Flutamide

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME  HIGH  MODERATE  LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Flutamide

STATEMENT OF HAZARDOUS NATURE

NFPA

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
Nonsteroidal antiandrogenic agent used in the palliative treatment of prostatic cancer; given by mouth. The material exerts its action by inhibiting androgen uptake and/or by inhibiting nuclear binding of androgen in target tissues or both. Prostatic cancer is known to androgen sensitive and responds to treatment that counteracts the effect of androgen and/or removes the source of androgen (e.g. castration).

SYNONYMS

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW
RISK
Harmful if swallowed.
May cause CANCER.
May cause SENSITIZATION by inhalation.
Possible risk of impaired fertility.
Irritating to eyes, respiratory system and skin.

**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.
- Limited evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.
- The substance and/or its metabolites may bind to hemoglobin inhibiting normal uptake of oxygen. This condition, known as "methemoglobinemia", is a form of oxygen starvation (anoxia). Symptoms include cyanosis (a bluish discoloration skin and mucous membranes) and breathing difficulties. Symptoms may not be evident until several hours after exposure.

At about 15% concentration of blood methemoglobin there is observable cyanosis of the lips, nose and earlobes. Symptoms may be absent although euphoria, flushed face and headache are commonly experienced. At 25-40%, cyanosis is marked but little if any occurs other than that produced on physical exertion. At 40-60%, symptoms include weakness, dizziness, lightheadedness, increasingly severe headache, ataxia, rapid shallow respiration, drowsiness, nausea, vomiting, confusion, lethargy and stupor. Above 80% symptoms include dyspnea, respiratory depression, tachycardia or bradycardia, and convulsions. Levels exceeding 70% may be fatal.
- At sufficiently high doses the material may be hepatotoxic (i.e. poisonous to the liver).

**EYE**
- This material can cause eye irritation and damage in some persons.
- Irritation of the eyes may produce a heavy secretion of tears (lachrymation).

**SKIN**
- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin irritation with the material may damage the health of the individual; systemic effects may result following absorption.
- Entry into the bloodstream, 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 produce toxic effects.
- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Irritating to respiratory system.

**CHRONIC HEALTH EFFECTS**
- Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.
- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

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returned to normal after treatment stopped. Conception rates were diminished in all treatment groups. Suppression of spermatogenesis was seen in rats dosed for 52 weeks at 3 times the human dose rate and in dogs dosed for 78 weeks at 1.4 times the human dose rate.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
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</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
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<tr>
<td>Reactivity</td>
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<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

NAME | CAS RN | %
-----|-------|-----
flutamide | 13311-84-7 | >98

Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

- If this product comes in contact with the eyes:
- Immediately hold eyelids apart and flush the eye continuously with 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.
- Continue flushing until advised to stop by the Poisons Information Center or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- 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.
- The material may induce methemoglobinemia following exposure.
- Initial attention should be directed at oxygen delivery and assisted ventilation if necessary. Hyperbaric oxygen has not demonstrated substantial benefits.
- Hypotension should respond to Trendelenburg's position and intravenous fluids; otherwise dopamine may be needed.
- Symptomatic patients with methemoglobin levels over 30% should receive methylene blue. (Cyanosis, alone, is not an indication for treatment). The usual dose is 1-2 mg/kg of a 1% solution (10 mg/ml) IV over 50 minutes; repeat, using the same dose, if symptoms of hypoxia fail to subside within 1 hour.

BIOLLOGICAL EXPOSURE INDEX - BEI

<table>
<thead>
<tr>
<th>Determinant</th>
<th>Index</th>
<th>Sampling Time</th>
<th>Comment</th>
</tr>
</thead>
</table>

Determinant Index Sampling Time Comment
1. Methemoglobin in blood
   1.5% of hemoglobin
   During or end of shift
   B, NS, SQ

B: Background levels occur in specimens collected from subjects NOT exposed
NS: Non-specific determinant; also observed after exposure to other materials
SQ: Semi-quantitative determinant - Interpretation may be ambiguous; should be used as a screening test or confirmatory test.

Since flutamide is highly protein bound, dialysis may not be any use as a treatment for overdose. As in the management of
overdosage with any drug, it should be borne in mind that multiple agents may have been taken. If vomiting does not occur
spontaneously, it should be induced in alert patients. General supportive care including frequent monitoring of the vital signs
and close observation of the patient, is indicated.

Flutamide is rapidly and extensively metabolised; at least six metabolites have been identified in the plasma. The major
metabolite is a biologically active alpha-hydroxylated derivative which accounts for 23% of radiolabel 1 hour after
administration. The major urinary metabolite is 2-amino-5-nitro-4-(trifluoromethyl)phenol. Flutamide and its metabolites are
excreted mainly in the urine with only 4.2% of the dose excreted in the faeces over 72 hours.

Methaemoglobin levels should be monitored in patients susceptible to aniline toxicity (e.g. individuals with glucose-6-phosphate
dehydrogenase deficiency or haemoglobin M disease as well as patients who smoke).
Laboratory abnormalities include elevated SGOT, SGPT, bilirubin values, SGGT, BUN and serum creatinine.

Section 5 - FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapour Pressure (mmHG)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not available</td>
</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**
- 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 breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Use water delivered as a fine spray to control fire and cool adjacent 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), hydrogen fluoride, nitrogen oxides (NOx), other
  pyrolysis products typical of burning organic material.
- May emit poisonous fumes.
- May emit corrosive fumes.

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

**PERSONAL PROTECTION**
- Glasses:
  - Chemical goggles.
- 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.

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.
■ 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.

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

■ 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.

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 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

[Symbolic representation of safe and unsafe storage combinations]
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- flutamide: CAS:13311-84-7

MATERIAL DATA

FLUTAMIDE:

- It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

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).

CEL TWA: 0.75 mg/m3 (Schering)

PERSONAL PROTECTION

Consult your EHS staff for recommendations

EYE

- When handling very small quantities of the material eye protection may not be required.
- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
  - Chemical goggles
  - Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
  - Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.
  - Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]

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

RESPIRATOR

<table>
<thead>
<tr>
<th>Protection Factor</th>
<th>Half-Face Respirator</th>
<th>Full-Face Respirator</th>
<th>Powered Air Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 x PEL</td>
<td>P1</td>
<td>-</td>
<td>PAPR-P1</td>
</tr>
<tr>
<td>Air-line*</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>50 x PEL</td>
<td>Air-line**</td>
<td>P2</td>
<td>PAPR-P2</td>
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<tr>
<td>100 x PEL</td>
<td>-</td>
<td>P3</td>
<td>-</td>
</tr>
<tr>
<td>100+ x PEL</td>
<td>-</td>
<td>Air-line*</td>
<td>-</td>
</tr>
</tbody>
</table>

* - 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 to be 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 into the exhaust system 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Range (°F)</td>
<td>233.6</td>
</tr>
<tr>
<td>Boiling Range (°F)</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point (°F)</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temp (°F)</td>
<td>Not available</td>
</tr>
<tr>
<td>Autoignition Temp (°F)</td>
<td>Not available</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility in water (g/L)</td>
<td>Partly miscible</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>pH (1% solution)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour Pressure (mmHG)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Specific Gravity (water=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative Vapor Density (air=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**APPEARANCE**

Buff-yellow powder with no odour; does not mix well with water. Light-sensitive.

**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.

**Section 11 - TOXICOLOGICAL INFORMATION**

**flutamide**

**TOXICITY AND IRRITATION**

- Oral (rat) LD50: 787 mg/kg
- Oral (rat) LD50: 3260 mg/kg *
- Inhalation (rat) LC50: >0.25 mg/l * (for BTA-C)
- Intrapertoneal (rat) LD50: 289 mg/kg
- Oral (dog) LD50: >2000 mg/kg

- Possible risk of impaired fertility.
- Oral (man) TDLo: 310 mg/kg/31 D - I Nil reported
- Inhalation (rat) LC50: >0.75 mg/l * (for BTA-C)
- Euphoria, haematuria, incontinence, body temperature decrease, altered sleep time, cyanosis, nausea/ vomiting, gastrointestinal changes, liver changes, androgenic changes, pigmented/ nucleated red blood cells, changes in prostrate weight, testicular tumours, specific developmental abnormalities (urogenital system, musculoskeletal system, skin, central nervous system, endocrine system, other developmental abnormalities), paternal effects, effect of fertility, effects on newborn recorded.

Equivocal carcinogen by RTECS criteria

* Schering

**Section 12 - ECOLOGICAL INFORMATION**

Refer to data for ingredients, which follows:

**FLUTAMIDE**

- 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>flutamide</td>
<td>HIGH</td>
<td>LOW</td>
<td>MED</td>
<td></td>
</tr>
</tbody>
</table>

**Section 13 - DISPOSAL CONSIDERATIONS**

**Disposal Instructions**

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

- Puncture containers to prevent re-use and bury at an authorized landfill.
- 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.
- Dispose of by: Burial in a licensed land-fill or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

flutamide (CAS: 13311-84-7) is found on the following regulatory lists:

- "Canada Domestic Substances List (DSL)"
- "US - California Air Toxics "Hot Spots" List (Assembly Bill 2588) Substances which need not be reported unless manufactured by the facility"
- "US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity"
- "US - California Proposition 65 - Reproductive Toxicity"
- "US - Maine Chemicals of High Concern List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Skin contact may produce health damage*.
- Inhalation may produce serious health damage*.
- Cumulative effects may result following exposure*.
- May be harmful to the fetus/embryo*.
- Exposure may produce irreversible effects*.

* (limited evidence).

Germany Hazard classification and labelling of medicines with antineoplastic effects (ATC Code L01 and L02)

<table>
<thead>
<tr>
<th>INN</th>
<th>CAS</th>
<th>Danger</th>
<th>CMR effects</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cat 1&amp;2</td>
<td>Cat 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R 45</td>
<td>R 36/37/38</td>
</tr>
<tr>
<td>Flutamid</td>
<td>13311-84-7</td>
<td>T</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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- 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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