



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 25-Jun-2018

Version: 1.2

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

### Product Identifier

**Material Name:** Sodium Bicarbonate Injection (Hospira, Inc)

**Trade Name:** NEUT  
**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used for electrolyte replacement

### Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 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 this substance ( 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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Sodium bicarbonate	144-55-8	205-633-8	Not Listed	1-10
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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
EDTA, disodium salt	139-33-3	205-358-3	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

#### Additional Information:

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

#### 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 to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, 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. May include oxides of carbon sodium

**Fire / Explosion Hazards:** Not applicable

#### Advice for Fire-Fighters

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

### 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

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

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

No special handling requirements for normal use of this material.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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

### Sodium bicarbonate

**Czech Republic OEL - TWA** 5 mg/m<sup>3</sup>

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Sodium bicarbonate

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

### Exposure Controls

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

**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

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	None	<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>	7.8 g/100 g @18C		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**Water for injection**  
No data available  
**Sodium bicarbonate**  
No data available  
**EDTA, disodium salt**  
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:

<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

**Reactivity:** No data available  
**Chemical Stability:** Stable  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** None  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 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:** 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.

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

##### Sodium bicarbonate

Rat Oral LD50 4220 mg/kg  
Mouse Oral LD50 3360mg/kg  
Rat Inhalation LC50 > 900mg/m<sup>3</sup>

##### EDTA, disodium salt

Rat Oral LD50 2800 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

**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**

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit Slight

##### **EDTA, disodium salt**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Slight

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **EDTA, disodium salt**

5 Day(s) Rat Inhalation 30 mg/m<sup>3</sup> LOAEL Larynx, Lungs  
13 Week(s) Rat Oral, in feed 500 mg/kg/day NOAEL Gastrointestinal system

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **EDTA, disodium salt**

*In Vivo* Micronucleus Mouse Bone Marrow Negative

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

### 12. ECOLOGICAL INFORMATION

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

#### **Toxicity:**

##### **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

**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:** 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

#### EDTA, disodium salt

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	205-358-3

#### Water for injection

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

#### Sodium bicarbonate

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	205-633-8

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### 16. OTHER INFORMATION

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

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 7 - Handling and Storage.

**Revision date:** 25-Jun-2018  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**