Baccatin III

**Material Safety Data Sheet**

**Hazard Alert Code Key:**
- **EXTREME**
- **HIGH**
- **MODERATE**
- **LOW**

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**Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**PRODUCT NAME**
Baccatin III

**STATEMENT OF HAZARDOUS NATURE**

**NFPA**
1 2 0

**SUPPLIER**
Company: Santa Cruz Biotechnology, Inc.
Address:
2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

**PRODUCT USE**
Precursor to paclitaxel/ taxol. Antileukaemic and antitumour agent isolated from the bark of the Pacific yew tree (Taxus brevifolia). Binds to tubules when they are assembled in the cell and stabilises the polymerised form of tubules so that they remain assembled even under conditions which microtubules dissociate into tubulin subunits.

**SYNONYMS**
C31-H38-O11, "(2aR-(2aalpha, 4beta, 4abeta, 6beta, 9alpha, 11alpha, 12", "alpha, 12aalpha, 12balpha))-6, 12b-bis(acetyloxy)-12"-(benzoyloxy)-1, 2a, 3, 4, 4a, 6, 9, 10, 11, 12, 12a, 12b-dode"-callychol-4, 9, 11-trihydroxy-4a, 8, 13, 13-tetramethylyl-7", 11-methano-5H-cyclodeca(3, 4)benz(1, 2-b)oxet-5-one", "paclitaxel/ taxol alkaloid precursor"

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**Section 2 - HAZARDS IDENTIFICATION**

**Canadian WHMIS Symbols**

**Emergency Overview**

**Risk**
Harmful if swallowed.
May cause heritable genetic damage.
Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
Irritating to eyes, respiratory system and skin.

**Potential Health Effects**

**Acute Health Effects**
Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells. Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation. Gout and renal failure can occur.

**EYE**
- This material can cause eye irritation and damage in some persons.

**SKIN**
- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- 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 can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- 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.
- Poisoning caused by taxoids show their signs 1 to 3 hours after exposure. These include nausea, a widespread abdominal pain, shallow breathing and heart disturbances similar to those seen in potassium overdose.
- Side effects of topoisomerase I and II inhibitors (acting as antineoplastics/ cytotoxics) include early diarrhoea which may occur within 24 hours of exposure to the drug; this may be accompanied by symptoms including runny nose, increased salivation, watery eyes, sweating, flushing, abdominal cramping. Late diarrhoea may occur after 24 hours and usually peaks at about 11 days after treatment. Because of concerns of dehydration and electrolyte imbalances with diarrhoea it is important to be in contact with health care professionals for monitoring, and for medication and diet modifications advice.

Other common side-effects of therapy may include nausea and vomiting which may also occur; low red and white blood cell counts may also result; anaemia may follow. Hair loss, poor appetite, fever and weight loss may also ensue. Less common symptoms include constipation, shortness of breath, insomnia, cough, headache, dehydration, chills, skin rash, flatulence, flushing of the face, mouth sores, heartburn and swelling of the feet and ankles.

**CHRONIC HEALTH EFFECTS**
- Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects. This has been demonstrated via both short- and long-term experimentation. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
- 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. Prime symptom is breathlessness; lung shadows show on X-ray.
- Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life-threatening. Digestive system effects may include inflammation of the mouth cavity, mouth ulcers, esophagus inflammation, abdominal pain and bleeds, diarrhea, bowel ulcers and perforation. Reversible hair loss can result and wound healing may be delayed. Long-term effects on the gonads may cause periods to stop and inhibit sperm production. Most anti-cancer drugs can potentially cause mutations and birth defects, and coupled with the effects of the suppression of the immune system, may also cause cancer.
- Large doses of taxoid result in nerve damage, characterized by weakness, numbness and paralysis of the hands and feet. Topoisomerase inhibitors represent a subgroup of plant alkaloids, which also encompasses the vinca alkaloids such as vincristine and vinblastine, taxanes and podophyllotoxin derivatives. Topoisomerase inhibitors act by preventing the unpackaging of DNA that must occur prior to transcription and replication. The earliest drugs in this class were inhibitors of topoisomerase II, however topoisomerase I inhibitors such as topotecan started entering the market in the mid-1990’s. DNA topoisomerase II inhibitors are among the most efficacious drugs for the treatment of cancer. Despite their widespread use, the use of topoisomerase II inhibitors is limited by severe adverse effects to normal tissues, including cardiotoxicity. In addition to problems associated with toxicity, sensitivity of cancer cells to topoisomerase II targeting agents is also, like many other cancer therapeutics susceptible to resistance. The efficacy of this class is thought to depend on the expression of the topoisomerase Ialpha isoform, and drug resistance is often associated with loss or mutation of this isoform.

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### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

#### HAZARD RATINGS

<table>
<thead>
<tr>
<th>Flammability:</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity:</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Body Contact:</td>
<td>2</td>
<td></td>
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<tr>
<td>Reactivity:</td>
<td>1</td>
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<tr>
<td>Chronic:</td>
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### Section 4 - FIRST AID MEASURES

**SWALLOWED**
- Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
- The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells. Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation. Gout and renal failure can occur.

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**NAME**
- **baccatin III**

<table>
<thead>
<tr>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>27548-93-2</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>
IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
For advice, contact a Poisons Information Center or a doctor.
Urgent hospital treatment is likely to be needed.
If conscious, give water to drink.
INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
NOTE: Wear a protective glove when inducing vomiting by mechanical means.
In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

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.
If pain persists or recurs seek medical attention.
Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN
If skin contact occurs:
Immediately remove all contaminated clothing, including footwear
Flush skin and hair with running water (and soap if available).
Seek medical attention in event of irritation.

INHALED
If fumes or combustion products are inhaled remove from contaminated area.
Lay patient down. Keep warm and rested.
Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
Transport to hospital, or doctor, without delay.

NOTES TO PHYSICIAN
Treat symptomatically.
For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.Following administration of antineoplastics, control of nausea and vomiting may be attempted by giving phenothiazines such as perphenazine, prochlorperazine, promethazine or thiethylperazine before antineoplastic agents are administered. In bone-marrow depression, transfusion of blood or platelets reduces the risk of life-threatening hemorrhage. Granulocyte transfusions and injection of antibiotics may be necessary to combat infection in the neutropenic patient. Hyperuricemia is avoided by the addition of allopurinol to treatment schedules and measures such as alkalization of the urine and hydration may be adopted. MARTINDALE: The Extra Pharmacopoeia, 28th Edition.
The severity of fluid retention and hypersensitivity reactions may require premedication with oral corticosteroids.
for taxol and its analogues:
The atrial P wave may be absent in intoxication. The syndrome complex suggests the need for temporary transvenous pacing, but human intoxications are so rare that there is little clinical experience.

<table>
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<tr>
<th>Vapour Pressure (mmHG):</th>
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<tr>
<td>Specific Gravity (water=1):</td>
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</tr>
<tr>
<td>Lower Explosive Limit (%):</td>
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</tr>
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</table>

EXTINGUISHING MEDIA
Foam.
Dry chemical powder.
BCF (where regulations permit).
Carbon dioxide.
Water spray or fog - Large fires only.

FIRE FIGHTING
Alert Emergency Responders and tell them location and nature of hazard.
Wear full body protective clothing with breathing apparatus.
Prevent, by any means available, spillage from entering drains or water course.
Use fire fighting procedures suitable for surrounding area.
DO NOT approach containers suspected to be hot.
Cool fire exposed containers with water spray from a protected location.
If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

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.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

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

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.

It is recommended that areas handling final finished product have cytotoxic spill kits available.

Spill kits should include:
- impermeable body covering,
- shoe covers,
- latex and utility latex gloves,
- goggles,
- approved HEPA respirator,
- disposable dust pan and scoop,
- absorbent towels,
- spill control pillows,
- disposable sponges,
- sharps container,
- disposable garbage bag and
- hazardous waste label

To avoid accidental exposure due to waste handling of cytotoxics:
- Place waste residue in a segregated sealed plastic container.
- Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container.
- Dispose of any cleanup materials and waste residue according to all applicable laws and regulations e.g, secure chemical landfill disposal.

All personnel likely to involved in a antineoplastic (cytotoxic) spill must receive practical training in:
- the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimize the risk of spills
- the location of the skill kit in the area
- the arrangements for medical treatment of any affected personnel
- the procedure for containment of the spill, and decontamination of personnel and the environment, including the different procedures for major and minor spills
- the procedure for waste disposal according to the nature and extent of the spill

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by all means available, spillage from entering drains or water courses.
- Consider evacuation (or protect in place).
- No smoking, naked lights or ignition sources.
- Increase ventilation.
- Stop leak if safe to do so.
- Water spray or fog may be used to disperse / absorb vapour.
- Contain or absorb spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
• After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.

• If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL

- **PROTECTIVE ACTION ZONE**

- **Isolation Distance**
  - 25 meters

- **Downwind Protection Distance**
  - 250 meters

FOOTNOTES

1. PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapour plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.

2. PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapour concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.

3. INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localised wind reversal may expose nearly all persons without appropriate protection to life-threatening concentrations of the material.

4. SMALL SPILLS involve a leaking package of 200 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres and compressed gas leaking from a small cylinder are also considered “small spills”. LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a “one-tonne” compressed gas cylinder.


6. IERG information is derived from CANUTEC - Transport Canada.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

- **AEGL 1**: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

- **AEGL 2**: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

- **AEGL 3**: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

**PROCEDURE FOR HANDLING**

- The National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment.

- Avoid all personal contact, including inhalation.

- Wear protective clothing when risk of exposure occurs.

- Use in a well-ventilated area.

- Prevent concentration in hollows and sumps.

- DO NOT enter confined spaces until atmosphere has been checked.

- DO NOT allow material to contact humans, exposed food or food utensils.

- Avoid contact with incompatible materials.

- When handling, DO NOT eat, drink or smoke.

- Keep containers securely sealed when not in use.

- Avoid physical damage to containers.

- Always wash hands with soap and water after handling.

- Work clothes should be laundered separately.

- Launder contaminated clothing before re-use.

- Use good occupational work practice.

- Observe manufacturer’s storing and handling recommendations.

- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

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.
- Lined metal can, Lined metal pail/drum
- Plastic pail
- Polyliner drum
- Packing as recommended by manufacturer.
- Check all containers are clearly labeled and free from leaks.
For low viscosity materials
- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.
For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):
- Removable head packaging;
- Cans with friction closures and
- Low pressure tubes and cartridges may be used.
- Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages *.
- In addition, where inner packagings are glass and contain liquids of pack group I and II there must be sufficient inert absorbent to absorb any spillage *.
- Unless the outer packaging is a close fitting molded plastic box and the substances are not incompatible with the plastic.

STORAGE REQUIREMENTS
- Antineoplastics (cytotoxics):
  - should be clearly identifiable to all personnel involved in their handling
  - should be stored in impervious break-resistant containers
  - should be stored in separate, clearly marked storage areas to minimize the risk of breakage, and to limit contamination in the event of leakage.
Spill kits should be available in storage areas.
- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

<table>
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<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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<tbody>
<tr>
<td>Canada - Alberta Occupational Exposure Limits</td>
<td>baccatin III (Turpentine and selected monoterpenes)</td>
<td>20</td>
<td>111</td>
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MATERIAL DATA

BACCATIN III:
- CEL TWA: 0.001 mg/m³.
Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION

Consult your EHS staff for recommendations

EYE
- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- 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. Lenses 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.

OTHER
- Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area.
- Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted.
- Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.
- Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood.
- Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- When handling antineoplastic materials, it is recommended that a disposal work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
- 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
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

RESPIRATOR
- Protection Factor Half-Face Respirator Full-Face Respirator Powered Air Respirator
  - 10 x PEL P1 - - PAPR-P1
  - 50 x PEL Air-line* - - -
  - 100 x PEL P2 P3 - -
  - 100+ x PEL Air-line* Air-line** - PAPR-P3
* - Negative pressure demand ** - Continuous flow

Explanation of Respirator Codes:
Class 1 low to medium absorption capacity filters.
Class 2 medium absorption capacity filters.
Class 3 high absorption capacity filters.
PAPR Powered Air Purifying Respirator (positive pressure) cartridge.
Type A for use against certain organic gases and vapors.
Type AX for use against low boiling point organic compounds (less than 65°C).
Type B for use against certain inorganic gases and other acid gases and vapors.
Type E for use against sulfur dioxide and other acid gases and vapors.
Type K for use against ammonia and organic ammonia derivatives
Class P1 intended for use against mechanically generated particulates of sizes most commonly encountered in industry, e.g. asbestos, silica.
Class P2 intended for use against both mechanically and thermally generated particulates, e.g. metal fume.
Class P3 intended for use against all particulates containing highly toxic materials, e.g. beryllium.
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.
Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

ENGINEERING CONTROLS

- Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.
- Work should be undertaken in an isolated system such as a "glove-box". Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
- Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.
- Open-vessel systems are prohibited.
- Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.
- Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.
- For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).
- Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.
- Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 150 feet/ min. with a minimum of 125 feet/ min. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES
Solid.
Does not mix with water.

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
<th>586.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Range</td>
<td>444.2 - 453.2</td>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Range</td>
<td>Not available</td>
<td>Solubility in water (g/L)</td>
<td>Immiscible</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available</td>
<td>pH (1% solution)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition</td>
<td>Not available</td>
<td>pH (as supplied)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition</td>
<td>Not available</td>
<td>Vapour Pressure (mmHG)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Upper Explosive Limit</td>
<td>Not available.</td>
<td>Specific Gravity (water=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit</td>
<td>Not available</td>
<td>Relative Vapor Density (air=1)</td>
<td>&gt;1</td>
</tr>
</tbody>
</table>

APPEARANCE
Solid; does not mix well with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY
- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY
- Avoid reaction with oxidizing agents.

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

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.
- Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

No significant acute toxicological data identified in literature search.

ECOTOXICITY:

For antineoplastics:

Ecotoxicity:

Because antineoplastics are genotoxic, mutagenic and carcinogenic concerns are warranted for their potential effect in the environment. There are a number of known mammalian toxic and nausea effects associated with antineoplastic treatment, which could indicate that similar effects, might be expected in non-target mammals, and possibly also in non-target species other than mammals. Total dosage over a whole therapy protocol is approximately 150 mg /kg body weight. Approximately 14-53% of the administered pharmaceutical is excreted unmetabolised into urine.

Antineoplastics as a class of drugs are of potential concern for environmental impacts, not just for their acute toxicity but perhaps more for their ability to effect subtle genetic changes, the cumulative impact of which over time can lead to more profound ecologic change. Hospitals are the major source of genotoxic drugs. publicly-owned waste-water treatment works (POTWs) that service hospitals, especially multiple hospitals, are likely candidates for releasing these chemicals into surface waters.

Antineoplastics are highly genotoxic compounds, primarily from hospitals, with poor removal from sewage treatment plants (STWs). Antineoplastic agents, antitumour agents primarily used only within hospitals for chemotherapy, are found sporadically and in a range of concentrations, probably because only small amounts are introduced to STWs via domestic sewage because of their long-lived physiologic retention.

These compounds act as nonspecific alkylating agents (i.e., specific receptors are not involved) and therefore have the potential to act as either acute or long-felt stressors (mutagens carcinogens/ teratogens/ embryotoxins) in any organism. Using well-established QSAR modelling techniques almost 1/5 of the commonly used antineoplastics were predicted to be very toxic to algae, and close to 1/3 were predicted to be non-toxic to plants. A third of the compounds were predicted to be very toxic to daphnids, and almost half were predicted to be non-toxic to daphnids. Slightly more than 1/5 were predicted to be very toxic to fish, and 47% were predicted to be non-toxic to fish.

DO NOT discharge into sewer or waterways.

Ecotoxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>baccatin III</td>
<td>HIGH</td>
<td>LOW</td>
<td>MED</td>
<td></td>
</tr>
</tbody>
</table>

Disposal Instructions

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

- Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into color-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking.
- Containers of special design are available for particular needs (such as disposal of sharps) and should be used.
- Once filled and closed, such containers must never be re-opened.
- Immediate containers must bear a nationally accepted symbol or device depicting cytotoxic substances and be labelled with the words: CYTOTOXIC WASTE - INCINERATE in a style of lettering approved by the national/ state authority.
- Where policies and procedures permit the merging of cytotoxic wastes with medical waste in an outer container used for medical waste, cytotoxic waste must first be placed in identifiable color-coded/ labelled cytotoxic containers prior to merging.
- Management procedures must ensure that merged medical and cytotoxic waste is subjected to the incineration requirements appropriate for the total destruction of the cytotoxic waste.

WASTE STORAGE OF CYTOTOXIC WASTES

For the storage of cytotoxic waste, segregated or merged with medical waste, provide:

- special storage areas with adequate lighting.
• waste security and restriction of access to authorized persons.
• storage areas designed to facilitate easy routine cleaning and maintenance to hygienic standards, or post-spill decontamination.
• storage of cytotoxic waste in standard, identifying bins or other appropriate containers.

COLLECTION OF CYTOTOXIC WASTES
• Procedures for the collection of cytotoxic wastes, which are compatible with existing operational needs, and which protect workers, other people and the environment, must be developed.
• Waste must be removed from the site by contractors whose workers have been instructed in the protective methods to be used against the hazards involved, and who comply with the safe work practices established by internal and/or national/state policies. Contractors must instruct, train and direct their personnel in the safe and legal handling of cytotoxic wastes. Contractor's personnel should observe the operating procedures of the waste-generator.
• Transport of cytotoxic wastes, through the community, must comply with the appropriate national/state codes.

DESTRUCTION OF CYTOTOXIC WASTES
• Destruction of cytotoxic wastes should be carried out in multi-chambered incinerators, licenced for this purpose, operating at 1100 deg. C. or more, with a residence time of at least 1 second.
• Operators must be trained in handling procedures and hazards involved with handling the waste.
• Waste which arrives at the incinerator inappropriately packaged should NOT be returned to the waste generator. An authorized representative of the waste generator must attend the incinerator site to rectify the situation.

Section 14 - TRANSPORTATION INFORMATION

DOT:

Symbols: None
Identification Numbers: UN1544
Label Codes: 6.1
Packaging: Exceptions: 153
Quantity Limitations: Cargo aircraft only: 200 kg
Vessel stowage: None

Hazardous materials descriptions and proper shipping names:
Alkaloids, solid, n.o.s. or Alkaloid salts, solid, n.o.s. poisonous

Air Transport IATA:
ICAO/IATA Class: 6.1
UN/ID Number: 1544
Special provisions: A3

Maritime Transport IMDG:
IMDG Class: 6.1
UN Number: 1544
Limited Quantities: 5 kg

Shipping Name: ALKALOID SALTS, SOLID, N.O.S. *(CONTAINS BACCATIN III)

Section 15 - REGULATORY INFORMATION

baccatin III (CAS: 27548-93-2) is found on the following regulatory lists;
*Canada - Alberta Occupational Exposure Limits*; *Canada National Pollutant Release Inventory (NPRI)*

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE
• Inhalation may produce health damage*.
• Cumulative effects may result following exposure*.
• Possible cancer-causing agent*.
* (limited evidence).

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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 mixture 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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