Material Safety Data Sheet

Spiramycin
sc-251064

Hazard Alert Code Key:
EXTREME | HIGH | MODERATE | LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Spiramycin

STATEMENT OF HAZARDOUS NATURE

NFPA

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
Foromacidin, Kitasamycin, Leucomycin, NSC-64393, Provamycin, Rovamycina, R.P.5337, Selectomycin, Sequamycin, "macrolide antibiotic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability:</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity:</td>
<td>2</td>
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<tr>
<td>Body Contact:</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Reactivity:</td>
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<tr>
<td>Chronic:</td>
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</table>

CANADIAN WHMIS SYMBOLS
None

EMERGENCY OVERVIEW
RISK

POTENTIAL HEALTH EFFECTS
ACUTE HEALTH EFFECTS
SWALLOWED
- Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident.
- Accidental ingestion of the material may be damaging to the health of the individual.
- Macrolides comprise a large group of antibiotics derived from Streptomyces spp. having in common a macrocyclic lactone ring to which one or more sugars are attached. They are all weak bases.

EYE
- 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
- Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course.
- 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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
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<tr>
<td>spiramycin</td>
<td>8025-81-8</td>
<td></td>
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<tr>
<td>being a mixture of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>spiramycin I</td>
<td>24916-50-5</td>
<td>63–</td>
</tr>
<tr>
<td>spiramycin II</td>
<td>24916-51-6</td>
<td>24–</td>
</tr>
<tr>
<td>spiramycin III</td>
<td>24916-52-7</td>
<td>13–</td>
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</table>

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.

EYE
- 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 or hair contact occurs: · Flush skin and hair with running water (and soap if available). · Seek medical attention in event of irritation.

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
- Treat symptomatically.
- Irregularly absorbed from the gastrointestinal tract and widely distributed through he tissues. High tissue concentrations may be achieved and maintained long after plasma concentrations fall to low levels. Slowly eliminated with substantial amounts appearing in the bile and about 10% appearing in the urine. High concentrations occur in the milk of nursing mothers.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG): Negligible
Upper Explosive Limit (%): Not available
Specific Gravity (water=1): Not available
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), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

**FIRE INCOMPATIBILITY**
- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

**PERSONAL PROTECTION**
- Glasses:
- Gloves:
- Respirator:
  - Particulate

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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.

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**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.
- Keep containers securely sealed.
- Store at temperatures not exceeding 5 deg C. Protect from light.

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**Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION**

**EXPOSURE CONTROLS**

<table>
<thead>
<tr>
<th>Source</th>
<th>Material</th>
<th>TWA ppm</th>
<th>TWA mg/m³</th>
<th>STEL ppm</th>
<th>STEL mg/m³</th>
<th>Peak ppm</th>
<th>Peak mg/m³</th>
<th>TWA F/CC</th>
<th>Notes</th>
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<tr>
<td>Location</td>
<td>Chemical</td>
<td>Particulate Characteristics</td>
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<td>US - California</td>
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<td>Canada - Prince Edward Island</td>
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<td>(Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)</td>
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<tr>
<td>US OSHA</td>
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<td>US - Hawaii</td>
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<tr>
<td>US - Hawaii</td>
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<td>(Particulates not otherwise regulated - Respirable fraction)</td>
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ENDOELTABLE

PERSONAL PROTECTION
RESPIRATOR
Particulate
Consult your EHS staff for recommendations

EYE
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 lenses 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].

HANDS/FEET
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
- 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).
- 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) 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) 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.
- 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
- fluorocautchouc
- 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.
- Eye 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.

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
<th>Mixture</th>
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<tbody>
<tr>
<td>Melting Range (°F)</td>
<td>Not available</td>
<td>Viscosity</td>
<td>Not Applicable</td>
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</table>
Boiling Range (°F) | Not applicable | Solubility in water (g/L) | Miscible
Flash Point (°F) | Not available | pH (1% solution) | Not available
Decomposition Temp (°F) | Not available | pH (as supplied) | Not available
Autoignition Temp (°F) | Not available | Vapour Pressure (mmHG) | Negligible
Upper Explosive Limit (%) | Not available | Specific Gravity (water=1) | Not available
Lower Explosive Limit (%) | Not available | Relative Vapor Density (air=1) | Not Applicable
Volatile Component (%vol) | Negligible | Evaporation Rate | Not Applicable

APPEARANCE
White or slightly yellow amorphous powder with slight odour and bitter taste; mixes with water (1:50), alcohol, chloroform.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY
• Presence of incompatible materials.
• Product is considered stable.

STORAGE INCOMPATIBILITY
• Avoid strong acids, bases.
• Avoid reaction with oxidizing agents.
Heat, light and oxygen accelerate decomposition.
For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

SPIRAMYCIN

TOXICITY AND IRRITATION
unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

SPIRAMYCIN:

TOXICITY

IRRITATION
Oral (rat) LD50: 3550 mg/kg
Nil Reported
Intrapertoneal (rat) LD50: 575 mg/kg
Subcutaneous (rat) LD50: 1000 mg/kg
Intravenous (rat) LD50: 170 mg/kg
Oral (mouse) LD50: 2900 mg/kg
Intraperitoneal (mouse) LD50: 322 mg/kg
Subcutaneous (mouse) LD50: 1470 mg/kg
Oral (dog) LD50: 5200 mg/kg
Intraperitoneal (rabbit) LD50: 1130 mg/kg
Intravenous (rabbit) LD50: 182 mg/kg
Intravenous (mouse) LD50: 130 mg/kg
Diarrhoea and other gastrointestinal changes recorded.
ADI: 0.75 mg/kg/day
NOEL: 75 mg/kg/day

SPIRAMYCIN I:
Subcutaneous (mouse) LD50: 1010 mg/kg

SPIRAMYCIN II:

Oral (rat) LD50: >13000 mg/kg
Nil Reported
Oral (mouse) LD50: 4000 mg/kg
Subcutaneous (mouse) LD50: 1520 mg/kg
Intravenous (mouse) LD50: 250 mg/kg
Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

<table>
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<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
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<tbody>
<tr>
<td>spiramycin</td>
<td>HIGH</td>
<td></td>
<td>LOW</td>
<td></td>
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</tbody>
</table>

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

spiramycin (CAS: 8025-81-8) is found on the following regulatory lists;
*Canada - Prince Edward Island Occupational Exposure Limits*;
*Canada National Pollutant Release Inventory (NPRI)*;
*US - California Permissible Exposure Limits for Chemical Contaminants*;
*US - Michigan Exposure Limits for Air Contaminants*;
*US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants*;
*US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants*

Regulations for ingredients

spiramycin I (CAS: 24916-50-5) is found on the following regulatory lists;
*Canada - Prince Edward Island Occupational Exposure Limits*;
*Canada National Pollutant Release Inventory (NPRI)*;
*US - California Permissible Exposure Limits for Chemical Contaminants*;
*US - Michigan Exposure Limits for Air Contaminants*;
*US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants*;
*US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants*

spiramycin II (CAS: 24916-51-6) is found on the following regulatory lists;
*Canada - Prince Edward Island Occupational Exposure Limits*;
*Canada National Pollutant Release Inventory (NPRI)*;
*US - California Permissible Exposure Limits for Chemical Contaminants*;
*US - Michigan Exposure Limits for Air Contaminants*;
*US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants*;
*US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants*

spiramycin III (CAS: 24916-52-7) is found on the following regulatory lists;
*US - Hawaii Air Contaminant Limits*;
*US - Oregon Permissible Exposure Limits (Z-3)*;
*US OSHA Permissible Exposure Levels (PELs) - Table Z3*

Section 16 - OTHER INFORMATION

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or
consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

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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