Material Safety Data Sheet

Dacarbazine

sc-219954

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Dacarbazine

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
C6-H10-N6-O, (dimethyltriazeno)imidazolecarboxamide, 4-(dimethyltriazeno)imidazole-5-carboxamide, "4-{3, 3-dimethyl-1-triazeno}imidazole-5-carboxamide", "4-{5, 3-dimethyl-1-triazeno}imidazole-5(4)-carboxamide", 5-(dimethyltriazeno)imidazole-4-carboxamide, "5-(3, 3-dimethyl-1-triazeno)imidazole-4-carboxamide", "1H-imidazole-4-carboxamide, 5-(3, 3-dimethyl-1-triazenyl)", Deticene, DIC, DTIC, DTIC-Dome, NCI-C04717, NSC-45388, antineoplastic

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

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

CANADIAN WHMIS SYMBOLS
EMERGENCY OVERVIEW

RISK
Heating may cause an explosion.
May cause CANCER.
May cause heritable genetic damage.
Harmful by inhalation, in contact with skin and if swallowed.
Irritating to eyes, respiratory system and skin.
May be harmful to the foetus/embryo*.
May possibly affect fertility*.
*(limited evidence).

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

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.

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

SKIN
■ Skin contact with the material may be harmful; systemic effects may result following absorption.
■ This material can cause inflammation of the skin in 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
■ Inhalation of dusts, generated by the material, during the course of normal handling, may be harmful.
■ The material can cause respiratory irritation in some persons.
The body's response to such irritation can cause further lung damage.

CHRONIC HEALTH EFFECTS
■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.

Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.
There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby.
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.
Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
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, oesophagus inflammation, abdominal pain and bleeds, diarrhoea, 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.
Alkylating agents damage the stem cell (precursor to blood cells). Loss of the stem cell may result in loss of all types of blood cells, with a latency period corresponding to the lifetime of the individual blood cells. Loss of granular white cells develops within days and loss of platelets within 1-2 weeks, whilst no signs of loss of red blood cells occur until several months later. Aplastic anaemia develops due to complete destruction of the stem cells.
Imidazole is structurally related, and has been used to counteract the effects of histamine. Imidazoles have been reported to disrupt male fertility, through disruption of the function of the testes.
Blood disorders (leucopenia, thrombocytopenia) may be severe and delayed. Anorexia, nausea and vomiting occur frequently. Other side effects include a flu-like syndrome, facial flushing and paraesthesia. Hepatic toxicity accompanied by hepatic vein thrombosis and hepatocellular necrosis has resulted in death.
When administered orally in the diet dacarbazine induced thymic and splenic lymphosarcomas and mammary adenosarcomas in rats of
both sexes and cerebral ependymomas and pulmonary alveolar carcinomas in female rats. Intravenous injection induced lung tumours, lymphomas and splenic haemangiomas in male mice and lung tumours and uterine tumours in female mice. A single case of acute leukaemia after treatment with dacarbazine in combination with other cytotoxics has been reported.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
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<tbody>
<tr>
<td>dacarbazine</td>
<td>4342-03-4</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>

Section 4 - FIRST AID MEASURES

SWALLOWED
- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- 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.

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.
- Seek medical attention without delay; 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.

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.
- Poorly absorbed from the gastrointestinal tract. Rapidly distributed in the body with initial plasma half-life of about 20 minutes and terminal half-life of about 5 hours. About half the absorbed dose is excreted unchanged in the urine.

Section 5 - FIRE FIGHTING MEASURES

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<th>Vapour Pressure (mmHG):</th>
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<tbody>
<tr>
<td>Upper Explosive Limit (%):</td>
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</tr>
<tr>
<td>Specific Gravity (water=1):</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%):</td>
<td>Not available</td>
</tr>
</tbody>
</table>

EXTINGUISHING MEDIA
- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

FIRE FIGHTING
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
Prevent, by any means available, spillage from entering drains or water courses.
Use water delivered as a fine spray to control fire and cool adjacent area.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
WARNING: May EXPLODE on heating!!!

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- 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 (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

WARNING: Heating to the melting point (212 deg C) may result in explosive decomposition.

FIRE INCOMPATIBILITY
- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result in the formation of an explosive mixture.

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.

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,

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 minimise the risk of spills
- the location of the spill 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

MAJOR SPILLS
- Clear area of personnel and move upwind.
- Alert Fire Brigade 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.

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.

**RECOMMENDED STORAGE METHODS**
- Glass container is suitable for laboratory quantities
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

**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 minimise 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.

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

**EXPOSURE CONTROLS**
The following materials had no OELs on our records
- dacarbazine: CAS: 4342-03-4

**PERSONAL PROTECTION**

**RESPIRATOR**

**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 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**
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
- 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]

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

**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.

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.

ENGINEERING CONTROLS

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

- Process controls which involve changing the way a job activity or process is done to reduce the risk.
- Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Mixes with water.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>State</td>
<td>Divided solid</td>
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<tr>
<td>Molecular Weight</td>
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<td>Melting Range (°F)</td>
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<td>pH (as supplied)</td>
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<td>Upper Explosive Limit (%)</td>
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<tr>
<td>Evaporation Rate</td>
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</table>

APPEARANCE

Solid; mixes with water. A colour change of a reconstituted solution from pale yellow to pink indicates decomposition.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents

Solutions of pure dacarbazine are light-sensitive and rapidly photolyse to 5-diazoimidazole-4-carboxamide and then to 2-azahypoxanthine. Both are biologically active.

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

Section 11 - TOXICOLOGICAL INFORMATION
dacarbazine

TOXICITY AND IRRITATION

- 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.
WARNING: This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.
Tenth Annual Report on Carcinogens: Substance anticipated to be Carcinogen
[National Toxicology Program: U.S. Dep. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

<table>
<thead>
<tr>
<th>CARCINOGEN</th>
<th>DACARBAZINE</th>
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<tr>
<td>Dacarbazine</td>
<td>International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs</td>
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<tr>
<td>dacarbazine</td>
<td>US - Rhode Island Hazardous Substance List</td>
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<tr>
<td>DACARBAZINE</td>
<td>US Environmental Defense Scorecard Recognized Carcinogens</td>
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<tr>
<td>dacarbazine</td>
<td>US - Maine Chemicals of High Concern List</td>
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<table>
<thead>
<tr>
<th>REPROTOXIN</th>
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<tbody>
<tr>
<td>dacarbazine</td>
<td>US - California Proposition 65 - Reproductive Toxicity</td>
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Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

<table>
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<tr>
<th>Ingredient</th>
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<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
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<td>LOW</td>
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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. In most instances the supplier of the material should be consulted.
- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into colour-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 colour-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 authorised 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 authorised representative of the waste generator must attend the incinerator site to rectify the situation.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

dacarbazine (CAS: 4342-03-4) is found on the following regulatory lists;


Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ May be harmful to the foetus/embryo*.  
■ May possibly affect fertility*.  

*(limited evidence).

Denmark Advisory list for selfclassification of dangerous substances

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<thead>
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<th>Substance</th>
<th>CAS</th>
<th>Suggested codes</th>
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<td>Carc3; R40 Mut3; R68 Rep3; R63</td>
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Germany Hazard classification and labelling of medicines with antineoplastic effects (ATC Code L01 and L02)

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<th>INN</th>
<th>CAS</th>
<th>Danger</th>
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<td>R 20/21/22 R</td>
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<td>T</td>
<td>R 45 R 46</td>
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Classification of the preparation and its individual components has been 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.

For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:
OSHA Standards - 29 CFR:
1910.132 - Personal Protective Equipment - General requirements
1910.133 - Eye and face protection
1910.134 - Respiratory Protection
1910.136 - Occupational foot protection
1910.138 - Hand Protection
Eye and face protection - ANSI Z87.1
Foot protection - ANSI Z41
Respirators must be NIOSH approved.

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