



SAFETY DATA SHEET

Sodium Acetate Injection, USP

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Sodium Acetate Injection USP, (100 mEq/50 mL and 200 mEq/100 mL) (2 mEq/mL)

Trade Name: Not established

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as electrolyte replacement

Manufactured for Somerset Therapeutics, LLC. Somerset, NJ 08873

Customer Care 1-800-417-9175

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards No data available

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection USP	7732-18-5	231-791-2	Not Listed	*
Sodium Acetate Anhydrous USP	127-09-3	204-823-8	Not Listed	*
Glacial Acetic Acid USP	64-19-7	--	Not Listed	

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Additional Information:

* Proprietary

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures**Eye Contact:**

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash skin with soap and water. If skin irritation persists, call a physician.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Move to fresh air if discomfort persists, get medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed**Symptoms and**

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Effects of**Exposure:**

None known

Medical Conditions**Aggravated by****Exposure:**

Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media:

As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture**Hazardous Combustion**

Formation of toxic gases is possible during heating or fire. May include oxides of phosphorous

Products:

Not applicable

Fire / Explosion Hazards:**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Additional Consideration for Large Spills:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None known

Specific end use(s): Pharmaceutical product used for electrolyte replacement

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified. Refer to available public information for specific member state Occupational Exposure Limits.

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Somerset Therapeutics, LLC. Somerset, NJ 08873

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Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Colourless			
Odor:	No data available.	Odor Threshold:	No data available.			
Molecular Formula:	Mixture	Molecular Weight:	Mixture			
Solvent Solubility:	No data available					
Water Solubility:	Soluble					
pH:	6.0-7.0					
Melting/Freezing Point (°C):	No data available					
Boiling Point (°C):	No data available.					
Partition Coefficient: (Method, pH, Endpoint, Value)						
Sodium Acetate						
No data available						
Decomposition Temperature (°C):	No data available.					
Evaporation Rate (Gram/s):	No data available					
Vapor Pressure (kPa):	No data available					
Vapor Density (g/ml):	No data available					
Relative Density:	No data available					
Viscosity:	No data available					

Flammability:

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Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties:	None
Conditions to Avoid:	None known
Incompatible Materials:	None known

Hazardous Decomposition Products:

Thermal decomposition products include Oxides of phosphorus

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the active ingredient(s).
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Acute Toxicity: (Species, Route, End Point, Dose)

Sodium Acetate

Rat	Oral	LD 50	3500 mg/kg
Mouse	Oral	LD 50	4960mg/kg

Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: State

Dispose of waste in accordance with all applicable laws and regulations. Member specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

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

Water for injection USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

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CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

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16. OTHER INFORMATION

Data Sources:	Publicly available toxicity information.
Reasons for Revision:	Updated Section 3 - Composition / Information on Ingredients
Revision date:	17.10.2025
Product Stewardship Hazard Communication	
Prepared by:	Maiva Pharma Private Limited

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END OF SAFETY DATA SHEET