incompatibilities

Storage conditions	:	Store at 20°C to 25°C (68°F to 77°F)
Specific end use(s)	:	Pharmaceutical drug product for patients

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls	:	Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
Personal Protective Equipment	:	All recommendation below is advisory in nature and risk Assessment should be performed by the employer/end user prior ton use of this product. The type of protective equipment must be selected based on the amount and concentration of the dangerous material being used in the working place.
Respiratory Protection	:	No personal respiratory protective equipment is normally required when product is being used / administered by a licensed healthcare practitioner (i.e. an end-user such as clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will carry according to the airborne concentrations and environmental conditions. A NISOH approved air purifying respirator with an organic vapour cartridge or canister may be permissible under certain circumstances.
Hands	:	Wear appropriate protective Gloves. Suitable gloves can be recommended by the gloves supplier.
Eye Protection	:	Wear Safety glasses with side-shields (Or goggles).
Skin protection	:	Wear suitable protective clothing. Wash hands thoroughly after handling.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Liquid Solution
Color	:	colorless solution
Appearance	:	Caffeine Citrate Injection USP 60mg/3ml: Clear, colorless solution.
Molecular Formula	:	C ₁₄ H ₁₈ N ₄ O ₉
Molecular Weight	:	386.31 g/mol

10. STABILITY AND REACTIVITY

Reactivity	:	The product is Stable and non reactive under normal conditions of use, storage and transport.
Conditions to Avoid	:	Contact with incompatible materials. Electrostatic Discharge. Eliminate all sources of ignition. Exposure to light. Protect from temperatures above: 30 °C. Protect from temperatures below: 15°C.
Incompatible Materials	:	Strong oxidizers, Strong bases, Strong acids.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	Harmful if swallowed. Acute Dermal LD50 Rat >2000 mg/kg (internal testing) Inhalation LC50 Rat 4094 mg/l, 4h (approximate) Oral LD50 Rat 367 mg/kg (internal testing)
Skin Irritation/Sensitization	:	Skin sensitizing effects were not observed in animal studies. Experimental/calculated data: Mouse Local Lymph Node Assay (LLNA) : Non-sensitizing. (OECD Guideline 429)
Eye irritation	:	May cause eye irritation.
Germ cell mutagenicity	:	In the majority of tests performed (bacteria/microorganisms/cell cultures) a mutagenic effect was not found. A mutagenic effect was also not observed in in-vivo assays.
Carcinogenicity	:	In long-term animal studies in which the substance was given in the drinking water in high doses, a carcinogenic effect was not observed. IARC Group 3 (not classifiable as to human carcinogenicity).
IARC:	:	3
NTP:	:	No data available
Reproductive toxicity:	:	In high doses a potential to impair fertility cannot be fully excluded.



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12. ECOLOGICAL INFORMATION

General Notes	: <p>Aquatic Acute Algae EC50 Desmodesmus subspicatus > 100 mg/l, 72 h (OECD Guideline 201,static)</p> <p>Crustacea EC50 Daphnia magna 182 mg/l, 48 h (DIN 38412 Part 11,static)</p> <p>Fish LC50 Leuciscus idus 87 mg/l, 96 h (DIN 38412 Part 15, static)</p> <p>Other Acute Bacteria EC50 Pseudomonas putida 3490 mg/l, 17 h (DIN 38412 Part 8, aerobic)</p> <p>Adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are not expected from this component.</p>
Toxicity:	: Harmful to aquatic life. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.
Persistence and degradability	: Readily biodegradable (by OECD criteria).The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Elimination information: 90 - 100 % DOC reduction (18 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)
Bioaccumulative potential	: Due to the distribution coefficient n - octanol / water (log Pow) is not expected to accumulate in organisms.
Mobility in soil	: Absorption to solid soil phase is not expected.
Results of PBT and vPvB	: No data available

13. DISPOSAL CONSIDERATIONS

Disposal instructions	: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local /regional/national/international regulations.
Waste from residues / unused products	: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	: Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.



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14. TRANSPORTATION INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	Not regulated for transport
Environmental hazards	:	No data available
Special precautions for user	:	No data available

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY / STATUTORY INFORMATION

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

- A) **Canada - DSL Status:** This product is listed in Canadian DSL.
- B) **United States - TSCA Status:** This product is listed in US TSCA inventory.
- C) **European Union - EINECS Status:** This product is registered with the EINECS.

15.2 Chemical Safety Assessment

No data available

16. OTHER INFORMATION

Date of preparation: 22/11/19

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet