

## 1. Product and Company Identification

---

**PRODUCT NAME: OXALIplatin injection**  
**50 mg/10 mL, 100 mg/20 mL (5 mg/mL)**

**Supplier:**

**Supplier:**

**Winthrop U.S.**

**A business of Sanofi U.S.**

**55 Corporate Drive**

**Bridgewater, NJ 08807**

**24-Hour Transport Emergency, US (Chemtrec): (800) 424-9300**

**24-Hour Transport Emergency, outside US (Chemtrec): (703) 527-3887**

**US Customer Service (800) 207-8049**

**24-Hour Emergency, sanofi-aventis US: (908) 981-5550**

**Product use: Pharmaceutical product.**

---

## 2. Hazards Identification

---

### 2.1 Classification in accordance with 29 CFR 1910.1200

**Classification:**

Serious eye damage, Category 1

Respiratory sensitization, Category 1B

Skin sensitization, Category 1

Germ cell mutagenicity, Category 2

Carcinogenicity, Category 2

Reproductive toxicity, Category 1B

Effects on or via lactation

Specific target organ toxicity - repeated exposure, Category 1

### 2.2 Label elements in accordance with 29 CFR 1910.1200

**Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200.  
The following information is provided for the drug substance, oxaliplatin:**

Signal Word: Danger

Hazard Statement(s):

Causes serious eye damage.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause an allergic skin reaction.  
Suspected of causing genetic defects.  
Suspected of causing cancer.  
May damage fertility. May damage the unborn child.  
May cause harm to breast-fed children.  
Causes damage to organs through prolonged or repeated exposure.

Symbol(s): Health hazard, Corrosion

Precautionary Statement(s):

- Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. In case of inadequate ventilation wear respiratory protection. Wear protective gloves, clothing, eye, and face protection. Wash hands thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Do not eat, drink or smoke when using this product.
- Response: If exposed or concerned: Get medical attention.  
If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If on skin: Wash with plenty of water and soap. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
- Storage: Store locked up.
- Disposal: Dispose of in accordance with applicable regional, national and local laws and regulations.

**2.3 Hazards Not Otherwise Classified (HNOC)**

Not classified.

---

**3. Composition/Information on Ingredients**

---

<u>Chemical Name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
Oxalato (trans-1-1,2-diaminocyclohexane) platinum(II)	Oxaliplatin	61825-94-3	50 mg or 100 mg per vial (5 mg/mL)

Inactive Ingredients: Water for injection.

---

## 4. First Aid Measures

---

### 4.1 First aid procedures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Skin contact: Wash with plenty of water and soap. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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

Nausea, vomiting, diarrhea, hair loss, anemia, liver toxicity, neurotoxicity.

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

Treat symptomatically and supportively.

---

## 5. Fire Fighting Measures

---

### 5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

### 5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen.

### 5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can

do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

---

## **6. Accidental Release Measures**

---

### **6.1 Personal Precautions and Protective Equipment:**

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

### **6.2 Emergency Procedures:**

#### Small Spills

If a small spill occurs within a ventilated cabinet, wear protective equipment to prevent inhalation or eye/skin contact (see Section 8). Wipe up spill with absorbent material and place in an impervious container.

#### Large Spills

During a large spill, evacuate non-essential personnel from the area. Wear protective equipment to prevent inhalation or eye/skin contact (see Section 8). Absorb the liquid with an inert absorbent material (e.g. absorbent pad, clay, vermiculite, etc.). Avoid excessive physical disturbance of spill during cleanup to minimize aerosol generation.

### **6.3 Methods for containment:**

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

### **6.4 Methods for clean-up:**

Wash the floor with dilute bleach and plenty of water, absorb or retain the cleaning water for disposal. Carefully place the waste in a labeled receptacle for safe disposal as a contaminated waste. Remove any contaminated clothing, personal protective equipment and barrier sheeting, and place in a double sealed, labeled waste container marked for disposal. Wash skin thoroughly after handling.

---

## **7. Handling and Storage**

---

## 7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation (see Section 8). Avoid contact with eyes, skin and clothing. To minimize hazards from accidental breakage or spills of containers and to simplify clean-up, store and transport within secondary containers, pans or trays. Use disposable protective coatings and/or barrier sheeting in use areas where possibility of spillage exists to simplify cleanup. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

## 7.2 Conditions for Safe Storage

This product should be stored in a closed secondary container that minimizes the risk of breakage. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Do not freeze and protect from light.

---

## 8. Exposure Controls/Personal Protection

---

### 8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, oxaliplatin: 0.5 micrograms/m<sup>3</sup>, 8-hour TWA.

### 8.2 Appropriate Engineering Controls

#### General Controls for Clinical Setting

A workplace risk assessment must be carried out in order to determine the correct engineering control measures, work practices and personal protective equipment.

Engineering Controls: Preparation of this product should be done in an area that is devoted solely to the preparation of hazardous drugs and is restricted to authorized personnel. This product should be prepared within a ventilated cabinet designed to protect workers and adjacent personnel from exposure. Transfers from primary packaging such as vials to dosing equipment should also be performed within a ventilated cabinet. Use closed-system, drug-transfer devices, glove bags and needleless systems within the ventilated cabinet. The final prepared product should be sealed in a plastic bag or other sealable container prior to removal from the cabinet. All waste containers in the cabinet should be sealed and wiped prior to removal for disposal.

### 8.3 Individual Protection Measures

Eye/face protection: At a minimum, safety glasses with side shields should be worn. Wear a face shield to avoid splash incidents involving the eyes, nose and mouth when adequate engineering controls are not available.

Skin protection: Use two pairs of approved chemotherapy gloves with the outer one covering the gown cuff at all times, including when unpacking product shipments. Gloves should be changed

every 30 minutes or when torn, punctured or contaminated and discarded immediately in the appropriate container. When working in a ventilated cabinet, the outer gloves should be removed and bagged for disposal inside the ventilated cabinet. Avoid skin contact by using a disposable gown made of non-linting and non-absorbent fabric. The gown should have a closed front, long sleeves and elastic or knit closed cuffs and should not be reused.

Respiratory protection: Respiratory protective equipment can only be used in place of engineering controls as a temporary measure in emergency situations or when control by other means is not feasible. Respiratory protection must be selected according to the risk from the work task or situation. In general, positive pressure, supplied air respiratory protective equipment (hood, half suit or full suit), which provides high factors of protection, is used when there is risk of airborne exposure above recommended exposure levels. All respiratory protection should be in compliance with the OSHA Respiratory Protection Standard, 29 CFR 1910.134, or other regulations applicable to the country of use.

General hygiene considerations: Health care workers who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific workplace handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, medical equipment, or in patient urine or feces. Wash hands with soap and water immediately before using personal protective clothing (such as disposable gloves and gowns) and after removing personal protective clothing, including gloves. Outer gloves and gowns should be removed and bagged for disposal in the appropriate container at the site of administration. The waste container should be double-bagged before removal of the inner gloves. Clean and decontaminate work areas before and after each activity and at the end of each shift. See Section 13 for guidance on waste handling.

Several general guidelines on the handling of oncolytic and cytotoxic agents are also available. See Section 16.

---

## 9. Physical and Chemical Properties

---

Appearance: White solid (powder).

Odor: No data available.

Odor threshold: No data available.

pH: 4.8 – 5.7 at 2 g/L

Melting point (oxaliplatin): From 198 °C

Initial boiling point/boiling point range: No data available.

Flash point: No data available.

Evaporation rate: No data available.

Flammability: No data available.

Upper/lower flammability or explosive limits: No data available.

Vapor pressure: No data available.

Vapor density: No data available.

Relative density: No data available.

Solubility (oxaliplatin): 6 g/L at 20 °C

Partition coefficient: n-octanol/water: Log Kow: -1.67 (experimental)

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.  
Viscosity: No data available.

---

## **10. Stability and Reactivity**

---

### **10.1 Reactivity**

Not a reactive material under normal handling conditions.

### **10.2 Chemical Stability**

Stable under normal handling conditions.

### **10.3 Possibility of hazardous reactions**

None known.

### **10.4 Conditions to Avoid**

Keep away from heat, sparks and flames.

### **10.5 Incompatible materials**

Strong oxidizing and reducing agents.

### **10.6 Hazardous decomposition products**

Carbon monoxide, carbon dioxide, oxides of nitrogen.

---

## **11. Toxicological Information**

---

### **The following information is for the active ingredient oxaliplatin unless otherwise noted:**

Information on likely routes of exposure: Not expected under normal handling conditions.  
Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Nausea, vomiting, diarrhea, hair loss, anemia (red blood cells/hemoglobin deficiency).

Effects of short-term (acute) exposure: Reversible peripheral sensory neurotoxicity.

Effects of long-term (chronic) exposure: Persistent peripheral sensory neurotoxicity. Hepatotoxicity. Myelosuppression, including anemia (low red blood cell count), leucopenia, neutropenia (low white blood cell count, with possible increased risk of infection), and thrombocytopenia (low platelet count, with possible increased risk of bleeding).

Acute toxicity (LD50):  
Oral route, rat: > 100 mg/kg

Skin corrosion/irritation: Not a skin irritant based on animal tests.

Serious eye damage/irritation: Strongly irritating to the eyes based on animal tests.

Sensitization: May cause sensitization by inhalation and skin contact.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): Hepatotoxicity and peripheral neuropathy have been observed in human clinical trials.

Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of oxaliplatin. May be carcinogenic based on genotoxicity data and on the pharmacological activity.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Based on direct interaction with DNA, oxaliplatin may cause fetal harm when administered to a pregnant woman. Reproductive toxicity studies in rats demonstrated adverse effects on fertility and embryo-fetal development at maternal doses that were below the recommended human dose based on body surface area.

Testicular damage was observed in dogs. A no-effect level was not identified. The daily dose was approximately one-sixth of the recommended human dose on a body surface area basis.

Mutagenicity: Oxaliplatin was not mutagenic to bacteria (Ames test) but was mutagenic to mammalian cells in vitro (L5178Y mouse lymphoma assay). Oxaliplatin was clastogenic both in vitro (chromosome aberration in human lymphocytes) and in vivo (mouse bone marrow micronucleus assay).

Aspiration hazard: No data available.

---

## 12. Ecological Information

---

**The following information is for the active ingredient oxaliplatin unless otherwise noted:**

### 12.1. Ecotoxicity

No data available.



## **12.2. Persistence and degradability**

Biological degradability: Not readily biodegradable. (OECD 301B)

## **12.3. Bioaccumulative potential**

No data available.

## **12.4 Mobility in soil**

Not a regulated material.

## **12.5 Other adverse effects**

Not a regulated material.

---

## **13. Disposal Considerations**

---

### **13.1 Disposal of product waste**

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. Wastes should be double contained (e.g. double sealed bags) and labeled indicating contents to ensure safe handling and disposal. Incineration of waste product is recommended.

### **13.2 Disposal of packaging waste**

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

---

## **14. Transport Information**

---

### **14.1 Basic shipping information, finished product**

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

---

## 15. Regulatory Information

---

### US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.

SARA Title III:

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.

Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

### State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.

Massachusetts Right-To-Know List: Not listed.

New Jersey Right-To-Know List: Not listed.

Pennsylvania Right-To-Know List: Not listed.

---

## 16. Other Information

---

Oxaliplatin is included in the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.

### Published Guidelines

1. NIOSH Alert: Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. 2004. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.
2. OSHA Technical Manual, TED 1-0.15A, Section VI: Chapter 2. Controlling Occupational Exposure to Hazardous Drugs. OSHA, 1999.
3. American Society of Health-System Pharmacists. (2006) ASHP Guidelines on Handling Hazardous Drugs.
4. Polovich, M., White, J. M., & Kelleher, L.O. (eds.) 2005. Chemotherapy and biotherapy guidelines and recommendations for practice (2nd. Ed.) Pittsburgh, PA: Oncology Nursing Society.

Other Information: The information contained herein is based upon data considered true and accurate. Winthrop U.S. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms

CAS: Chemical Abstracts Service

DOT: U.S. Department of Transportation

EST: Eastern standard time (U.S.)

IATA: International Air Transport Association

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

OEL: Occupational Exposure Limit

PPE: Personal Protection Equipment

SDS: Safety Data Sheet

STEL: Short-term exposure limit

TWA: Time-weighted average

U.S.: United States

Date Prepared: February 13, 2017; Third version.