

Mifepristone

sc-203134



The Power is Question

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

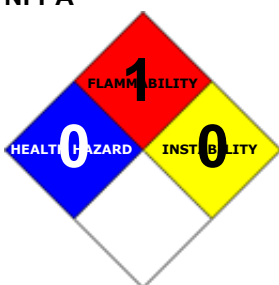
PRODUCT NAME

Mifepristone

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

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

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2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE

■ Steroid. Abortifacient steroid. Progesterone receptor antagonist. Binds strongly to progesterone and glucocorticoid receptors, weakly to androgen receptors, but has no anti-oestrogenic or mineralocorticoid activity. Inhibits ovulation when given in the late follicular phase of the menstrual cycle.

SYNONYMS

C29-H35-N-O2, C29-H35-N-O2, "estra-4, 9-diene-3-one, ", "estra-4, 9-diene-3-one, ", "11-[4-(dimethylamino)phenyl]-17-hydroxy-17-(1-propynyl)-, (11beta, ", 17beta)-, "11-[4-(dimethylamino)phenyl]-17-hydroxy-17-(1-propynyl)-, (11beta, ", 17beta)-, 17beta-hydroxy-11beta-(4-dimethylaminophenyl-1)-, "17alpha-(prop-1-ynyl)oestra-4, 9-dien-3-one", "17alpha-(prop-1-ynyl)oestra-4, 9-dien-3-one", Mifegyn, R-38486, R-38486, "RU 486", RU-486-6, "RU 38486", "abortifacient oestrogen/estrogen steroid", "morning after pill"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

May impair fertility.

May cause harm to the unborn child.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- The estrogens may produce dose-related nausea and vomiting, undesirable uterine growth, proliferation and withdrawal bleeding or loss of periods. It causes enlargement of the breasts in males. Other side effects include weight gain, swelling, breast tenderness, liver dysfunction, jaundice, depression, headache, and dizziness. Growth may be stunted due to premature closing of the growth plates. Skin reactions can include excess pigmentation of the face, rashes, and hives. Redness, itching and blistering has also been reported.

EYE

- Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

SKIN

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

INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

- Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material. Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

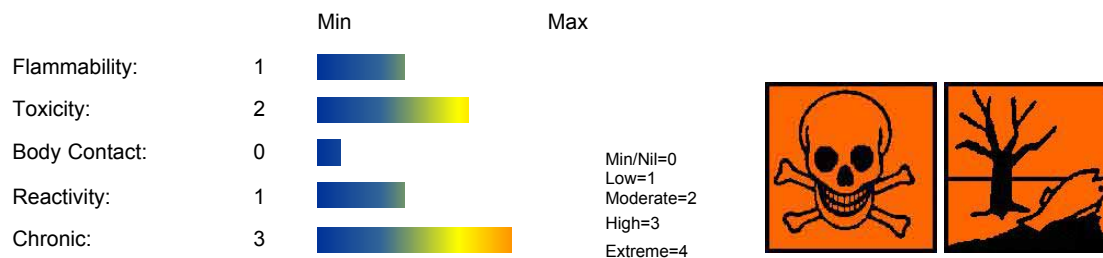
There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

Long term administration of estrogens can greatly increase the risk of endometrial cancer, especially after menopause. Males exposed can develop enlarged breasts and other feminizing effects, nipple pigmentation, withering of testicles, sterility, impotence and altered distribution of hair. Females exposed can develop breast enlargement and menstrual disorders and other effects on the reproductive system. Children born to exposed mothers can show breast enlargement in boys and early puberty in girls. Children who are themselves exposed may develop increased rate of bone maturation (leading to reduced final stature), strong pigmentation of the sexual organs and feminizing syndrome. Exposure before birth may be associated with limb defects and congenital heart deformities. Repeated swallowing can cause nausea, vomiting, abdominal cramps, loss of appetite, bowel inflammation, headache, dizziness, irritability, depression, general unwellness, involuntary jerky movements and convulsions. Swelling, weight change, increased blood pressure and risk of clotting, liver abnormalities, uremia have all been reported. Long-term users may also show an increased risk of developing gallstones, increased blood fats, acute pancreas inflammation and aggravation of porphyria. The eye may develop damage, increased corneal curvature with contact lens intolerance. Skin effects include itching, hives, inflammation, increased pigmentation, sensitivity to light, loss of scalp hair and hairiness. Allergic reactions include a red rash and jaundice. Susceptibility to Candida infections and changes to sex drive may occur. Application of estrogen-containing cream had produced breast enlargement.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS



NAME	CAS RN	%
mifepristone	84371-65-3	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

-
- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

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

INHALED

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

NOTES TO PHYSICIAN

- Treat symptomatically.

No serious adverse reactions were reported in tolerance studies in healthy non-pregnant female and healthy male subjects where mifepristone was administered in single doses greater than threefold that recommended for termination of pregnancy. If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

The oral acute lethal dose of mifepristone in the mouse, rat and dog is greater than 1000 mg/kg (about 100 times the human dose recommended for termination of pregnancy).

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

- - 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), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

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

- Environmental hazard - contain spillage.

- 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

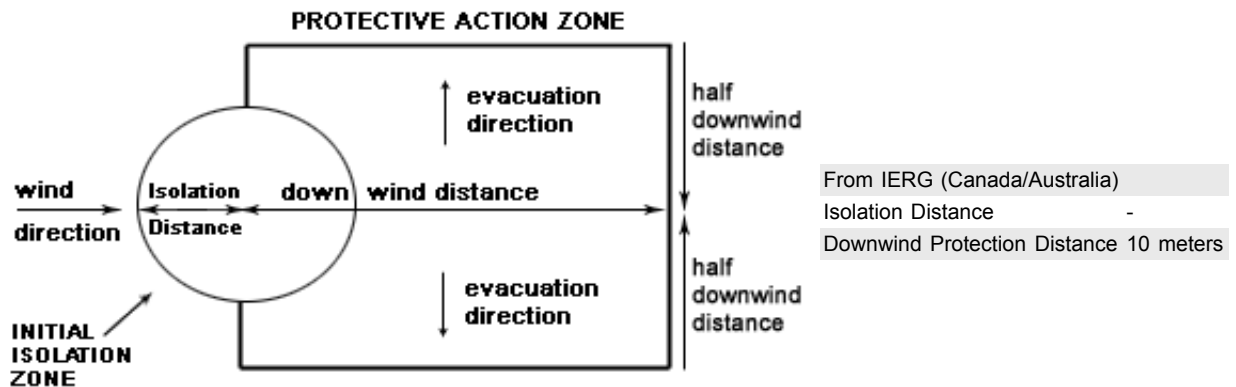
- Environmental hazard - contain spillage.
- Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL

WARNING

MAY DECOMPOSE EXPLOSIVELY AT HIGH TEMPERATURES.



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.
- 5 Guide 171 is taken from the US DOT emergency response guide book.
- 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

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

STORAGE REQUIREMENTS

- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X: Must not be stored together

O: May be stored together with specific preventions

+: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC	Notes
US - Oregon Permissible Exposure Limits (Z3)	mifepristone (Inert or Nuisance Dust: (d) Total dust)		10						*
US OSHA Permissible Exposure Levels (PELs) - Table Z3	mifepristone (Inert or Nuisance Dust: (d) Respirable fraction)		5						
US OSHA Permissible Exposure Levels (PELs) - Table Z3	mifepristone (Inert or Nuisance Dust: (d) Total dust)		15						
US - Hawaii Air Contaminant Limits	mifepristone (Particulates not other wise regulated - Total dust)		10						
US - Hawaii Air Contaminant Limits	mifepristone (Particulates not other wise regulated - Respirable fraction)		5						
US - Oregon Permissible Exposure Limits (Z3)	mifepristone (Inert or Nuisance Dust: (d) Respirable fraction)		5						*
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	mifepristone (Particulates not otherwise regulated Respirable fraction)		5						
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	mifepristone (Particulates not otherwise regulated (PNOR)(f)-Respirable fraction)		5						
US - Michigan Exposure Limits for Air Contaminants	mifepristone (Particulates not otherwise regulated, Respirable dust)		5						

MATERIAL DATA

MIFEPRISTONE:

- 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

■ 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
- fluorocarbon
- 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

-
- 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. 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
	Air-line*	-	-

50 x PEL	Air-line**	P2	PAPR-P2
100 x PEL	-	P3	-
		Air-line*	-
100+ x PEL	-	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

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

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

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapors, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	429.65
Melting Range (°F)	302	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable

Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable
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APPEARANCE

White crystalline powder; does not mix well with water. Soluble in chloroform.

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

mifepristone

TOXICITY AND IRRITATION

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

TOXICITY	IRRITATION
Oral (woman) TDLo: 12 mg/kg	Nil Reported
Oral (woman) TDLo: 14 mg/kg	
Oral (woman) TDLo: 12 mg/kg	
Oral (Human) TDLo: 10 mg/kg	
Oral (Human) TDLo: 2.86 mg/kg	
Oral (Human) TDLo: 6 mg/kg	
Subcutaneous (Rat) TDLo: 10 mg/kg	
Oral (Human) TDLo: 4 mg/kg	

- Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Abortion, effects on fertility, maternal effects, effects on newborn, specific developmental abnormalities (central nervous system, craniofacial) recorded.

The treatment procedure is designed to induce the vaginal bleeding and uterine cramping necessary to produce an abortion. Women also typically experience abdominal pain, including uterine cramping. Other commonly reported side effects were nausea, vomiting and diarrhea.

Allergic reaction (including rash, hives, itching), hypotension (including orthostatic), lightheadedness, loss of consciousness, post-abortion infection (including endomyometritis, parametritis), ruptured ectopic pregnancy, shortness of breath, and tachycardia (including racing pulse, heart palpitations, heart pounding) have been reported.

No long-term studies to evaluate the carcinogenic potential of mifepristone have been performed. Results from studies conducted in vitro and in animals have revealed no genotoxic potential for mifepristone.

Neonatal exposure to a single large dose of mifepristone in rats was not associated with any reproductive problems, although chronic low-dose exposure of newborn rats to mifepristone was associated with structural and functional reproductive abnormalities.

Because of the antiprogesterational activity of mifepristone, foetal losses were much higher than in control animals. Skull deformities were detected in rabbit studies at approximately 1/6 the human exposure, although no teratogenic effects of mifepristone have been observed to date in rats or mice. These deformities were most likely due to the mechanical effects of uterine contractions resulting from decreased progesterone levels.

Teratology studies in mice, rats and rabbits revealed teratogenicity for rabbits, but not rats or mice. The rate of birth defects in human infants exposed in utero to mifepristone and misoprostol is very low,[18] and may be due to misoprostol alone

CARCINOGEN

Progestogen-only contraceptives	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group 2B
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Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

MIFEPRISTONE:

- Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

- The presence of residual pharmaceuticals and environmental endocrine disruptors (EEDs) is increasingly significant due to their impact on human health and wildlife. Of the compounds implicated as EEDs, the most potent in their oestrogenic effect are the natural and synthetic estrogens. The occurrence of estrogenic compounds in the aquatic environment in particular is of interest. Steroid estrogens at sub-micrograms per liter levels are frequently detected in surface water. When at sub-micrograms per liter levels, these estrogenic chemicals show greater capacities of sorption by soils and sediments. Among these estrogenic chemicals, a group of synthetic steroids, such as 17 α -ethinylestradiol, is of particular concern. This concern arises in part from the increasing use of birth-control pills, formulated with exogeneous estrogenic and progestational chemicals that show high physiological activity at very low concentrations and have been associated to certain alarming effects on reproduction and developmental processes such as feminisation, decreased fertility or hermaphroditism.

Steroidal estrogen hormones such as estradiol, estrone, and estriol are also of concern because there is evidence that low nanogram per liter concentrations of estrogens in water can adversely affect the reproductive biology of fish and other aquatic vertebrate species.

The environmental fate of estrogens is not clearly known. Laboratory-based studies have found that the biological activity of these compounds is greatly reduced or eliminated within several hours to days due to degradation and sorption. On the other hand, field studies have demonstrated that estrogens are sufficiently mobile and persistent to impact surface and groundwater quality.

Unconjugated steroidal estrogens have low solubility in water (0.8-13.3 mg L⁻¹) and are moderately hydrophobic (log Kow 2.6-4.0). Therefore the potential for bioaccumulation exists. Estrogenic compounds are generally bioaccumulative and may biomagnify through the food chain resulting in adverse physiological effects. Accumulation into milk may be particularly worrying as it is fed to infants and children and their immune systems are not fully developed, therefore the physiological effects may be more serious.

■ DO NOT discharge into sewer or waterways.

Ecotoxicity

Ingredient mifepristone	Persistence: Water/Soil HIGH	Persistence: Air	Bioaccumulation LOW	Mobility LOW
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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



DOT:

Symbols:	G	Hazard class or Division:	9
Identification Numbers:	UN3077	PG:	III
Label Codes:	9	Special provisions:	8, 146, 335, B54, IB8, IP3, N20, T1, TP33
Packaging: Exceptions:	155	Packaging: Non-bulk:	213
Packaging: Exceptions:	155	Quantity limitations: Passenger aircraft/rail:	No limit
Quantity Limitations: Cargo aircraft only:	No limit	Vessel stowage: Location:	A
Vessel stowage: Other:	None		

Hazardous materials descriptions and proper shipping names:

Environmentally hazardous substance, solid, n.o.s

Air Transport IATA:

ICAO/IATA Class:	9	ICAO/IATA Subrisk:	9
UN/ID Number:	3077	Packing Group:	III
Special provisions:	A97		

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS MIFEPRISTONE)

Maritime Transport IMDG:

IMDG Class:	9	IMDG Subrisk:	None
UN Number:	3077	Packing Group:	III
EMS Number:	F-A,S-F	Special provisions:	274 909 944

Limited Quantities: 5 kg
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(contains mifepristone)

Section 15 - REGULATORY INFORMATION

mifepristone (CAS: 84371-65-3,83203-42-3) is found on the following regulatory lists;
"International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Ingestion may produce health damage*.
 - Limited evidence of a carcinogenic effect*.
- * (limited evidence).

Ingredients with multiple CAS Nos

Ingredient Name	CAS
mifepristone	84371-65-3, 83203-42-3

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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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