TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Oxaliplatin Injection

1. PRODUCT IDENTIFICATION

Product Name Oxaliplatin Injection
Product Use Medical Treatment; Antineoplastic
Manufacturer Teva Parenteral Medicines, Inc.
Address 11 Hughes
Irvine, CA 92618-1902

Chemtrec Emergency No. 1-800-424-9300 (United States)
1-202-483-7617 (International Collect)
Business Phone 1-800-729-9991
Website Address http://www.tevausa.com

Common Names Eloxatin®
Chemical Name [SP-4-2-(1R-trans)]-(1,2-Cyclohexanediamine-N,N`) {ethanedioato(2-)-O,O`] platinum or [1R,-2R)-1,2-cyclohexanediamine-N,N`][oxalto (2-)-O, O`] platinum
Chemical Formula $C_8H_{14}N_2O_4Pt$
Chemical Family Antineoplastic
How Supplied 5 mg/mL in glass vials containing 10 mL, 20 mL & 40 mL of solution

Date of Preparation: July 6, 2009

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	Wt%		EXPOSURE LIMITS IN AIR				
		10 & 20 mL Vial	40mL Vial	ACGIH		OSHA		Other
				TLV	C	PEL	C	
Oxaliplatin (exposure limit for Platinum, soluble salts as Platinum)	61825-94-3	0.5	0.498	0.002 mg/m3	NE	0.002 mg/m3	NE	0.002 mg/m3*
Gluconolactone	90-80-2	--	0.002	NE	NE	NE	NE	NE
Lactose Monohydrate	5989-81-1	4.5	--	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	95	99.5	NE	NE	NE	NE	NE

NE - Not Established C - Ceiling Limit *NIOSH REL

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a clear, colorless solution. Cytotoxic. Eye irritant. May cause damage to the blood, liver, pulmonary, reproductive and nervous systems. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy and while breastfeeding. Do not taste or swallow. Wash thoroughly after handling.

3. HAZARD IDENTIFICATION cont.

Symptoms of Overexposure by Route of Exposure: This material is intended for injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers. However, it may produce pulmonary fibrosis if inhaled.

Contact with Skin or Eyes: Contact may cause irritation. Effects may include stinging, watering, redness and swelling of the eyes and redness and a burning sensation on the skin. As with other platinum compounds, oxaliplatin may produce allergic reactions that have, on very rare occasions, been severe or life-threatening.

Ingestion: Ingestion is not an anticipated route of occupational exposure. Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including myelosuppression including anemia (low red blood cells), leucopenia, neutropenia (low white blood cells) and thrombocytopenia (low platelets), fever, anemia, nausea, vomiting, diarrhea, peripheral neuropathy (with cold sensitivity and rare laryngeal dysaesthesias [sensation of difficulty with breathing or swallowing]), abnormal liver function tests, and mucositis (sore mouth, or soreness of other mucous membranes) may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure **(An explanation in lay terms):**

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as myelosuppression including anemia (low red blood cells), leucopenia, neutropenia (low white blood cells) and thrombocytopenia (low platelets), fever, anemia, nausea, vomiting, diarrhea, peripheral neuropathy (with cold sensitivity and rare laryngeal dysaesthesias [sensation of difficulty with breathing or swallowing]), abnormal liver function tests, and mucositis (sore mouth, or soreness of other mucous membranes) may occur. Cancer: Oxaliplatin has not been tested in laboratory animals. However, it is considered possibly carcinogenic (see Section 11).

Chronic: Based on animal data, Oxaliplatin, is considered a potential carcinogen, reproductive and developmental toxicant (see Section 11).

Target Organs: Potential hazard to the blood, liver, pulmonary and nervous systems (see Section 11).

Pre-Existing Medical Conditions: Pre-existing blood, liver, lung and nervous systems disorders may be aggravated by exposure to this material.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

5. FIRE-FIGHTING MEASURES

Flash Point: Non-flammable Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable Upper: Not applicable

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures.: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS:		
	Health:	2 (Moderate)
	Flammability:	0 (Least)
	Reactivity:	0 (Least)

6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

OXALIPLATIN IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10). Store at 15-30°C (59-86°F). Protect from light.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	ND	Evaporation Rate (n-BuAc=1):	ND
Specific Gravity (water = 1):	ND	Melting/Freezing Point:	0°C (32°F))
Solubility in Water:	Sparingly	Boiling Point:	100°C (212°F)
Vapor Pressure, mm Hg @ 25°C.	ND	pH:	4.8-5.7
Odor Threshold: ND			
Appearance and Color: Clear, colorless to straw colored solution, free of visible particles			

ND = No Data

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility but keep away from oxidizing and reducing agents. Contact with aluminum may lead to the formation of a platinum precipitate.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Oxides of carbon and nitrogen and platinum-containing compounds with possible carcinogenic potential.

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Oxaliplatin, the active ingredient

IP LD50(mouse) = 19,800 ug/kg IP LD50(rat) = 14,300 ug/kg

Suspected Cancer Agent: The carcinogenic potential of Oxaliplatin has not been examined in test animals; however, compounds with similar mechanisms of action (e.g., cytotoxic) and mutagenicity profiles have been reported to be carcinogenic. It is not listed as carcinogenic by NTP, IARC or OSHA.

Irritancy of Product: This product is expected to be irritating to contaminated eyes and other tissues. The active ingredient is irritating to the eyes.

Sensitization to the Product: As with other platinum compounds, Oxaliplatin may produce allergic reactions that have, on very rare occasions, been severe or life-threatening.

Target Organ(s): Oxaliplatin has demonstrated effect on the blood (myelosuppression including anemia, leucopenia, neutropenia and thrombocytopenia. It has also been associated with pulmonary fibrosis liver effects (elevation of liver enzymes) and peripheral neuropathy (sensitivity to cold and rare laryngeal dysaesthesias (sensation fo difficulty with breathing or swallowing).

Reproductive Toxicity Information: Listed below is information concerning the effects of Oxaliplatin on human and animal reproductive systems. This material is classified as a Pregnancy Category D (Positive evidence of risk). Currently, there have been no studies in pregnant women.

Mutagenicity: Oxaliplatin is positive in both in vitro and in vivo mutagenesis assays. It interacts with DNA, blocking DNA replication and transcription.

Embryotoxicity/Teratogenicity: In a fertility study, male rats were given Oxaliplatin at 0, 0.5, 1 or 2 mg/kg/day for five days every 21 days for a total of three cycles prior to mating with females that received two cycles of Oxaliplatin on the same schedule. A dose of 2 mg/kg/day did not affect pregnancy rate, but caused developmental mortality (increased early resorptions, decreased live fetuses, decreased live births) and delayed growth (decreased fetal weight).

Testicular damage, characterized by degeneration, hypoplasia and atrophy were observed in dogs administered Oxaliplatin at 0.75 mg/kg/day X 5 days every 28 days fro three cycles. A no effect level was not identified.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

Oxaliplatin Injection

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: It is anticipated that this compound will decompose into a variety of organic compounds.

Effect of Materials on Plants or Animals: This product may be harmful to contaminated plant and animal life. See Section 11 (Toxicological Information) for additional information.

Effect of Chemicals on Aquatic Life: This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities.

13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not Applicable
Hazard Class Number and Description: Not Applicable
UN Identification Number: Not Applicable
Packing Group: Not Applicable
DOT Label(s) Required: Not applicable
North American Emergency Response Guidebook Number (1996):
MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: See above

15. REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. TSCA Inventory Status: Oxaliplatin is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain a chemical known to the State of California to cause cancer or reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Oxaliplatin is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): DANGER! Cytotoxic Agent. Can Cause Eye irritation. May cause damage to the blood, liver, pulmonary, reproductive and nervous systems. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Oxaliplatin should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Do not eat, drink or smoke when handling Oxaliplatin. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

16. OTHER INFORMATION

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