

MATERIAL SAFETY DATA SHEET

Levetiracetam Injection

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Section I – Chemical Product & Company Identification

Product Identification Levetiracetam Injection 100 mg/mL			WHMIS classification	
General Use Adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy			Type of container Vials	
Manufacturer's Name Hikma Farmacêutica, S.A.		Supplier's Information This material is intended for IV injection under the supervision of physicians		
Manufacturer's Address Estrada do Rio da Mó, 8, 8A, 8B, Fervença				
City Terrugem SINTRA	Postal Code 2705-906	Country Portugal		MSDS Preparer's name AMBR
Phone + (351) 21 960 84 10	E-mail geral@hikma.pt	Fax + (351) 21 961 51 02		Date of MSDS October 2011
Other useful information (-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide				

Section II - Composition/Information on Ingredients

Hazardous Ingredients	% (by weight)	CAS identification	LD ₅₀ (species and route)	LC ₅₀ (species)
Levetiracetam, USP	100 mg/mL	102767-28-2		
Glacial Acetic Acid for pH adjustment	-	64-19-7		
Sodium Chloride	9 mg/mL	7647-14-5		
Sodium Acetate Trihydrate	1.64 mg/mL	6131-90-4		
Water for Injection, USP	QS	7732-18-5		

Section III - Hazards Identification & Emergency Overview

Route of entry	Skin ☒	Eye ☒	Inhalation ☒	Ingestion ☒
Emergency Overview Not considered hazardous when handled under normal conditions with good housekeeping.				
Potential Health Effects <u>Inhalation:</u> Harmful by inhalation <u>Ingestion:</u> Harmful if swallowed <u>Skin contact:</u> Harmful if in contact with skin <u>Eye contact:</u> n/f.				
Medical Conditions Aggravated by Exposure NA Interactions with other Chemicals				
Warning Symbols				

Section IV - First Aid Measures

Skin Contact Wash skin thoroughly with soap and water. If irritation develops, consult a physician	
Eye Contact Flush eyes with plenty of water for up to 30 minutes. Obtain medical attention if an irritation develops	
Inhalation If inhaled, remove to fresh air. If not breathing, give artificial respiratory. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.	
Ingestion If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.	
Antidotes	Other Measures Treatment of an overdose will be symptomatic and may include hemo dialysis. The dialyzer extraction efficiency is 60% for Levetiracetam

Section V - Fire Fighting Measures

Flammable YES ☐ NO ☒	If yes, under which conditions?	
Means of Extinction Use foam or all-purpose dry chemicals to extinguish		
Flashpoint (°C.) and Method Not determined	Upper flammable limit (% by volume) Not Available	Lower flammable limit (% by volume) Not Available
Auto ignition (°C.) None	Explosion Data – Impact None	Explosion Data – Static Discharge None
Hazardous Combustion Products None		
Fire Fighting Recommendations (specific if necessary) Use whatever is available for surrounding fire		

Section VI - Accidental Release Measures

Leak and Spill Procedures Wipe up and rinse with water.
General Precautions (Fire, Environmental and Personal)
Decontamination

Section VII - Handling & Storage

Handling Procedures & Equipment
Storage Requirements Store at room temperature 59° to 86°F (15° to 30°C). Do not refrigerate. Keep tightly closed and out of the reach of children. Protect from excess humidity and direct light.

Section VIII - Exposure Controls & Personal Protection

Exposure Limits ACGIH TLV ☐ OSHA PEL ☐ Other (specify) ☐
Specific Engineering Controls (ventilation, enclosed process, etc)
Personal Protective Equipment Gloves ☒ Respirator ☒ Eye ☒ Footwear ☐ Clothing ☒ Other ☐
Specify type of checked equipment Respiratory Protection: Dust respirator. Be sure to use an approved/certified respirator or equivalent. Eye/Skin and Body Protection: Avoid unintentional injection. Use appropriate PPE when handling syringe/needle. Ventilation: General
Hygiene Measures Use appropriate PPE when handling syringe, needle, or liquid solution (in the unlikely event of broken glass vial)

Section IX - Physical & Chemical Properties

Physical State (STP) Liquid	Odour & Appearance Clear and aqueous solution	Odour Threshold (ppm) Not available
Specific Gravity Approximate to water	Vapour Density (air=1) Not available	Vapour Pressure (mmHg) Not available
Evaporation Rate Not available	Boiling Point (°C.) Not available	Freezing Point (°C.) Not available
pH 5.0 – 6.0	Coefficient of Water/Oil distribution Not available	Solubility in water Soluble in water

Section X - Stability & Reactivity Data

Chemical Stability YES ☒ NO ☐	If no, under which conditions?
Incompatibility with other substances YES ☒ NO ☐	If yes, which ones? Avoid contact with strong acids and oxidants
Reactivity and under what conditions	
Hazardous Decomposition Products None known	
Hazardous Polymerization Will not occur	
Conditions to Avoid	

Section XI - Toxicological Information

Effects of acute exposure LD ₅₀ (mice) > 1g/kg IV	
Effects of chronic exposure Toxicity: No observed toxic effect level (NOTEL) Acute and Chronic Effects: No observed toxic effect level (NOTEL) Signs and Symptoms of Exposure: The substance is used for the treatment of epilepsy and is generally well tolerated after repeated oral intake up to 3000 mg/mL. The most frequently reported adverse events are drowsiness, weakness and dizziness.	
Irritancy of Product	
Skin Sensitization	Respiratory Sensitization
Carcinogenicity IARC ☐ ACGIH ☐ Other ☐	Explanation Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data available on the product itself
Reproductive Toxicity	Teratogenicity
Embriotoxicity	Mutagenicity
Name of synergistic Products/Effects	

Section XII - Ecological Information

Aquatic Toxicity & other Environmental Issues

Section XIII - Disposal Considerations

Waste Disposal Waste disposal must be in accordance with appropriate Federal, State, and Local Regulations.
Contaminated Packaging Dispose of in accordance with local regulations.

Section XIV - Transport Information

Special Shipping Information (general) This material is not hazardous as defined by 49 CFR 172.101 by the US Department of Transportation.
Specific Local Transport Information or Classifications DOT: None TDG (Canada): None ADR/RID: None ICAO/IATA: None IMO/IMDG: None

Section XV - Regulatory Information

General Regulatory Information SARA 313 listed?: NO CERCLA listed?: NO RCRA listed?: NO
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Specific Local Regulatory Information or Classification

US TSCA Inventory Status: NO

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): NO

Other US Federal Regulations: Based on this products use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable

Section XVI - Other Information

1. Use of this product should be through or under the direction of a physician.

This MSDS does not address the therapeutic use of this material.

2. Persons administering this drug to patients must be careful to avoid needle sticks from syringes and other sharp used in the administration. All needle sticks must be reported to your company management.

Disclaimer:

This information is based upon sources believed to be reliable information. However, Hikma does not guarantee their accuracy or completeness. None of this information should constitute a warranty, whether expressed or implied, as to the safety of the goods, the merchantability of the goods or the fitness of the goods for a particular purpose.