



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 15-Feb-2017

Version: 1.0

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

### Product Identifier

**Material Name:** Levetiracetam Injection (Hospira, Inc.)

**Trade Name:** Not established  
**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 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

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
Sodium acetate trihydrate	6131-90-4	Not Listed	Not Listed	**
Levetiracetam	102767-28-2	Not Listed	Not Listed	10
Acetic acid USP - glacial	64-19-7	200-580-7	Skin Corr.1A (H314) Flam. Liq.3 (H226)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	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 workplace safety. 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:** Due to the nature of this material first aid is not normally required.  
**Skin Contact:** Due to the nature of this material first aid is not normally required.  
**Ingestion:** Due to the nature of this material first aid is not normally required.  
**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:** As for primary cause of fire.

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

**Hazardous Combustion Products:** Not applicable  
**Fire / Explosion Hazards:** Not applicable

**Advice for Fire-Fighters**

Not applicable

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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable

#### Environmental Precautions

None

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Wipe up with a damp cloth and place in container for disposal.

**Additional Consideration for Large Spills:** None

### 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):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### SODIUM CHLORIDE

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

#### Acetic acid USP - glacial

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m <sup>3</sup>
Australia TWA	10 ppm
	25 mg/m <sup>3</sup>
Austria OEL - MAKs	10 ppm
	25 mg/m <sup>3</sup>
Belgium OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Bulgaria OEL - TWA	25.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Czech Republic OEL - TWA	25 mg/m <sup>3</sup>
Denmark OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Estonia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Finland OEL - TWA	5 ppm
	13 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany - TRGS 900 - TWAs	10 ppm 25 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 ppm 25 mg/m <sup>3</sup>
Greece OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Hungary OEL - TWA	25 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Latvia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Luxembourg OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Malta OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Netherlands OEL - TWA	25 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 ppm 25 mg/m <sup>3</sup>
Poland OEL - TWA	25 mg/m <sup>3</sup>
Portugal OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Romania OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Slovakia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Spain OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 ppm 13 mg/m <sup>3</sup>
Switzerland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Vietnam OEL - TWAs	25 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 CHLORIDE

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

#### Levetiracetam

**Pfizer Occupational Exposure Band (OEB):** B-OEB 1 (control exposure to the range of >= 10000 µg/day)

#### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
<b>Respiratory protection:</b>	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>	Solution	<b>Color:</b>	Clear, colorless
<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>	5.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>SODIUM CHLORIDE</b>			
No data available			
<b>Water for injection</b>			
No data available			
<b>Levetiracetam</b>			
No data available			
<b>Acetic acid USP - glacial</b>			
No data available			
<b>Sodium acetate trihydrate</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	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		
<b>Flammability:</b>			
<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	

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Lower Explosive Limits (Liquid) (% by Vol.): No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**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:** Mild eye irritant in experimental animals (based on components)

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

##### **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3g/kg  
Mouse Oral LD 50 4g/kg  
Rabbit Dermal LD 50 > 10g/kg

##### **Levetiracetam**

Rat Oral LD50 > 5000 mg/kg  
Rat Para-periosteal LD50 > 1000mg/kg

**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 CHLORIDE**

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

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

##### **Levetiracetam**

6 Month(s) Rat Oral >=50 mg/kg/day LOAEL Liver, Kidney, Central nervous system

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Levetiracetam**

Embryo / Fetal Development Rat Oral 70 mg/kg/day NOEL Fetotoxicity, Embryotoxicity  
Embryo / Fetal Development Rabbit Oral 200 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity, Maternal Toxicity  
Peri-/Postnatal Development Rat Oral Dose not specified No effects at maximum dose

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### 11. TOXICOLOGICAL INFORMATION

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

##### Levetiracetam

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Micronucleus Mouse Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Levetiracetam

80 Week(s) Mouse Oral Dose not specified Not carcinogenic  
104 Week(s) Rat Oral 1800 mg/kg/day NOAEL Not carcinogenic

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 harmful effects to aquatic organisms are expected.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**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.

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### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### SODIUM CHLORIDE

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	231-598-3

#### 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 acetate trihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Levetiracetam

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Acetic acid USP - glacial

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3



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Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage  
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

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

**Reasons for Revision:** New data sheet.

**Revision date:** 15-Feb-2017

**Prepared by:** Product Stewardship Hazard Communication  
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**