Haloperidol hydrochloride

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Haloperidol hydrochloride

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
Major butyrophenone tranquiliser (antipsychotic/ neuroleptic) which depresses the central nervous system. 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, in the management of Gilles de la Tourette’s syndrome. Given by mouth or by injection (as the decanoate). CAUTION: May modify behaviour and state of alertness; exposed individuals taking charge of vehicles or machinery should be warned of the hazards. Regenant

SYNONYMS
C21-H23-Cl-F-N-O2, C21-H23-Cl-F-N-O2, "1-butanone, 4-(4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl)-1-", "1-butane, 4-(4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl)-1-", (4-fluorophenyl), "butyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxybutyrophenone)-", "butyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxybutyrophenone)-", gamma-(4-(4-chlorophenyl)-4-hydroxybutyrophenone)-p-fluorobutyrophenone, gamma-(4-(4-chlorophenyl)-4-hydroxybutyrophenone)-p-fluorobutyrophenone, 4-(4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl)-1-(4-fluorophenyl), 4-(4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl)-1-(4-fluorophenyl), 1-butane, 1-butane, 1-(3-p-fluorobenzoylpropyl)-4-p-chlorophenyl-4-hydroxybutyrophenone, 1-(3-p-fluorobenzoylpropyl)-4-p-chlorophenyl-4-hydroxybutyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxybutyrophenone)-butyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxybutyrophenone)-butyrophenone, 4'-fluoro-4-(4-(p-chlorophenyl)-4-hydroxybutyrophenone)-butyrophenone, 4'-fluoro-4-(4-hydroxy-4'-chloro-4-phenylpiperidino)-4'-fluorobutyrophenone, 4'-fluoro-4-(4-hydroxy-4'-chloro-4-phenylpiperidino)-4'-fluorobutyrophenone, Aldo, Aloperidin, Aloperidolo, Aloperid, Brotopon, Dozic, "Einalon S", Eukystol, Fortunan, Galoperidol, Haldol, Halidol, Halol, Halopan, Halopidol, Halopiodal, Halosten, Keselan, "Lealgin Compositum", "Linton N", MCN-JR-1625, Peluces, Pernox, R-1625, R-1625, Serenace, Serenase, Serenellf, Seras, Semel, Ullolind, Ulcolind, Vesalium, "tranquiliser/ antipsychotic/ neuroleptic/ ataractic"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS
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 (invoking 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 dysphoria (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, unsuit behaviour, 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, oculoglycic attack, opistothonos. These symptoms, linked to inhibition of D2 dopaminergic receptors of the striatum, are distressing but may be controlled by anticholinergic antiparkinsonian drugs such as trihexyphenidyl. The frequency of acute dyskinesias is lower with atypical neuroleptics like clozapine, olanzapine, risperidone that 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 akinines (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.
Possible implication of neuroleptics in sudden deaths has been evoked.

Endocrine
Hyperprolactinaemia at the origin of galactorrhea, gynaecomastia, amenorrhea, 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
Phototoxicity
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 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.

**EYE**
- This material can cause eye irritation and damage in some persons.
- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

**inhaled**
- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

**chronic health effects**
- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
- Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.
- 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).

- 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.

- Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). The anxiolytic sedatives, hypnotics and neuroleptics may produce dependence in susceptible individuals; dependency is characterized by a strong need to continue taking the drug; a tendency to increase the dose, a psychic dependence on the effects of the drug, and a physical dependence on the effects of the drug for the maintenance of homeostasis, with a characteristic abstinence syndrome on withdrawal.

**HAZARD RATINGS**
- **Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS**
- **Min**
- **Max**
Section 4 - FIRST AID MEASURES

SWALLOWED
- Give a slurry of activated charcoal in water to drink. NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK.
- At least 3 tablespoons in a glass of water should be given.
- Although induction of vomiting may be recommended (IN CONSCIOUS PERSONS ONLY), such a first aid measure is dissuaded because to the risk of aspiration of stomach contents. (i) It is better to take the patient to a doctor who can decide on the necessity and method of emptying the stomach. (ii) Special circumstances may however exist; these include non-availability of charcoal and the ready availability of the doctor.
- REFER FOR MEDICAL ATTENTION WITHOUT DELAY.
- 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:
  - 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
- 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. In severe overdose the stomach should be emptied by aspiration and lavage. Do NOT use emetics. Acute hypotension may be countered by placing the patient in the head-down position, but it has been advised that strenuous efforts should not be made to raise the blood pressure providing urine is being produced. Plasma expanders may be given for some severe hypotensions. Some sources advocate cautious intravenous administration of alpha-adrenergic sympathomimetics, noradrenaline and phenylephrine (not adrenaline or other pressor amines) - other sources advice against such administration. In general the are probably not desirable or necessary.
- Anti-arrhythmic agents may be required for cardiac arrhythmias. Convulsions may be controlled with diazepam.
- Haloperidol is readily absorbed from the gastrointestinal tract and is reported to have a plasma half-life of 13 to nearly 40 hours. Plasma half-life is prolonged during the night. Extensively bound to plasma protein, widely distributed in the body and crosses the blood-brain barrier.

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

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

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

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

PERSONAL PROTECTION
Glasses:
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

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 any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labeled containers for recycling.
- Neutralize/decontaminate residue.
- Collect solid residues and seal in labeled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL
**FOOTNOTES**

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

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

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

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


6 IERG information is derived from CANUTEC - Transport Canada.

**ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)**

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

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

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

**Section 7 - HANDLING AND STORAGE**

**PROCEDURE FOR HANDLING**

- 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.
- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.
- Metal drum with sealed plastic liner.
For low viscosity materials
- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):
- Removable head packaging;
- Cans with friction closures and
- low pressure tubes and cartridges may be used.

- Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages *.
- In addition, where inner packagings are glass and contain liquids of packing group I and II there must be sufficient inert absorbent to absorb any spillage *.
- * unless the outer packaging is a close fitting molded plastic box and the substances are not incompatible with the plastic.

**STORAGE REQUIREMENTS**
- 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**

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

**EXPOSURE CONTROLS**
The following materials had no OELs on our records
- haloperidol: CAS:52-86-8

**MATERIAL DATA**

HALOPERIDOL:
- 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).

**PERSONAL PROTECTION**
Consult your EHS staff for recommendations

**EYE**
- 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 lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.
  - Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lenses should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

**HANDS/FEET**
- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
  - frequency and duration of contact,
  - chemical resistance of glove material,
  - glove thickness and dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

**OTHER**
- 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.

**RESPRATOR**

<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>-</td>
<td>-</td>
<td>PAPR-P1</td>
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<tr>
<td>50 x PEL</td>
<td>Air-line*</td>
<td>-</td>
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<tr>
<td>100 x PEL</td>
<td>Air-line**</td>
<td>P2</td>
<td>PAPR-P2</td>
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<td>100+ x PEL</td>
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<td>Air-line*</td>
<td>-</td>
<td>Air-line**</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 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

- For potent pharmacological agents:
  - Powders
    - To prevent contamination and overexposure, no open handling of powder should be allowed.
    - Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
    - In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
    - Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
    - An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
    - Powder should be put into solution or a closed or covered container after handling.
    - If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Solutions Handling:

- Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.
- Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.
- In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
- Ensure gloves are protective against solvents in use.

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.

### Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL PROPERTIES**

- **State**: Solid.
- **Does not mix with water.**
- **Melting Range (°F)**: Not applicable
- **Boiling Range (°F)**: Not applicable
- **Flash Point (°F)**: Not available
- **Decomposition Temp (°F)**: Not Available
- **pH (as supplied)**: Not applicable
- **pH (1% solution)**: 7 (sat. soln)
- **Solubility in water (g/L)**: Partly miscible
- **Viscosity**: Not Applicable
- **Molecular Weight**: 355.3
- **Density**: Not Available
- **Flash Point (°F)**: Not applicable
- **Viscosity**: Not Applicable
- **Melting Point (°F)**: Not available
- **Boiling Point (°F)**: Not available
- **Decomposition Temp (°F)**: Not Available
- **pH (as supplied)**: Not applicable
**APPEARANCE**
White or faintly yellow, odourless, tasteless, amorphous or microcrystalline powder; does not mix well with water. Soluble in alcohol (1:15), chloroform (1:20), ethyl acetate (1:55).

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**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**

**haloperidol**

**TOXICITY AND IRRITATION**

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (rat)</td>
<td>128 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal (rat)</td>
<td>27 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous (rat)</td>
<td>60 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intravenous (rat)</td>
<td>15 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (mouse)</td>
<td>71 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal (mouse)</td>
<td>30 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous (mouse)</td>
<td>41 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intravenous (mouse)</td>
<td>13 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (dog)</td>
<td>90 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous (dog)</td>
<td>90 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intravenous (dog)</td>
<td>18 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous (monkey)</td>
<td>&gt;1.25 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

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

- Fasciculation, somnolence, hallucinations, tremor, excitement, change in motor activity, muscle weakness, ataxia, rigidity, spasticity, gastrointestinal tumours, agranulocytosis, leukaemia, paternal and maternal effects, effects on fertility, foetotoxicity, foetolethality, specific developmental abnormalities (central nervous system, eye, ear, craniofacial, body-wall, musculoskeletal system, cardiovascular system), effects on newborn recorded.

Refer to data for ingredients, which follows:

**HALOPERIDOL:**

- log Kow (Sangster 1997): 3.36
- Very toxic to aquatic organisms.
- 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.
- 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>
</table>
Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.
Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:
- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

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: None Hazard class or Division: 6.1
Identification Numbers: UN3249
Label Codes: 6.1
Packaging: Exceptions: 153
Packaging: Non-bulk: 213

Special provisions: T1, TP33

Quantity Limitations: Cargo aircraft only: 5 kg Vessel stowage: Location: C

Vessel stowage: Other: 40
Hazardous materials descriptions and proper shipping names:
Medicine, solid, toxic, n.o.s.

Air Transport IATA:
ICAO/IATA Class: 6.1 ICAO/IATA Subrisk: None
UN/ID Number: 3249 Packing Group: III
Special provisions: A3

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(CONTAINS HALOPERIDOL)
Maritime Transport IMDG:
IMDG Class: 6.1 IMDG Subrisk: None
UN Number: 3249 Packing Group: III
EMS Number: F-A,S-A Special provisions: 221 223 944
Limited Quantities: 5 kg
Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(contains haloperidol)

Section 15 - REGULATORY INFORMATION

haloperidol (CAS: 52-86-8) is found on the following regulatory lists;

Section 16 - OTHER INFORMATION
LIMITED EVIDENCE

■ Inhalation and/or skin contact may produce health damage*.
■ Cumulative effects may result following exposure*.
■ Limited evidence of a carcinogenic effect*.

* (limited evidence).

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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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Issue Date: Mar-15-2009
Print Date: Apr-21-2010