MATERIAL SAFETY DATA SHEET

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

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Material Name: Sodium Bicarbonate Intravenous Infusion BP 8.4%

Trade Name: Not established
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for electrolyte replacement

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Minimal eye irritant in experimental animals . May cause slight skin irritation. (based on components) .
Known Clinical Effects: Clinical use has resulted in changes in electrolytes and/or blood chemistry changes.
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium bicarbonate	144-55-8	205-633-8	Not Listed	1-10

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%

Water for injection	7732-18-5	231-791-2	Not Listed	*
EDTA, disodium salt	139-33-3	205-358-3	Not Listed	0-1

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution

Skin Contact: If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

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: Not an expected route of exposure.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon, sodium.

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

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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

General Handling: No special handling requirements for normal use of this material.
Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium bicarbonate

Czech Republic OEL - TWA	5 mg/m^3
Latvia OEL - TWA	5 mg/m^3

Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Not required for the normal use of this product.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product.
Respiratory protection: None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: None
Molecular Weight: Mixture
Color: Colorless
Molecular Formula: Mixture

Water solubility: 7.8 g/100 g @18C

10. STABILITY AND REACTIVITY

Chemical Stability: Stable
Conditions to Avoid: None
Incompatible Materials: None

11. TOXICOLOGICAL INFORMATION

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

Acute Toxicity: (Species, Route, End Point, Dose)

EDTA, disodium salt
Rat Oral LD50 > 5000 mg/kg

Sodium bicarbonate
Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360 mg/kg
Rat Inhalation LC50 > 900 mg/m^3
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

11. TOXICOLOGICAL INFORMATION

Sodium bicarbonate
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Slight

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

12. ECOLOGICAL INFORMATION

Environmental Overview: No acute toxicity to aquatic organisms is expected Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium bicarbonate
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

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

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium bicarbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-633-8

Water for injection

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

EDTA, disodium salt

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet