Safety Data Sheet (SDS)

MATERIAL: Sodium Bicarbonate Injection	SUPPLIER(S): Exela Pharma Sciences, LLC	SDS NO.: SDS-FP-022-01	ISSUE DATE: 01/19/2024

Section 1 – Chemical Product and Company

Distributor:		**Emergency Telephone:**	ChemTrec 1-800-424-9300
Exela Pharma Sciences, LLC 1245 Blowing Rock Blvd Lenoir, NC 28645 (828) 758-5474		**Product Identifier:**	Sodium Bicarbonate Injection, USP
		Product Code:	51754-5012-1, 51754-5012-4, 51754-5002-1, 51754-5002-5, 51754-5011-1, 51754-5011-4, 51754-5001-1, 51754-5001-5, 51754-5001-4, 72572-740-01 and 72572-740-20, 72572-740-25.
		Common/Trade Name:	Sodium Bicarbonate Injection, USP
Product Use:	Pharmaceutical	**Product Type:**	Regulated Prescription Drug
Container Information:	Vials		

Section 2 – Hazards Identification

U.S. OSHA Classification:	Not classified
Precautionary Statements:	Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. If exposed or concerned, get medical advice/attention.
Primary Physical and Health Hazards:	This material should be considered potentially irritating to the eyes.
Routes of Entry:	Inhalation, eye/skin contact, or ingestion.

Section 3 – Composition / Information on Ingredients

Ingredient	Weight	CAS No.
Sodium Bicarbonate	1-10%	144-55-8
Water for Injection	N/A	7732-18-5

Section 4 – First Aid Measures

Eye Exposure:	Immediately flush with plenty of water. Seek medical attention.
Skin Exposure:	Immediately remove from skin with dry cloth followed by flushing with plenty of water for at least 15 minutes.
Ingestion:	Flush mouth out with water. Obtain medical attention immediately if ingested.
Inhalation:	Move exposed subject to fresh air immediately. Obtain medical attention if ill effects occur.

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Section 4 – First Aid Measures

Notes to Physician:	See patient package insert in shipping carton for complete information.

Section 5 – Fire Fighting Measures

Flash Point:	Not established
Auto-ignition Temperature:	Not established
Flammable Limits in Air:	**Lower %:** Not established **Upper %:** Not established
Flammable Limits:	Not established
Extinguishing Media:	Extinguish fires with $C0_2$, extinguishing powder, foam, or water.
Products of Combustion:	Formation of toxic gases is possible during heating or fire. May include oxides of carbon sodium.
Special Fire Fighting Procedures:	No special provisions required beyond normal fire-fighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 – Accidental Release Measures

Spill:	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

Section 7 – Handling and Storage

General Handling:	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 well ventilated area.
Storage Conditions:	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.
Waste Disposal Method:	Dispose of in accordance with federal, state, and local regulations.

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Section 8 – Exposure Controls / Personal Protection

Respiratory Protection:	Under normal conditions of product use, respiratory protection is not required.
Eye Protection:	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Ventilation:	Local exhaust or general ventilation is recommended.
Skin Protection:	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Other Protective Equipment:	Not required.
Additional Exposure Precautions:	Not required.

Exposure Limits

Compound	Issuer	Type	TWA
Sodium Bicarbonate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

NE = Not Established

Section 9 – Physical and Chemical Properties

Physical State:	Aqueous Solution	**Specific Gravity:**	Approximately 1.0
Appearance and Odor:	Colorless, odorless	**Evaporation Rate:**	Not available
Odor Threshold:	Not applicable	**Flammability (solid, gas):**	Not available
Boiling Point:	Not available	**Melting Point:**	Not available
Vapor Pressure:	Not applicable	**Solubility in Water:**	7.8 g/100 g @18°C
Vapor Density:	Not applicable	**pH:**	7.0-8.5
		Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition Temperature:	Not applicable	**Decomposition Temperature:**	Not applicable

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Section 10 – Stability and Reactivity

Stability:	Normally stable under standard storage and use conditions.
Incompatibility (Materials to Avoid):	Not determined.
Hazardous Decomposition:	Not determined.
Hazardous Polymerization:	Not determined.
Conditions to Avoid:	Not determined.

Section 11 – Toxicological Information

Acute Toxicity				
Component	**Type**	**Route**	**Species**	**Dosage**
Sodium Bicarbonate	LD_{50}	Oral	Rat	4220 mg/kg
Sodium Bicarbonate	LD_{50}	Oral	Mouse	3360 mg/kg
Sodium Bicarbonate	LD_{50}	Inhalation	Rat	> 900mg/m^3
Dermal Irritation/Corrosion:	None anticipated from normal handling of this product.			
Ocular Irritation/Corrosion:	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation with redness and tearing.			
Signs and Symptoms of Exposure:	None known from workplace exposure.			
Carcinogenicity:	None known.			
Chemical Listed as Carcinogen:	**NTP:** No **IARC:** No **OSHA:** No			
Reproductive Toxicity:	Not applicable.			
Target Organ Effects:	Based on rabbit studies, possible target organs include, skin and eyes. Minimal eye irritant in experimental animals and may cause slight skin irritation.			

Section 12 – Ecological Information

Aquatic Toxicity:	Not available for product. Information for sodium bicarbonate (139-33-3) is as follows: *Daphnia magna* (Water Flea) EC50 48 Hours 2350 mg/L *Lepomis macrochirus* (Bluegill Sunfish) LC50 96 Hours 8250 mg/L *Gambusia affinis* (Mosquitofish) LC50 96 Hours 7550 mg/L

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Section 13 – Disposal Considerations

Waste Disposal:	Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 – Transport Information

Regulatory Organizations:	**DOT:** Not Regulated
	ICAO/IATA: Not Regulated
	IMO: Not Regulated

Section 15 – Regulatory Information

Below is selected regulatory information chosen primarily for possible Exela Pharma Sciences usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations	
TSCA	Not on this list
CERCLA	Not on this list
SARA 302	Not on this list
SARA 313	Not on this list
OSHA Substance Specific	No
RCRA Status	Not Listed

Section 16 – Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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