



AMERICAN REGENT, INC.

MATERIAL SAFETY DATA SHEET**Section 1: PRODUCT AND COMPANY INFORMATION**

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PRODUCT NAME: Caffeine and Sodium Benzoate Injection, USP

PRODUCT CODE (NDC): 250 mg/mL: 0517-2502-10

Section 2: HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW**

Appearance / Odor

Clear, colorless, odorless solution.

WARNING!

Skin, eye and respiratory irritant

Causes irritation of the eyes, skin and respiratory tract.

Toxicity to fish/aquatic organisms

Sodium Benzoate is known to be toxic to fish; 96 hour LC₅₀ - 484 mg/liter - Fathead Minnow

Potential Health Effects: See Section 11 for more information

Likely Routes of Exposure

Eye contact, skin contact, inhalation and ingestion.

Eye

Causes irritation of the eye.

Skin

Causes irritation of the skin.

Inhalation

Can cause irritation of the respiratory tract.

Ingestion

Ingestion of large amounts may cause irritation of the gastrointestinal tract.

Skin Absorption

Cannot be absorbed through the skin.

Medical Conditions Aggravated by Exposure

Hypersensitivity to the product.

Target Organs

Eyes, skin, liver, cardiovascular, central nervous system and respiratory tract.

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Section 2: HAZARDS IDENTIFICATION (continued)	
<i>Potential Environmental Effects: See Section 12 for more information</i>	Sodium Benzoate is known to be toxic to fish; 96 hour LC50 - 484 mg/liter - Fathead Minnow
This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS		
Component	CAS Number	Percentage (%) by Weight
Caffeine	58-08-2	12.5 percent
Sodium Benzoate	532-32-1	12.5 percent
Hydrochloric Acid	7647-01-0	used for pH adjustment
Sodium Hydroxide	1310-73-2	used for pH adjustment
Water for Injection	7732-18-5	75.0 percent

Section 4: FIRST AID MEASURES	
Eye Contact	Can cause irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	Can cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	Can cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	Ingestion of large amounts of product can cause irritation. Flush mouth out with water. Do not induce vomiting unless directed by emergency medical personnel. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Inhalation of product can irritate the mucous membranes of the respiratory tract. Acute overexposure to this product may result in palpitation, excitement, insomnia, dizziness, headache, nausea, digestive disturbances and constipation. Skin rash may be observed following direct contact. See prescribing information.

Section 5: FIRE FIGHTING MEASURES	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO ₂). Caution: CO ₂ will displace air in confined spaces and may cause an oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, this product thermally decomposes to form acrid and toxic vapors consisting of Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides and Benzoic Acid.
<u>Protection for firefighters:</u> Caffeine and Sodium Benzoate 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.	

Section 6: ACCIDENTAL RELEASE MEASURES	
Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not known to be a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

Section 7: HANDLING AND STORAGEHandling:

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. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Caffeine	Not Listed	Not Listed	
Sodium Benzoate	Not Listed	Not Listed	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Hydrochloric Acid	5 parts per million - Ceiling	2 parts per million - Ceiling	
Water for Injection	Not Listed	Not Listed	
Personal Protective Equipment	Description		
Ventilation	Local exhaust or general ventilation is recommended.		
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 cartridges.		
Eye Protection	Wear ANSI approved chemical splash goggles or safety glasses.		
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.		

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Color	Clear, colorless solution.
Odor / Odor Threshold	Generally odorless.
Physical State	Liquid
pH	6.5 to 8.5
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Above 226 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)	
Vapor Density	Not applicable
Specific Gravity	Approximately 1.1
Solubility (water)	Freely soluble in water.
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

Section 10: STABILITY AND REACTIVITY	
Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. 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.
Possibility of Hazardous Reaction	Hazardous polymerization will not occur.

Section 11: TOXICOLOGY INFORMATION	
Acute Effects	
Oral (LD ₅₀) - Caffeine	LD ₅₀ : 127 mg/kg oral - mouse LD ₅₀ : 192 mg/kg oral - rat LD ₅₀ : 224 mg/kg oral - rabbit LD ₅₀ : 320 mg/kg oral - human child LD ₅₀ : 400 mg/kg oral - human female
Oral (LD ₅₀) - Sodium Benzoate	LD ₅₀ : 1600 mg/kg oral - mouse LD ₅₀ : 4070 mg/kg oral - rat LD ₅₀ : 2000 mg/kg oral - rabbit
Intravenous (LD ₅₀) - Caffeine	LD ₅₀ : 62 mg/kg intravenous - mouse LD ₅₀ : 105 mg/kg intravenous - rat
Intravenous (LD ₅₀) Sodium Benzoate	LD ₅₀ : 1440 mg/kg intravenous - mouse LD ₅₀ : 1714 mg/kg intravenous - rat
Intraperitoneal (LD ₅₀) - Caffeine	LD ₅₀ : 168 mg/kg intraperitoneal - mouse LD ₅₀ : 240 mg/kg intraperitoneal - rat
Dermal (LD ₅₀) Caffeine & Sodium Benzoate	No data available.

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Section 11: TOXICOLOGY INFORMATION (continued)	
Subcutaneous (LD ₅₀) - Caffeine	LD ₅₀ : 242 mg/kg subcutaneous - mouse LD ₅₀ : 170 mg/kg subcutaneous - rat
Subcutaneous (LD ₅₀) Sodium Benzoate	LD ₅₀ : 2000 mg/kg subcutaneous - rabbit LD ₅₀ : 2000 mg/kg subcutaneous - rat
Inhalation	Can cause respiratory irritation.
Eye Irritation	Can cause eye irritation.
Skin Irritation	Can cause skin irritation.
Sensitization	Sensitization is possible.
Chronic Effects	
Organ Systems	Potentially toxic to eyes, skin, mucous membranes (pulmonary and gastrointestinal tract), cardiovascular system, liver, central nervous system and hemopoietic system.
Carcinogenicity	Based on animal test data, caffeine is considered a potential carcinogen.
Mutagenicity	Caffeine is considered mutagenic for mammalian somatic cells, bacteria and yeast.
Reproductive Effects	Caffeine has been detected in the breast milk of nursing mothers. Sodium Benzoate is a suspected reproductive toxin. No adequate and well controlled studies in humans.
Developmental Effects	Caffeine and Sodium Benzoate are both considered possible teratogens. Animal studies have determined that caffeine causes birth defects in animals. No adequate and well controlled studies in humans. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
Ecotoxicity	Sodium Benzoate 96 hour LC ₅₀ - 484 mg/liter - Fathead minnow
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products are not considered more hazardous than the product.
Bioaccumulation / Accumulation	No appreciable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air.

Section 13: DISPOSAL CONDITIONS	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

Section 14: TRANSPORTATION INFORMATION	
Regulatory Agency	Shipping Description
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.

Section 15: REGULATORY INFORMATION	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	EV6475000 - Caffeine DH6650000 - Sodium Benzoate
TSCA	8b Inventory - Yes - Caffeine and Sodium Benzoate
NFPA Rating	Health - 2, Fire - 1, Reactivity - 0
WHMIS (Canada)	Not Controlled.

Section 16: OTHER INFORMATION

Caffeine and Sodium Benzoate Injection, USP has been used in conjunction with supportive measure to treat respiratory depression associated with overdosage with CNS depressant drugs. However, because of questionable benefit and transient action, most authorities believe caffeine and other analeptics should not be used in these conditions and recommend other supportive therapy.

Refer to Luitpold / American Regent's prescribing information for further information at http://www.americanregent.com/product_index.asp

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