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SECTION 1: Identification

1.1. Identification

Product name : Oxaliplatin Injection

Other means of identification : 50 mg per 10 mL (5 mg / mL): 10 mL single dose vial packaged individually in a carton NDC 55150-331-01 100 mg per 20 mL (5 mg / mL): 20 mL single dose vial packaged individually in a carton NDC 55150-332-01

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics

279 Princeton Highstown Road East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Sens. 1 H317 Carc. 2 H351

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US)



07 GH

Signal word (GHS US) : Warning

Hazard statements (GHS US) : H317 - May cause an allergic skin reaction

H351 - Suspected of causing cancer

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P272 - Contaminated work clothing must not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P321 - Specific treatment (see supplemental first aid instruction on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P363 - Wash contaminated clothing before reuse.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

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| Name | Product identifier | % | GHS US classification |
|-------------|----------------------|------|------------------------------------------------------------------------------------------------------|
| Water | (CAS-No.) 7732-18-5 | > 99 | Not classified |
| Oxaliplatin | (CAS-No.) 61825-94-3 | 0.5 | Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 Carc. 2, H351 STOT SE 3, H335 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.

First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

First-aid measures after 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

Symptoms/injuries after inhalation : None anticipated during normal product use.

Symptoms/injuries after skin contact : May cause skin irritation May cause an allergic skin reaction.

Symptoms/injuries after eye contact : May cause eye irritation.

Symptoms/injuries after ingestion : May be harmful if swallowed.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained

breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose

according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment.

Observe good industrial hygiene practices.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20° to 25°C (68° to 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

Not applicable

Oxaliplatin (61825-94-3)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : No protection is ordinarily required under normal conditions of use.

Eye protection : Wear safety glasses or goggles. Skin and body protection : Wear suitable working clothes.

Respiratory protection : No protection is ordinarily required under normal conditions of use.

: No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear
Color : Colorless
Odor : Odorless

Odor threshold : No data available No data available Melting point No data available No data available Freezing point No data available Boiling point Flash point : No data available Relative evaporation rate (butyl acetate=1) No data available Flammability (solid, gas) : No data available Vapor pressure : No data available Relative vapor density at 20 °C : No data available Relative density : No data available Solubility completely soluble. Partition coefficient n-octanol/water (Log Pow) No data available Auto-ignition temperature : No data available Decomposition temperature : No data available : No data available Viscosity, kinematic Viscosity, dynamic No data available **Explosion limits** No data available : No data available Explosive properties

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Oxidizing properties

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

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10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| Water (7732-18-5) | | |
|-----------------------------------|--------------------------------------|--|
| LD50 oral rat | > 90 ml/kg | |
| Skin corrosion/irritation | Not classified | |
| Serious eye damage/irritation | Not classified | |
| Respiratory or skin sensitization | May cause an allergic skin reaction. | |

Germ cell mutagenicity : Not classified

Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

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SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

No additional information available

SECTION 16: Other information

Full text of H-phrases:

| Carc. 2 | Carcinogenicity Category 2 |
|---------------|-------------------------------------------------------------|
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| Skin Sens. 1 | Skin sensitization, Category 1 |
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |
| H351 | Suspected of causing cancer |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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