



# MATERIAL SAFETY DATA SHEET

Revision date: 03-Dec-2007

Version: 1.0

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

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**Emergency telephone number:**  
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**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**ChemSafe (24 hours): +44 (0)208 762 8322**

**Material Name: Sodium Bicarbonate Intravenous Infusion BP 8.4%**

<b>Trade Name:</b>	Not established
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	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	Classification	%
Sodium bicarbonate	144-55-8	205-633-8	Not Listed	1-10

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Ingredient	CAS Number	EU EINECS/ELINCS List	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

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

Sodium bicarbonate  
Latvia OEL - TWA = 5 mg/m<sup>3</sup> TWA

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**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:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	None	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

**Water solubility:** 7.8 g/100 g @18C

## 10. STABILITY AND REACTIVITY

**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<sup>3</sup>

**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)**

**Sodium bicarbonate**

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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* 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

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

### 14. TRANSPORT INFORMATION

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.

#### **Canada - WHMIS: Classifications**

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## 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.

## 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

## Sodium bicarbonate

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

## 16. OTHER INFORMATION

**Data Sources:** Publicly available toxicity information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc 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**