lopamidol

sc-211653

Material Safety Data Sheet



The Power to Oscotion

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Iopamidol

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA FLAMM BILITY HEALT DAZARD INST BLITY

SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

EMERGENCY:

ChemWatch

Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C17-H22-I3-N3-O8, "1, 3-benzenedicarboxamide, N, N' -bis(2-hydroxy-1-(hydroxymethyl)ethyl)-5-", "((2-hydroxy-1-oxopropyl)amino-2, 4, 6-triiodo-, (S)-", B-15000, "L-(+)-N, N' -bis(2-hydroxy-1-hydroxymethylethyl)-2, 4, 6-triiodo-5-", lactamide, isophthalimide, "L-5alpha-hydroxypropionylamino-2, 4, 6-triidoisophthalic acid di(1, 3-", dihydroxy-2-propylamide), Lopamiro, Lopamiron, Isovue-370, "Jopamiron 200", "Niopam 300", "Solutrast 370", "SQ 13396", "radiopaque contrast medium"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

| | | Min | Max |
|---------------|---|-----|---------------------|
| Flammability: | 1 | | |
| Toxicity: | 2 | | |
| Body Contact: | 0 | | Min/Nil=0 Low=1 |
| Reactivity: | 1 | | Moderate=2 |
| Chronic: | 2 | | High=3 Extreme=4 |

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW RISK

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- lodinated contrast media are classified as ionic or nonionic and, additionally, as monomeric and dimeric.

Nonionic contrast media, such as metrizamide and its congeners, are used as high-contrast media in diagnostic radiology.

FYF

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

- The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).

Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.

There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.

Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, on the basis that similar materials tested in appropriate animal studies provide some suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

lodine and iodides, may give rise to local allergic reactions such as hives, rupture of skin blood vessels, pain in joints or diseases of the lymph nodes

lodine and iodides cause goiter and diminished as well as increased activity of the thyroid gland. A toxic syndrome resulting from chronic iodide overdose and from repeated administration of small amounts of iodine is characterized by excessive saliva production, head cold, sneezing, conjunctivitis, headache, fever, laryngitis, inflammation of the bronchi and mouth cavity, inflamed parotid gland, and various skin rashes.

Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

| NAME | CAS RN | % |
|-----------|------------|-----|
| iopamidol | 60166-93-0 | >98 |

Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

FYF

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

citing from:

MARTINDALE: The Extra Pharmacopoeia, 27th Ed.

A 62 year old man who had undergone lumbar myelopgraphy with 10 ml iopamidol developed headache, nausea and vomiting. Rapidly worsening confusion followed and the patient became uncommunicative. On arrival at hospital he was febrile with marked neck stiffness, and was irritable and restless. There were no abnormal neurological signs or evidence of infection and the patient was discharged after 5 days without residual symptoms.

| Section 5 - FIRE FIGHTING MEASURES | | | | |
|------------------------------------|----------------|--|--|--|
| Vapour Pressure (mmHG): | Negligible | | | |
| Upper Explosive Limit (%): | Not available. | | | |
| Specific Gravity (water=1): | 0.796-1.048 | | | |
| Lower Explosive Limit (%): | Not available | | | |

EXTINGUISHING MEDIA

- · Water spray or fog.
- · Foam.

FIRE FIGHTING

- · Alert Emergency Responders and tell them location and nature of hazard.
- · Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- · Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen iodide, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
- · May emit poisonous fumes.
- May emit corrosive fumes.

FIRE INCOMPATIBILITY

· Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

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Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- · Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- · Wear protective clothing, gloves, safety glasses and dust respirator.
- · Use dry clean up procedures and avoid generating dust.
- · Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- · Dampen with water to prevent dusting before sweeping.
- · Place in suitable containers for disposal.

MAJOR SPILLS

- | Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- · Do NOT cut, drill, grind or weld such containers.
- · In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- | Glass container.
- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- · Store in original containers.
- · Store at -20° C.
- · Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records
• iopamidol: CAS:60166-93-0 CAS:62883-00-5

PERSONAL PROTECTION



RESPIRATOR

•Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

FYF

When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- · Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- · Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin

59], [AS/NZS 1336 or national equivalent].

HANDS/FEET

NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- · frequency and duration of contact,
- chemical resistance of glove material,
- · glove thickness and
- · dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- · PVC gloves.
- · Protective shoe covers. [AS/NZS 2210]
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- · polychloroprene
- · nitrile rubber
- · butyl rubber
- · fluorocaoutchouc
- · polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- · For quantities up to 500 grams a laboratory coat may be suitable.
- · For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- · For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- · Eve wash unit.
- · Ensure there is ready access to an emergency shower.
- · For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid

Mixes with water.

| State | Divided solid | Molecular Weight | 777.12 |
|---------------------------|----------------|--------------------------------|----------------|
| Melting Range (°F) | Not applicable | Viscosity | Not Applicable |
| Boiling Range (°F) | Not applicable | Solubility in water (g/L) | Miscible |
| Flash Point (°F) | Not available | pH (1% solution) | Not available |
| Decomposition Temp (°F) | ~572 | pH (as supplied) | Not applicable |
| Autoignition Temp (°F) | Not available | Vapour Pressure (mmHG) | Negligible |
| Upper Explosive Limit (%) | Not available. | Specific Gravity (water=1) | 0.796-1.048 |
| Lower Explosive Limit (%) | Not available | Relative Vapor Density (air=1) | Not Applicable |
| Volatile Component (%vol) | Negligible | Evaporation Rate | Not applicable |

APPEARANCE

White crystalline, odourless powder; mixes with water, methanol. Decomposes without melting. pKa (25 deg C); 10.70. Low-osmolal, nonionic and monomeric.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- · Presence of incompatible materials.
- · Product is considered stable.

STORAGE INCOMPATIBILITY

· Protect from light.

Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

iopamidol

TOXICITY AND IRRITATION

IOPAMIDOL:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY IRRITATION

Intraspinal (man) TDLo: 0.214 mg/l Oral (rat) LD50: >49000 mg/kg

Intraperitoneal (rat) LD50: 35000 mg/kg Subcutaneous (rat) LD50: >49000 mg/kg

Intravenous (rat) LD50: 22044 mg/kg Intraarterial (rat) LD50: 13268 mg/kg

Oral (mouse) LD50: >49000 mg/kg

Intraperitoneal (mouse) LD50: 40825 mg/kg

Subcutaneous (mouse) LD50: >49000 mg/kg

Intravenous (mouse) LD50: 33000 mg/kg

Intracerebral (mouse) LD50: 3000 mg/kg

Intravenous (dog) LD50: 35000 mg/kg

Intravenous (rabbit) LD50: 20000 mg/kg

Parenteral (rabbit) LD50: 510 mg/kg

Intravenous (man) TDLo: 600 mg/kg/3S - C

Intravenous (man) TDLo 1657 mg/kg

Muscle weakness, contractions, change in cardiac rate, changes in kidney

tubules, convulsions, tremour, miosis, chronic pulmonary oedema, dyspnea,

recorded.

Section 12 - ECOLOGICAL INFORMATION

Nil Reported

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- · Reduction
- Reuse
- · Recycling
- · Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- · Recycle wherever possible.
- · Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

No data for iopamidol (CAS: , 60166-93-0, 62883-00-5)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Ingestion may produce health damage*.
- Cumulative effects may result following exposure*.
- Possible respiratory and skin sensitiser*.
- May possibly be harmful to the foetus/ embryo*.
- * (limited evidence).

Denmark Advisory list for selfclassification of dangerous substances

Substance CAS Suggested codes iopamidol 60166- 93- 0 R52/53 iopamidol 62883- 00- 5 R52/53

Ingredients with multiple CAS Nos

Ingredient Name CAS iopamidol 60166-93-0, 62883-00-5

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

 A list of reference resources used to assist the committee may be found at:

 www.chemwatch.net/references.
- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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