

**SAFETY DATA SHEET**  
**Zinc Chloride Injection, USP [10 mg/10 mL (1 mg/ mL)]**

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

**Product Identifier**

**Material Name:** Zinc Chloride Injection, USP [10 mg/10 mL (1 mg/ mL)]

**Trade Name:** Not established  
**Chemical Family:** Not determined

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

**Intended Use:** Not determined

**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** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**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**

**Hazardous**

<b>3. COMPOSITION / INFORMATION ON INGREDIENTS</b>				
<b>Ingredient</b>	<b>CAS Number</b>	<b>EU EINECS/ELINCS List</b>	<b>GHS Classification</b>	<b>%</b>
Sodium Chloride, USP	7647-14-5	231-598-3	Not Listed	*
Zinc Chloride, USP	7646-85-7	231-592-0	Acute Tox. 4 (H302) Skin Corr. 1B (H314) Aquatic Chronic 1 (H410) Aquatic Acute 1 (H400)	<1.0
Sodium Hydroxide, NF	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Hydrochloric Acid, NF	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection, USP	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
 \*\* to adjust pH  
 Ingredient(s) indicated as hazardous have been assessed under standards for workplacesafety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

**4. FIRST AID MEASURES**

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed Notes**

**5. FIRE FIGHTING MEASURES**

**to Physician:** None

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**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:** Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

**Additional Consideration for Large Spills:** 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.

**Specific end use(s):** Pharmaceutical product

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Control Parameters**

**Sodium chloride, USP**

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

**Zinc Chloride, USP**

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup>
ACGIH Threshold Limit Value (STEL)	2 mg/m <sup>3</sup>
Australia STEL	2 mg/m <sup>3</sup>
Australia TWA	1 mg/m <sup>3</sup>
Belgium OEL - TWA	1 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Denmark OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	1 mg/m <sup>3</sup>
Greece OEL - TWA	1 mg/m <sup>3</sup>
Ireland OEL - TWAs	1 mg/m <sup>3</sup>

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Lithuania OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA Portugal	1 mg/m <sup>3</sup>
OEL - TWA	1 mg/m <sup>3</sup>
Spain OEL - TWA	1 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1 mg/m <sup>3</sup>

**SODIUM HYDROXIDE, NF**

ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

**HYDROCHLORIC ACID, NF**

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m <sup>3</sup>
Austria OEL - MAKs	5 ppm
	8 mg/m <sup>3</sup>
Belgium OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Czech Republic OEL - TWA	8 mg/m <sup>3</sup>
Estonia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm
	3.0 mg/m <sup>3</sup>
Greece OEL - TWA	5 ppm
7	mg/m <sup>3</sup>
Hungary OEL - TWA	8 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 ppm
8	mg/m <sup>3</sup>

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

<b>Italy OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Japan - OELs - Ceilings</b>	2 ppm 3.0 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Luxembourg OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	8 mg/m <sup>3</sup>
<b>Poland OEL - TWA</b>	5 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Romania OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	5 ppm 8.0 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	5 ppm 8 mg/m <sup>3</sup>
<b>Spain OEL - TWA</b>	5 ppm 7.6 mg/m <sup>3</sup>
<b>Switzerland OEL -TWAs</b>	2 ppm 3.0 mg/m <sup>3</sup>
<b>Vietnam OEL - TWAs</b>	5 mg/m <sup>3</sup>

**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. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**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.) Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.) *Use most conservative level of protection based on band or limit.* Individuals with known sensitivity should wear protective gloves to avoid skin contact.

**Eyes:**

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:**

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**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**

<b>Physical State:</b>	No data available.	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Sodium chloride**

No data available

**HYDROCHLORIC ACID**

No data available

**SODIUM HYDROXIDE**

No data available

**Zinc Chloride**

No data available

**Water for Injection**

No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

**Flammability:**

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

**10. STABILITY AND REACTIVITY**

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

**SAFETY DATA SHEET****Zinc Chloride Injection, USP [10 mg/10 mL (1 mg/ mL)]****11. TOXICOLOGICAL INFORMATION****Information on Toxicological Effects****General Information:**

The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:**

May cause eye and skin irritation (based on components)

**Known Clinical Effects:**

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired.

**Acute Toxicity: (Species, Route, End Point, Dose)****Sodium chloride**

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000

mg/kg

**HYDROCHLORIC ACID**

Rat Oral LD 50 238-277 mg/kg

**Zinc Chloride**

Rat Oral LD50 350 mg/kg

**Irritation / Sensitization: (Study Type, Species, Severity)****Sodium chloride**

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)****HYDROCHLORIC ACID**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Micronucleus Rat Negative

**Carcinogen Status:**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**HYDROCHLORIC ACID****IARC:**

Group 3 (Not Classifiable)

**12. ECOLOGICAL INFORMATION****Environmental Overview:**

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:****Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)****Persistence and Degradability:**

No data available

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**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

**13. DISPOSAL CONSIDERATIONS**

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State 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**

**Sodium chloride**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65 Inventory - United States TSCA - Sect. 8(b)</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Present
	231-598-3

**Zinc Chloride**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</b>	1000 lb
	454 kg
<b>California Proposition 65 Inventory - United States TSCA - Sect. 8(b)</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2
	Schedule 6
<b>EU EINECS/ELINCS List</b>	Present
	231-592-0



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**15. REGULATORY INFORMATION**

**Water for Injection, USP**

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

**SODIUM HYDROXIDE, NF**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</b>	1000 lb
	454 kg
<b>California Proposition 65 Inventory - United States TSCA - Sect. 8(b)</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Present
	Schedule 5
	Schedule 6
<b>EU EINECS/ELINCS List</b>	215-185-5

**HYDROCHLORIC ACID, NF**

<b>CERCLA/SARA 313 Emission reporting</b>	1.0 %
<b>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</b>	5000 lb
	2270 kg
	500 lb
<b>CERCLA/SARA - Section 302 Extremely Hazardous TPQs</b>	5000 lb
<b>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</b>	
<b>California Proposition 65 Inventory - United States TSCA - Sect. 8(b)</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Present
	Schedule 5
	Schedule 6
<b>EU EINECS/ELINCS List</b>	231-595-7



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**16. OTHER INFORMATION**

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

**Data Sources:** Safety data sheets for individual ingredients. Publicly available toxicity information.

**Prepared Date:** 05.08.2024

**Prepared by:** Somerset Therapeutics Limited

Somerset Therapeutics Limited, believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**