



AMERICAN REGENT, INC.

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

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PRODUCT NAME: **Bacteriostatic Water for Injection, USP**

PRODUCT CODE (NDC): **0517-0662-25**

Section 2: HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW**

Appearance / Odor	Clear, colorless solution, with odor of Benzyl Alcohol.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Not known to cause any health affects.
Skin	Not known to cause any health affects.
Inhalation	Not known to cause any health affects.
Ingestion	Not known to cause any health affects.
Skin Absorption	Not likely to be absorbed through the skin.
Medical Conditions Aggravated by Exposure	None.
Target Organs	Eyes, gastrointestinal tract and respiratory tract.
<i>Potential Environmental Effects: See Section 12 for more information</i>	This product is not known to be toxic to fish.

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Section 2: HAZARDS IDENTIFICATION (continued)

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
Benzyl Alcohol	100-51-6	0.9 percent
Water for Injection	7732-18-5	99.1 percent

Section 4: FIRST AID MEASURES

Eye Contact	Not likely to cause irritation. Flush for 15 minutes with copious quantities of water. Seek medical advice.
Skin Contact	Not likely to cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical advice.
Inhalation	Not likely to cause respiratory tract irritation. Remove person to fresh air. Remove contaminated clothing. Seek medical advice.
Ingestion	Not likely to cause irritation of the gastrointestinal tract. Flush mouth out with water if necessary. Do not induce vomiting unless directed by emergency medical personnel. Seek medical advice.
Injection	See prescribing information.
Note to Physicians	See prescribing information. This product contains benzyl alcohol that is used as a preservative. Benzyl Alcohol has been associated with "Gasping Syndrome" in neonates.

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, water thermally decomposes to water vapor.

Protection for firefighters: This product thermally decomposes to form water vapor. When heated, water vapor can cause burns to the eyes, skin and 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 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.

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
Benzyl Alcohol	Not Listed	Not Listed	
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	Odor of Benzyl Alcohol.
Physical State	Liquid
pH	4.5 to 7.0
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Approximately 212 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	17.5 mm Hg (68 Degrees Fahrenheit)
Vapor Density	Not applicable
Specific Gravity	Approximately 1.0
Solubility (water)	Freely soluble in water.
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0.9 percent (Benzyl Alcohol used as a preservative)
Volatile Organic Compounds (%)	0.9 percent (Benzyl Alcohol used as a preservative)

Section 10: STABILITY AND REACTIVITY	
Stability	Stable.
Conditions to Avoid	Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form water vapor.
Incompatible Materials	Reactive with sodium and potassium metal. Electrolysis of water can lead to the formation of explosive hydrogen and oxygen.
Hazardous Decomposition Products	Water vapor may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
Section 11: TOXICOLOGY INFORMATION	
Acute Effects (Benzyl Alcohol)	
Oral (LD ₅₀)	LD ₅₀ : 1230 mg/kg oral - rat LD ₅₀ : 1360 mg/kg oral - mouse
Intravenous (LD ₅₀)	LD ₅₀ : 53 mg/kg intravenous - rat LD ₅₀ : 324 mg/kg intravenous - mouse
Intraperitoneal (LD ₅₀)	LD ₅₀ : 400 mg/kg intraperitoneal - rat LD ₅₀ : 650 mg/kg intraperitoneal - mouse
Dermal (LD ₅₀)	No data available.
Subcutaneous (LD ₅₀)	LD ₅₀ : 1700 mg/kg subcutaneous - rat
Inhalation	Respiratory irritation is not probable.
Eye Irritation	Eye irritation is not probable.
Skin Irritation	Skin irritation is not probable.
Sensitization	Sensitization is not probable.
Chronic Effects	
Organ Systems	Potential impact to eyes, mucous membranes (pulmonary and gastrointestinal tract) and mucous membranes.
Carcinogenicity	No evidence that water is classified as a carcinogen.
Mutagenicity	Benzyl Alcohol used as a preservative is considered mutagenic for bacteria and yeast.
Reproductive Effects	No adequate and well controlled studies in humans.
Developmental Effects	No adequate and well controlled studies in humans. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
Ecotoxicity	No data available.
Persistence / Degradability	Short term and long term products of biodegradation are not likely.
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.
ICAO (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	Not available.
TSCA	8b Inventory - No
NFPA Rating	Health - 0, Fire - 0, Reactivity - 0
WHMIS (Canada)	Not Controlled.

Section 16: OTHER INFORMATION

Bacteriostatic Water for Injection, USP is used for preparing and diluting sterile solutions.

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

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