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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Levetiracetam Injection (Hospira, Inc.)

Product Code(s) PZ03336
Trade Name: Not applicable
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used for electrolyte replacement

1.3. 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

Pfizer Ireland Pharmaceuticals

OSG Building

Ringaskiddy, Co. Cork.

Ireland

+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

2.2. Label elements

Signal word Not Classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

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Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

Classification

Specific

M-Factor

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M-Factor

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Weight-%

3.1 Substances

Substances

Not applicable

REACH

3.2 Mixtures

Chemical name

Hazardous

	Š	Registration Number		according to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
+ ACETIC ACID (CAS #: 64-19-7)	**		200-580-7	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1A :: C>=90% Skin Corr. 1B :: 25%<=C<90% Skin Irrit. 2 :: 10%<=C<25%	No data available	No data available
NonHazardous	144 1 1 . 64			l a	1 6 10 1		
Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Levetiracetam (CAS #: 102767-28-2)	10		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Sodium acetate trihydrate (CAS #: 6131-90-4)	**		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

EC No

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available

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Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	
Levetiracetam 102767-28-2	> 5000	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
+ ACETIC ACID 64-19-7	3310	1060	11.4	No data available	No data available

Additional information + Substance with a Union workplace exposure limit

* Proprietary ** to adjust pH

Non-hazardous ingredients provided for completeness. 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.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and

effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

Fine particles (such as mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

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chemical

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Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Not applicable.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions None.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area thoroughly.

Prevention of secondary hazards None.

6.4. Reference to other sections

See section 8 for more information. See section 13 for more information. Reference to other sections

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

SODIUM CHLORIDE

Latvia 5 mg/m³ MAC: 5 mg/m³ Russia

+ ACETIC ACID

STEL: 15 ppm ACGIH TLV

10 ppm Austria 10 ppm

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25 mg/m³ STEL 20 ppm STEL 50 mg/m³ Page 5/12

STEL: 50 mg/m³ Bulgaria STEL: 20 ppm

25 mg/m³ 10 ppm 25 mg/m3

Czech Republic Ceiling: 50 mg/m³

10 ppm Denmark 25 mg/m³

10 ppm Estonia 25 mg/m³

STEL: 10 ppm STEL: 25 mg/m³

50 mg/m³ STEL; 20 ppm STEL **European Union**

25 mg/m³ TWA; 10 ppm TWA Finland 5 ppm

13 mg/m³ STEL: 10 ppm STEL: 25 mg/m³ 25 mg/m³

France 10 ppm Germany 25 mg/m³

Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m³

Germany 10 ppm

25 mg/m³ 25 mg/m³ Hungary STEL: 50 mg/m³

Ireland 20 ppm

50 mg/m³ STEL: 20 ppm STEL: 50 mg/m³

25 ppm Italy

10 mg/m³ STEL: 50 mg/m³ STEL: 20 ppm 10 ppm

25 mg/m³ STEL: 50 mg/m³

STEL: 20 ppm 25 mg/m3 STEL: 50 mg/m³

STEL: 50 mg/m³ Poland

25 mg/m³ 10 ppm 25 mg/m³

STEL: 20 ppm STEL: 50 mg/m³

MAC: 5 mg/m³ Russia

Skin Slovakia 10 ppm

25 mg/m³ 10 ppm Spain 25 mg/m³

STEL: 20 ppm STEL: 50 mg/m³

Switzerland 10 ppm

25 mg/m³

Latvia

Netherlands

Romania

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STEL: 20 ppm STEL: 50 mg/m³

OSHA PEL 10 ppm 25 mg/m³

(vacated) TWA: 10 ppm (vacated) TWA: 25 mg/m³

United Kingdom (vacated) TWA: 25 mg/s

TWA: 25 mg/m³ STEL: 20 ppm STEL: 50 mg/m³

Pfizer Occupational Exposure Band

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(OEB) Statement: 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

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revision when new information becomes available.

Levetiracetam

Pfizer Occupational Exposure

Band (OEB):

B-OEB 1 (control exposure to the range of $>= 10000 \mu g/day$)

SODIUM CHLORIDE

Pfizer Occupational Exposure

Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. 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.

Environmental exposure controls No information available.

Personal protective equipment 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.

Eve/face protection 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.).

Hand protection 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.).

Skin and body protection 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.).

Respiratory protectionUnder 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.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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9.1. Information on basic physical and chemical properties

Physical state Solution
Color Clear, colorless

Odor No information available.
Odor threshold No information available

Molecular formula Mixture
Molecular weight Mixture

<u>Property</u> <u>Values</u>

pH 5.5

Melting point / freezing point No data available

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

No data available Vapor pressure Vapor density No data available Relative density No data available Water solubility No data available Solubility(ies) No data available No data available Partition coefficient **Autoignition temperature** No data available No data available **Decomposition temperature** No data available Kinematic viscosity No data available **Dynamic viscosity**

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available. **Sensitivity to Static Discharge** No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

ingredients

Short term Mild eye irritant in experimental animals (based on components) Based on available data, the classification criteria are not met. Acute toxicity Based on available data, the classification criteria are not met. Serious eye damage/eye irritation Based on available data, the classification criteria are not met. Skin corrosion/irritation Respiratory or skin sensitization Based on available data, the classification criteria are not met. STOT - single exposure Based on available data, the classification criteria are not met. STOT - repeated exposure Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met. **Aspiration hazard** Based on available data, the classification criteria are not met.

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

Levetiracetam

Rat Oral LD50 > 5000 mg/kg

Rat Para-periosteal LD50 > 1000 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

+ ACETIC ACID

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H

Rat Oral LD 50 3310 mg/kg Rabbit Dermal LD 50 1060 uL/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
	-		
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
			-
+ ACETIC ACID	= 3310 mg/kg (Rat)	= 1060 mg/kg (Rabbit)	= 11.4 mg/L (Rat) 4 h

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 13 Week(s) Mouse Oral 60 mg/kg/day NOAEL Liver

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

Levetiracetam

Reproductive & Fertility Rat Oral 70 mg/kg/day NOAEL Fetotoxicity, Embryotoxicity

Reproductive & Fertility Rat Oral 1800 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 3600 mg/kg/day NOAEL Maternal Toxicity

Embryo / Fetal Development Rat Oral 1200 mg/kg/day NOAEL Fetotoxicity

Embryo / Fetal Development Rabbit Oral 200 mg/kg/day LOAEL Maternal Toxicity

Embryo / Fetal Development Rabbit Oral 200 mg/kg/day NOAEL Embryotoxicity

Peri-/Postnatal Development Rat Oral 1800 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity

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 960 mg/kg/day NOAEL Not carcinogenic 104 Week(s) Rat Oral 1800 mg/kg/day NOAEL Not carcinogenic

Carcinogenicity

None of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties of the formulation

have not been investigated.

12.1. Toxicity

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

+ ACETIC ACID

Fathead Minnow NPDES LC-50 96 hours 88 mg/L Bluegill Sunfish NPDES LC-50 96 hours 75 mg/L Goldfish NPDES LC-50 24 hours 423 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

<u>Bioaccumulation</u> No information available.

12.4. Mobility in soil

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Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment	
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does	
	not apply	
+ ACETIC ACID	The substance is not PBT / vPvB PBT assessment does	
	not apply	

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Special precautions for user:

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 wastewater 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.

Section 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.

Not applicable

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):

Not applicable
Not applicable
Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present

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231-791-2 **EINECS AICS** Present Levetiracetam CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed Standard for Uniform Scheduling of Medicines and Schedule 4 Poisons (SUSMP) SODIUM CHLORIDE CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present 231-598-3 **EINECS AICS** Present Sodium acetate trihydrate CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Not Listed **EINECS AICS** Present + ACETIC ACID CERCLA/SARA Section 313 de minimus % Not Listed **Hazardous Substances RQs** 5000 lb **California Proposition 65** Not Listed Present **TSCA EINECS** 200-580-7 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6 Schedule 2

France

Occupational Illnesses (R-463-3, France)

Codepational infecces (it 400 of France)					
Chemical name	French RG number	Title			
SODIUM CHLORIDE	RG 78	-			
7647-14-5					

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

11110 [1110 1111 1111 1111 1111 1111 11		***************************************	
Chemical name	Restricted substance per REACH	Substance subject to authorization per	
	Annex XVII	REACH Annex XIV	
+ ACETIC ACID - 64-19-7	Use restricted. See item 75.		

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)	
SODIUM CHLORIDE - 7647-14-5	Plant protection agent	
+ ACETIC ACID - 64-19-7	Plant protection agent	

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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

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.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the

Company/Undertaking.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.