

## 1. Identification

Product identifier	Oxaliplatin Related Compound D	
Other means of identification		
Catalog number	1481248	
CAS number	61758-77-8	
Synonyms	S,S-enantiomer of oxaliplatin	
Chemical name	(SP-4-2)-[(1S,2S)-cyclohexane-1,2-diamine-KN,KN'][(ethanedioato(2-)-KO1,KO2)]platinum	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
	Serious eye damage/eye irritation	Category 2A
	Sensitization, respiratory	Category 1B
	Sensitization, skin	Category 1B
	Germ cell mutagenicity	Category 2
	Carcinogenicity	Category 2
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



**Signal word** Danger

**Hazard statement** Toxic if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of causing genetic defects. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

## Precautionary statement

### Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

### Response

If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.

### Storage

Store locked up.

### Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

### Hazard(s) not otherwise classified (HNOC)

None known.

### Supplemental information

Pharmaceutical related compound of unknown potency.

## 3. Composition/information on ingredients

### Substance

Chemical name	Common name and synonyms	CAS number	%
Oxaliplatin Related Compound D	S,S-enantiomer of oxaliplatin	61758-77-8	100

## 4. First-aid measures

### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

### Skin contact

Wash off with soap and plenty of water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention.

### Eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

### Ingestion

Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

### Most important symptoms/effects, acute and delayed

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

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

Provide general supportive measures and treat symptomatically.

### General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

### Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

### Unsuitable extinguishing media

None known.

### Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

### Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up** For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### U.S. - OSHA

Material	Type	Value	Form
Oxaliplatin Related Compound D (CAS 61758-77-8)	TWA	0.002 mg/m3	Platinum

#### ACGIH

Material	Type	Value	Form
Oxaliplatin Related Compound D (CAS 61758-77-8)	TWA	0.002 mg/m3	Platinum

#### U.S. - NIOSH

Material	Type	Value	Form
Oxaliplatin Related Compound D (CAS 61758-77-8)	TWA	0.002 mg/m3	Platinum

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

**Hand protection** Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.

**Other** Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

**Respiratory protection** Choose respiratory protection appropriate to the task and the level of existing engineering controls. Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup.

<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. Pharmacological effects may be seen with occupational exposure.

## 9. Physical and chemical properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Crystalline powder.
<b>Color</b>	White. Off-white.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Platinum analog.
<b>Molecular formula</b>	C <sub>8</sub> H <sub>14</sub> N <sub>2</sub> O <sub>4</sub> Pt
<b>Molecular weight</b>	397.3

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . Pt. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Skin contact</b>	May cause an allergic skin reaction.

<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Toxic if swallowed.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Platinum containing compounds: Ringing in ears. Hearing problems. Tiredness. Weakness. Gastrointestinal disturbances. Numbness, pain, tingling, or weakness in hands or feet. Fever. Chills. Cough. Bleeding or bruising. Rash. Dizziness. Difficulty breathing. It is not known if this material causes the same effects.

#### Information on toxicological effects

<b>Acute toxicity</b>	Toxic if swallowed.
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Respiratory hypersensitivity reactions have been reported with occupational exposure to platinum-containing compounds.
<b>Skin sensitization</b>	May cause an allergic skin reaction. Skin hypersensitivity reactions have been reported with occupational exposure to platinum-containing compounds.
<b>Germ cell mutagenicity</b>	Suspected of causing genetic defects.
<b>Carcinogenicity</b>	Suspected of causing cancer. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use. Although information is limited, available data seem to indicate that the carcinogenic risk is greatest with the alkylating agents. It is not known if this material causes the same effects.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

<b>Reproductive toxicity</b>	Suspected of damaging fertility or the unborn child. Adverse reproductive effects were seen in animal studies with a related material. It is not known if this material causes the same effects.
<b>Specific target organ toxicity - single exposure</b>	Knowledge about health hazard is incomplete.
<b>Specific target organ toxicity - repeated exposure</b>	Causes damage to organs through prolonged or repeated exposure.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.
<b>Further information</b>	Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Dispose of contents/container in accordance with local/regional/national/international regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products**

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

**DOT**

UN number	UN3467
UN proper shipping name	Organometallic compound, toxic, solid, n.o.s. (Oxaliplatin Related Compound D)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III

**IATA**

UN number	UN3467
UN proper shipping name	Organometallic compound, toxic, solid, n.o.s. (Oxaliplatin Related Compound D)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Other information	

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

**DOT; IATA****General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**SARA 313 (TRI reporting)**  
Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 03-26-2008

**Revision date** 10-19-2018

**Version #** 04

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