

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

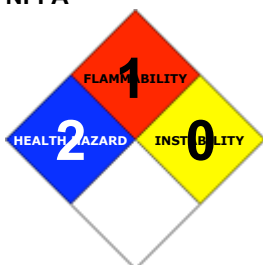
PRODUCT NAME

Prochlorperazine dimaleate

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

Emergency Tel: From outside the US and Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE

■ CAUTION: May modify behaviour and state of alertness; exposed individuals taking charge of vehicles or machinery should be warned of the hazards. The sedative effect of tricyclic antidepressants is NOT delayed. Major tranquilliser (antipsychotic/ neuroleptic) which depresses the central nervous system and possesses alpha-adrenergic blocking activity. A dopamine inhibitor. Widely used in the management of psychotic conditions, to control hyperkinetic states and aggression, for the control of anxiety and tension, as an anti-emetic to control nausea and vomiting. Also for treatment of vertigo. Prochlorperazine is a phenothiazine (tricyclic) derivative with a piperazine side-chain.

SYNONYMS

C20-H24-Cl-N3-S.(C4-H4-O4)2, "phenothiazine, 2-chloro-10-[3-(1-methyl-4-piperazinyl)propyl]-", "phenothiazine, 2-chloro-10-[3-(1-methyl-4-piperazinyl)propyl]-", "dimaleate", "2-chloro-10-[3-(1-methyl-4-piperazinyl)propyl]phenothiazine dimaleate", "2-chloro-10-[3-(1-methyl-4-piperazinyl)propyl]phenothiazine dimaleate", "2-chloro-10-[3-(4-methyl-1-piperazinyl)propyl]phenothiazine-", "2-chloro-10-[3-(4-methyl-1-piperazinyl)propyl]phenothiazine-", "(Z)-2-butenedioate (1:2)", "(Z)-2-butenedioate (1:2)", "prochlorperazine dimaleate", "prochlorperazine hydrogen maleate", "prochlorperazine maleate", Buccastem, Compazine, Emetiral, "Meterazin maleate", "Nibromin A", Pasotomin, "Stemetil dimaleate", Vertigon, "phenothiazine (tricyclic)", "tranquilliser/ antipsychotic/ neuroleptic/ ataractic/ anti-emetic"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS



Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

EMERGENCY OVERVIEW

RISK

May cause SENSITIZATION by skin contact.

Harmful by inhalation, in contact with skin and if swallowed.

Irritating to eyes 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.

■ Side effects of tricyclic antidepressants include dry mouth, sour or metallic taste, constipation, retention of urine, blurred vision and changes in focusing, palpitations, and fast heart beat. Gastrointestinal disturbances (including nausea and vomiting), drowsiness, tremor, low blood pressure when standing, dizziness, sweating, weakness and fatigue, inco-ordination, epilepsy-like seizures, and speech difficulties may occur. Allergic skin reactions and sensitivity to light have been reported, as well as jaundice and blood disorders. Effects on the heart muscle may produce conduction defects and irregularities in heart beat. Endocrine effects may produce changes in sexdrive, impotence, enlarged breasts and copious milk production. Changes in blood sugar levels and reduced levels of antidiuretic hormone may also occur. Overdose may produce excitement and restlessness with dry mouth, dilated pupils, increased heart rate, retention of urine and absence of bowel sounds. More severe poisoning may produce convulsions and muscle spasms, low blood pressure and depression of breathing and the heart. There may be life-threatening heartbeat irregularities that occurs some days after apparent recovery.

■ Antipsychotics (also known as neuroleptics) are a group of psychoactive drugs commonly but not exclusively used to treat psychosis, which is typified by schizophrenia. Both first generation drugs (typical antipsychotics) and second generation drugs (atypical antipsychotics) tend to block receptors in the brain's dopamine pathways, but antipsychotic drugs encompass a wide range of receptor targets. A number of side effects have been observed in relation to specific medications, including weight gain, agranulocytosis (a potentially dangerous reduction in the number of white blood cells in the body), tardive dyskinesia (involving involuntary, repetitive movements), tardive akathisia (characterised by unpleasant sensations of "inner" restlessness that manifests itself with an inability to sit still or remain motionless), tardive psychoses and tardive dysphrenia (worsening of psychiatric symptoms)

Detrimental effects on short term memory, which affect the way one figures and calculates (although this also may be purely subjective), may also be observed on high enough dosages.

All antipsychotic drugs tend to block D2 receptors in the dopamine pathways of the brain. This means that dopamine released in these pathways has less effect. Excess release of dopamine in the mesolimbic pathway has been linked to psychotic experiences. It is the blockade of dopamine receptors in this pathway that is thought to control psychotic experiences. Antipsychotic agents do not induce psychological addiction

A dopamine antagonist is a drug which blocks dopamine receptors (dopaminergics) by receptor antagonism. They are used, typically as antipsychotics, antiemetics and antidepressants. As peripheral and central dopaminergic receptors are similar, the specificity of action of an antagonist on peripheral or central receptors depends primarily on its pharmacokinetic features. If the drug does not cross the blood-brain barrier to a substantial degree, the peripheral effects will prevail (dopamine antagonists of this type are known as "prokinetic" agents); the opposite is true in the case of good penetration in the brain (the antipsychotics or neuroleptics).

The central effects of antipsychotics prevail over their peripheral effects which, nevertheless, remain present.

Psychoses, schizophrenia in particular, are very complex diseases involving negative symptoms (poverty of speech and expression, indifference, carelessness etc.) and productive symptoms (hallucinations, delusion, unsuited behavior, , aggressiveness). Antipsychotics, improve most of these symptoms, (especially the productive ones).

In animal experiments, antipsychotics agents elicit:

- sedation, reduced motility
- in high doses, catalepsy, i.e. maintenance of unusual positions given to animals by the experimenter
- inhibition of conditioned reflexes with maintenance of primary reflexes
- inhibition of agitation, stereotypes, and vomiting induced by apomorphine or amphetamine.

In human beings, the effects of antipsychotics are different in healthy subjects compared to patients with psychosis:

In healthy subjects they elicit

- drowsiness, indifference, and several adverse effects of the same type as those which are described further.

In psychotic patients, they have three principal effects:

- sedation which results in drowsiness, diminution of vigilance, agitation and excitement
- antideliriant and anti-hallucinogenic effects: decrease of delusion and hallucinations
- anti-autistic effect: patients become more communicative and have a better contact with reality

Antipsychotics have many adverse effects including.

- Sedation, drowsiness.
- Acute dyskinesia which occurs in first hours or first days after the initiation of the treatment by a neuroleptic. Acute dyskinesia is characterised by intermittent muscular spasms, affecting especially face and neck: torticollis, trismus, tongue protrusion, oculogyric attack, opistothonos. These symptoms, linked to inhibition of D2 dopaminergic receptors of the striatum, are distressing but may be

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

controlled by anticholinergic antiparkinsonian drugs such as trihexyphenidyl. The frequency of acute dyskinesias is lower with atypical neuroleptics like clozapine, olanzapine, risperidone than with conventional neuroleptics.

- Tardive dyskinesia, or lingual-facial-buccal dyskinesia, which occurs after a long treatment with high doses of antipsychotics. Sufferers may show repetitive, involuntary, purposeless movements often of the lips, face, legs, or torso. It is believed that there is a greater risk of developing tardive dyskinesia with the older, typical antipsychotic drugs, although the newer antipsychotics are now also known to cause this disorder. The development of this syndrome appears to be related to the duration of treatment and the total cumulative dose of antipsychotic drugs administered; the syndrome can, however, develop after relatively brief treatment periods at low doses. These abnormal movements persist a long time after the discontinuation of neuroleptic agents, discontinuation which can worsen them. They are not improved by anticholinergic drugs such as trihexyphenidyl.
- Pseudo-parkinsonism with akinesia (slowness of movements), rest and postural tremor, rigidity, hypertonicity. The incidence of these effects is less frequent with atypical antipsychotics.
- Akathisia or impossibility of remaining motionless.
- Rare but severe hyperthermia accompanied by muscular rigidity, called neuroleptic malignant syndrome whose mechanisms are complex.
- Decrease of seizure threshold, for example with clozapine.
- Confusional syndrome: the antimuscarinic effect of most of antipsychotics contributes to appearance of confusional states.
- Passivity and perhaps a certain depressive state.

Digestive

- Mouth dryness
- Hypersalivation, with clozapine for example
- Constipation, often linked to antimuscarinic effects.

Cardiovascular

- Postural hypotension
- Electrocardiographic disorders. A lengthening of QT space was observed during the use of neuroleptics such as droperidol which now is not available in many countries and sultopride by injectable route in the treatment of agitation
- possible implication of neuroleptics in sudden deaths has been evoked.

Endocrine

- Hyperprolactinaemia at the origin of galactorrhoea, gynaecomastia, amenorrhoea, decreased libido, erection and ejaculation disorders
- weight gain, in particular with atypical neuroleptics such as olanzapine.

Neuroleptics such as clozapine and olanzapine have been suspected to increase the risk of diabetes.

Allergic reactions

- Photosensitisation
- Blood disorders: thrombocytopenia, agranulocytosis particularly with clozapine.

Teratogenesis: The old neuroleptic agents such as chlorpromazine are not teratogenic.

- Antipsychotics, particularly atypicals, appear to cause diabetes mellitus and fatal diabetic ketoacidosis, especially (in US studies) in African Americans.
- Antipsychotics may cause pancreatitis
- The atypical antipsychotics (especially olanzapine) seem to cause weight gain more commonly than the typical antipsychotics. The well-documented metabolic side effects associated with weight gain include diabetes, which can be life-threatening.
- Clozapine also has a risk of inducing agranulocytosis, a potentially dangerous reduction in the number of white blood cells in the body.
- A potentially serious side effect of many antipsychotics is that they tend to lower an individual's seizure threshold. Another antipsychotic side effect is deterioration of teeth due to a lack of saliva.
- Another serious and potentially fatal side effect is sometimes referred to as Neuroleptic Malignant Syndrome, in which the drugs appear to cause the temperature regulation centers to fail, resulting in a medical emergency, as the patient's temperature suddenly increases to dangerous levels. Other signs include muscle rigidity altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria, rhabdomyolysis, and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated.
- Other clinical manifestations include hyperpyrexia, muscle rigidity, altered mental state, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure.
- Other side-effects of drug therapy may include a disruption to the body's ability to reduce body core temperature and dysphagia (oesophageal dysmotility and aspiration - aspiration pneumonia is a common cause of morbidity or mortality in elderly patients especially those with advanced Alzheimer's dementia).

Dopamine has an emetic effect and inhibits digestive motility; its antagonists have antiemetic and digestive motility stimulant effects. Dopaminergic receptors in the chemoreceptor trigger zone responsible for vomiting are accessible to dopaminergic antagonists which do not cross the blood-brain barrier. Drugs stimulating gastrointestinal motility are called prokinetic agents and are used specially in treating gastroesophageal reflux.

■ Patients of any age with Major Depressive Disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Patients should be closely monitored, especially at the beginning of therapy or when the dose is changed, until such

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

improvement occurs.

There has been a long-standing concern that some antidepressants may have a role in the emergence of suicidality in some patients. The possible risk of increased suicidality in patients applies to all classes of antidepressant medicines, as available data are not adequate to exclude this risk for any antidepressant. Therefore, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms. Generally, when stopping an antidepressant, doses should be tapered rather than stopped abruptly.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania and mania, have been reported in adult and paediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.

Mania and Bipolar Disorder: A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with any antidepressant alone may increase the likelihood of a mixed-manic episode in patients at risk for bipolar disorder. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder.

- Those with a piperazine side-chain are considered to be the most potent of the phenothiazine sedatives as they produce a higher incidence of loss of muscle tone.

- Phenothiazine sedatives and related tranquilizers cause central depression though less so than barbiturates and benzodiazepines. Side effects include dry mouth, constipation, urinary retention, dilated pupils, agitation, sleep disturbance, depression, convulsion, blocked nose, fast heart rate, ECG changes, low blood pressure, pinpoint pupils, blurred vision, and sexual dysfunction. Allergies may cause blistering and redness, and also jaundice. Loss of white blood cells may be seen in blood cell distribution and this can be fatal. Phenothiazines also disrupt neurotransmitter function resulting in spastic or flaccid muscles, shaking (Parkinson), inability to sit still, fever, sensitivity to light, involuntary movements and tremor around the mouth. There may be cessation of periods in women, breast development in men, weight gain, high blood glucose and changes in glucose tolerance.

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 on contact in some persons.

- The material may accentuate any pre-existing dermatitis condition.

- Open cuts, abraded or irritated skin should not be exposed to this material.

- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- Inhalation of dusts, generated by the material, during the course of normal handling, may be harmful.

- The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

- 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

- Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

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 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.

Antipsychotic drugs have been shown to chronically elevate prolactin levels in rodents. Increases in mammary neoplasms have been found in rodents after chronic administration of antipsychotic drugs and are considered to be prolactin-mediated.

Increased prolactin levels in serum are a secondary consequence of chronic dopamine antagonism of pituitary lactotrophs.

The relevance of the increased incidence of prolactin-mediated mammary gland tumours in rats, to human risk, is unknown.

Reproductive and developmental toxicity may also result from exposure to dopamine antagonists; these may result from elevation of serum prolactin. Effects may include prolonged oestrus, pre-implantation loss and alterations to the length of the gestational cycle.

Prolonged use of phenothiazines may discolor the eye or skin; cloudiness in the cornea or lens can occur. There can be allergic reactions.

Chronic constipation and faecal impaction may occur over a long period.

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

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

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

	Min	Max	
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

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

NAME	CAS RN	%
prochlorperazine maleate	84-02-6	>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.
- If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

EYE

- If this product comes in contact with the eyes:
 - Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - If pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

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

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

NOTES TO PHYSICIAN

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

- The management of NMS (Neuroleptic Malignant syndrome) should include:
 - immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy;
 - intensive symptomatic treatment and medical monitoring and
 - treatment of any concomitant serious medical problems for which specific treatments are available.
 - There is no general agreement about specific pharmacological regimes for NMS.

Following recent ingestion of an overdose of phenothiazine sedatives, the stomach should be emptied by gastric lavage, and aspiration. Management should include intensive symptomatic, and supportive therapy. In particular attention should be paid to the maintenance of respiratory and renal function and to the maintenance of electrolyte balance. Phenothiazine-induced hypotension should NOT be managed with adrenalin or other sympathomimetics with beta-adrenergic agonist properties since the alpha- blocking effects of phenothiazines impair vasoconstriction and these agents may exacerbate hypotension MARTINDALE: The Extra Pharmacopoeia, 29th Edition.

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), hydrogen chloride, phosgene, nitrogen oxides (NO_x), sulfur oxides (SO_x), 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:

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

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

- 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.

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.

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

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

- 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

- - 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



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

The following materials had no OELs on our records

- prochlorperazine maleate: CAS:84-02-6

MATERIAL DATA

PROCHLORPERAZINE MALEATE:

■ 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

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

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).

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

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

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

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

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

- 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
- - 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.

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

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

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	606.14
Melting Range (°F)	442.4	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
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

APPEARANCE

Minute crystalline solid; does not mix well with water (less than 0.1%, 20C).

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.

Prochlorperazine dimaleate

sc-204213



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

- 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

prochlorperazine maleate

TOXICITY AND IRRITATION

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

TOXICITY

IRRITATION

Oral (rat) LD50: 750 mg/kg

Intraperitoneal (mouse) LD50: 191 mg/kg

Intravenous (mouse) LD50: 85 mg/kg

■ Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitization potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitizing substance which is widely distributed can be a more important allergen than one with stronger sensitizing potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

Oral (woman) TDLo: 0.6 mg/kg/18 h - I Nil reported

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

PROCHLORPERAZINE MALEATE:

- DO NOT discharge into sewer or waterways.

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.

Prochlorperazine dimaleate

sc-204213

Material Safety Data Sheet



The Power is Question

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

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

No data for prochlorperazine maleate (CAS: , 84-02-6)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Cumulative effects may result following exposure*.
- Limited evidence of a carcinogenic effect*.

* (limited evidence).

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

- Classification of the 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.

This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH. TEL (+61 3) 9572 4700.

Issue Date: May-3-2009

Print Date: May-11-2010