

MATERIAL SAFETY DATA SHEET

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name	PAROXETINE HYDROCHLORIDE
Chemical Name	""trans-(-)-3-((1, 3-benzodioxol-5-yloxy)methyl)-"
Synonyms	"4-(4-fluorophenyl)piperidine hydrochloride", (-)-trans-4-(p-fluorophenyl)-3-, "((3, 4-(methylenedioxy)phenoxy)methyl)piperidine hydrochloride", "(-)-alpha-4-(4-fluorophenyl)-3-(1, 3-benzodioxolyl)-(3)-", "oxymethylpiperidine hydrochloride", "bicyclic antidepressant"
Molecular Formula	C19-H20-F-N-O3.HCl
Usage	A bicyclic antidepressant used in the treatment of depression. Inhibits uptake of serotonin. CAUTION: May modify behaviour and state of alertness; exposed individuals taking charge of vehicles or machinery should be warned of the hazards.

Manufacture/supplier identification :

Company	Ipca Laboratories Limited, 48, Kandivli Industrial Estate, Kandivli (West), Mumbai - 400 067 Telephone : 66474747:Telefax 2868 2875
Contact for information:	Ipca Laboratories Limited, Post Box No. 33, P.O. Sejavta, Dist. Ratlam (M.P.) 457 002
Emergency telephone No.:	Telephone:(07412)278000,279080-81,Telefax (07412)279083
E Mail	ipcartm@ipca.co.in

Section 2 – HAZARD IDENTIFICATION

HAZARD RATINGS

	Min	Max	
Flammability:	1		
Toxicity:	2		Min/Nil=0
Body Contact:	2		Low=1
Reactivity:	1		Moderate=2
Chronic:	2		High=3
			Extreme=4

GHS Classification

Acute Aquatic Hazard Category 1

Acute Toxicity (Oral) Category 4
Reproductive Toxicity Category 2
Skin Corrosion/Irritation Category 3



EMERGENCY OVERVIEW

HAZARD

WARNING

Determined by Chemwatch using GHS criteria:

H302 H316 H361 H400

Harmful if swallowed

Causes mild skin irritation

Suspected of damaging the unborn child

Very toxic to aquatic life

PRECAUTIONARY STATEMENTS

Prevention

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P264: Wash thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P273: Avoid release to the environment.

P281 Use personal protective equipment as required.

.

Response

P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P308+313: IF exposed or concerned: Get medical advice/ attention.

P330: Rinse mouth.

P332+313: If skin irritation occurs: Get medical advice/ attention.

P391: Collect spillage..

Storage

P405 Store locked up.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
Paroxetine Hydrochloride	78246-49-8	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

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

EYE

- If this product comes in contact with the eyes:
 - Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - Seek medical attention without delay; if pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

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

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.

]

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

NOTES TO PHYSICIAN

- For selective serotonin reuptake inhibitors (SSRIs):

Serotonin toxicity is more pronounced following supra-therapeutic doses and overdoses, and they merge in a continuum with the toxic effects of overdose. The serotonergic toxicity of SSRIs increases with dose, but even in over-dose it is insufficient to cause fatalities from serotonin syndrome in healthy adults. The syndrome occurs in approximately 14 to 16 percent of persons who overdose on SSRIs. It is usually only when drugs with different mechanisms of action are mixed together that elevations of central nervous system serotonin reach potentially fatal levels.

The symptoms are often described as a clinical triad of abnormalities:

- Cognitive effects: mental confusion, hypomania, hallucinations, agitation, headache, coma.
- Autonomic effects: shivering, sweating, fever, hypertension, tachycardia, nausea, diarrhea.
- Somatic effects: myoclonus/clonus (muscle twitching), hyperreflexia, tremor.

Symptom onset is usually rapid, often occurring within minutes after self-poisoning or a change in medication. Serotonin syndrome encompasses a wide range of clinical findings. Mild symptoms may only consist of tachycardia, shivering, diaphoresis (sweating), mydriasis (dilated pupils), myoclonus (intermittent tremor or twitching), as well as overactive or over-responsive reflexes. Moderate intoxication includes additional abnormalities such as hyperactive bowel sounds, hypertension and hyperthermia; a temperature as high as 40 C (104 F) is common in moderate intoxication. The overactive reflexes and clonus in moderate cases may be greater in the lower limbs than in the upper limbs. Mental status changes include hyper-vigilance and agitation. Severe symptoms include severe hypertension and tachycardia that may lead to shock. Severe cases often have agitated delirium as well as muscular rigidity and high muscular tension. Temperature may rise to above 41.1 C (106.0 F) in life-threatening cases. Other abnormalities include metabolic acidosis, rhabdomyolysis, seizures, renal failure, and disseminated intravascular coagulation, these effects usually arise as a consequence of hyperthermia.

SSRIs appear to be safer in overdose when compared with traditional antidepressants such as the tricyclic antidepressants. This relative safety is supported both by case series and studies of deaths per numbers of prescriptions. However, case reports of SSRI poisoning have indicated that severe toxicity can occur and deaths have been reported following massive single ingestions, although this is exceedingly uncommon when compared to the tricyclic antidepressants. Because of the wide therapeutic index of the SSRIs, most patients will have mild or no symptoms following moderate overdoses. The most commonly reported severe effect following SSRI overdose is serotonin syndrome; serotonin toxicity is usually associated with very high overdoses or multiple drug ingestion. Other reported significant effects include coma, seizures, and cardiac toxicity.

Treatment for SSRI overdose is mainly based on symptomatic and supportive care. Medical care may be required for agitation, maintenance of the airways, and treatment for serotonin syndrome. ECG monitoring is usually indicated to detect any cardiac abnormalities.

Supportive care includes:

- the control of agitation,
- the administration of serotonin antagonists (cyproheptadine or methysergide),
- the control of autonomic instability, and the control of hyperthermia.

The intensity of therapy depends on the severity of symptoms. If the symptoms are mild, treatment may only consist of:

- discontinuation of the offending medication or medications,
- offering supportive measures,
- giving benzodiazepines for myoclonus, and waiting for the symptoms to resolve.

Moderate cases should have:

- all thermal and cardiorespiratory abnormalities corrected and
- can benefit from serotonin antagonists such as cyproheptadine.

Critically ill patients should receive the above therapies as well as:

- sedation, neuromuscular paralysis, and
- intubation with artificial ventilation.

Upon initiation of therapy and the discontinuation of serotonergic drugs most cases of serotonin syndrome resolve within 24 hours. although delirium may persist for a number of days. Cases have reported muscle pain\ and weakness persisting for months although antidepressant withdrawal may contribute to ongoing features.

Following appropriate medical management, serotonin syndrome is generally associated with a favorable prognosis.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

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

FIRE FIGHTING

- Alert Fire Brigade 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.

FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion.

Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.
- 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.
- All movable parts coming in contact with this material should have a speed of less than 1-meter/sec
- A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source
- One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).

- Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen fluoride, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

FIRE INCOMPATIBILITY

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

Personal Protective Equipment

.Chemical splash suit.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

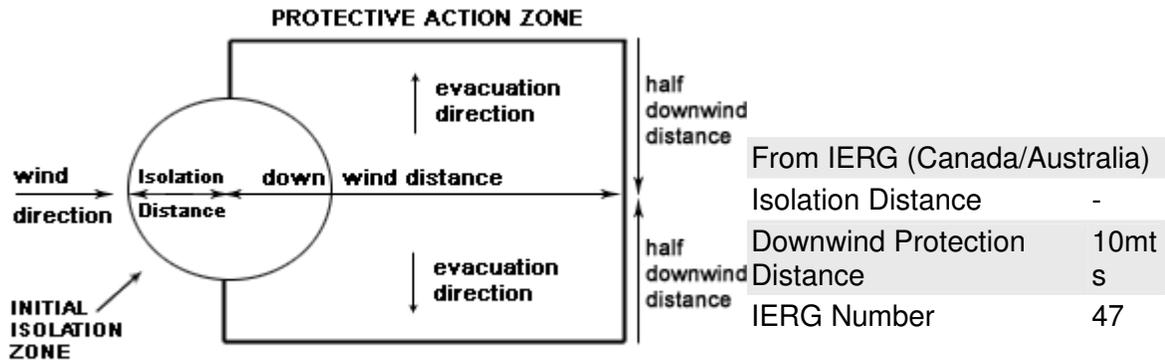
- Environmental hazard - contain spillage.
- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or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

MAJOR SPILLS

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

- If contamination of drains or waterways occurs, advise Emergency Services.

PROTECTIVE ACTIONS FOR SPILL



From US Emergency Response Guide 2000 Guide No guide found.

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 lifethreatening 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".
- 5 LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one-tonne" compressed gas cylinder.
- 5 Guide 151 is taken from the US DOT emergency response guide book.
- 6 IERG information is derived from CANUTEC - Transport Canada.

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

SUITABLE CONTAINER

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

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents

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..

For major quantities:

- Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams}.

- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+

X

+

X

X

+

+: May be stored together

O: May be stored together with specific preventions

X: Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- paroxetine hydrochloride: CAS:78246- 49- 8

MATERIAL DATA

PAROXETINE HYDROCHLORIDE:

■ 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

Ipca Laboratories Limited

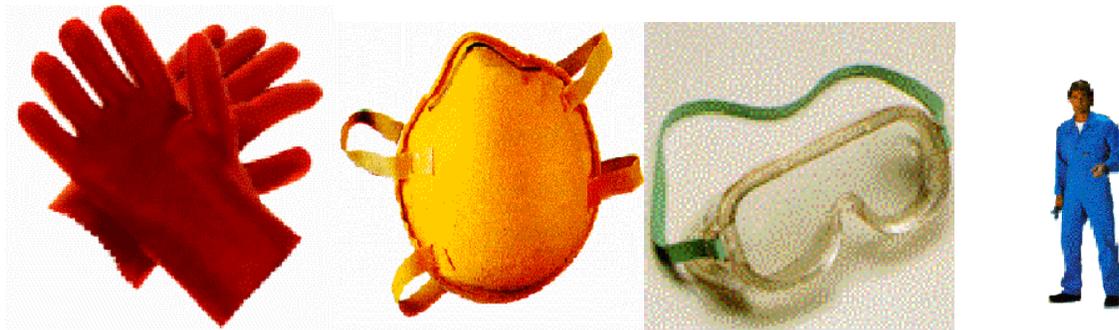
eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure 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 vapour 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



EYE

- When handling very small quantities of the material eye protection may not be required.

Ipca Laboratories Limited

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly.

Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

Ipca Laboratories Limited

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

RESPIRATOR

- 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 xES	P1 Air- line*	- -	PAPR- P1 -
50 xES	Air- line**	P2	PAPR- P2
100 xES	-	P3	-
		Air- line*	-
100+ xES	-	Air- line**	PAPR- P3

* - Negative pressure demand

** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

IpcA Laboratories Limited

ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

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

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

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, vapours, 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.)

IpcA Laboratories Limited

Within each range the appropriate value depends on:

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only.
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 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.

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.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

- 10; high efficiency particulate (HEPA) filters or cartridges
- 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.
- 25-50; a full face-piece negative pressure respirator with HEPA filters
- 50-100; tight-fitting, full face-piece HEPA PAPR
- 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

White crystalline powder; does not mix well with water.

PHYSICAL PROPERTIES

Solid.
Does not mix with water.

State	Divided solid	Molecular Weight	365.83
Melting Range (°C)	118	Viscosity	Not applicable
Boiling Range (°C)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°C)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°C)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°C)	Not available	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not available.	specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapour Density	Not applicable
(air=1)			
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

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

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- Serotonin selective re-uptake inhibitors is used in the treatment of depression but has several abnormal side effect which includes serotonin syndrome (due to toxic levels of serotonin in the body), psychotic, general and systemic defects including sexual dysfunction, electrolyte imbalance, heart diseases, musculoskeletal manifestations, thoughts of suicide, defect in carbohydrate metabolism, foetal toxicity, neonatal and adult abstinence/withdrawal syndrome.

EYE

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

SKIN

■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.

■ There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.

■ This material is a photosensitiser. Certain individuals working with this substance may show allergic reaction of the skin under sunlight. This results in sensitivity to sunburn (may be severe) unless protective covering and 15+PF sunscreen are used. Responses may vary from sunburn-like effects to swelling and blistering lesions.

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

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

INHALED

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

■ 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.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

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.

TOXICITY AND IRRITATION

- No significant acute toxicological data identified in literature search.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

PAROXETINE HYDROCHLORIDE:

Marine Pollutant: Yes

- 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.

- For selective serotonin reuptake inhibitors (SSRIs):

Selective serotonin reuptake inhibitors (SSRIs) are a major class of widely prescribed antidepressants and obsessive-compulsive regulators that includes Prozac, Zoloft, Luvox, and Paxil. The function of serotonin in a wide array of aquatic creatures could prove highly significant in any discussion of the importance of low levels of pharmaceuticals in the environment. The potential for dramatic physiologic effects on nontarget species (such as invertebrates) by low (ppb) concentrations of pharmaceuticals is the subject of many studies. Serotonin is a biogenic amine common in both vertebrate and invertebrate nervous systems. SSRIs increase serotonin neurotransmission by inhibiting its reuptake at the synapses by inhibiting the transporter enzymes. In addition to playing a key role in mammalian neurotransmission, serotonin is involved in a wide array of physiologic regulatory roles in molluscs, among most other creatures. For bivalves, reproductive functions including spawning, oocyte maturation, and parturition are regulated by serotonin. Serotonin controls a wide spectrum of additional behaviors and reflexes in molluscs, including heartbeat rhythm, feeding/biting, swimming motor patterns, beating of cilia, and induction of larval metamorphosis. It also stimulates release of various neurohormones in crustaceans (hyperglycemic hormone, red pigment-dispersing hormone, neurodepressing hormone, and molt-inhibiting hormone) and ovarian maturation. It has long been known that serotonin at concentrations of 10^{-4} to 10^{-3} M (~0.18-1.8 g/L) induces spawning in bivalves. Some commercial farmers make use of this by adding serotonin to induce spawning. Prozac (fluoxetine) and Luvox (fluvoxamine) are the most potent inducers ever found, eliciting spawning behavior in zebra mussels at aqueous concentrations many orders of magnitude lower than serotonin.

Fluoxetine elicited significant spawning in male mussels at concentrations of 10^{-7} M (~150 ug/L); females were an order of magnitude less sensitive at 10^{-6} M. Fluvoxamine was the most potent of the SSRIs, eliciting significant spawning in male mussels, at 10^{-9} M (~0.318 ug/L); females were two orders of magnitude less sensitive, at 10^{-7} M. In males, spawning was complete in the first hour, while females were slower (within 2 hr). Paxil (paroxetine) was the least potent of these three

SSRIs, eliciting male spawning, but to a lesser degree, at 10^{-6} M, and having no inducing effect on females at any concentration. It should be noted that the evidence is not clear whether these compounds are indeed acting as SSRIs, or via some other mechanism. It is also unknown how these compounds are taken up by molluscs. In another study, fluvoxamine induces significant parturition in fingernail clams at 1 nM; 1 nM fluvoxamine also potentiated the effect of 10 μ M 5-hydroxytryptophan (5-HT, a precursor of serotonin) by almost 5-fold. Paroxetine was less potent, requiring a concentration of 10 μ M to effect significant parturition. In contrast, even at concentrations of 100 μ M, fluoxetine displayed no effect, although it was capable at 5 μ M of potentiating 5-HT at concentrations that were otherwise subthreshold. It is interesting that the order of potency for inducing parturition in clams differs from the order for induction of spawning in mussels (above). This points to the complexity of considering any approach involving extrapolations from one species to another or from one drug to another within a given class. In crustaceans, fluoxetine significantly potentiates the effect of 5-HT in crayfish, enhancing the release of ovary-stimulating hormone, which results in larger oocytes with enhanced amounts of vitellin; any ecologic consequences of higher vitellin protein levels are unknown. Similarly, in fiddler crabs, fluoxetine at a dose of 125 nmol stimulates (through 5-HT) the production of gonad-stimulating hormone, which accelerates testicular maturation. It is clear that aquatic life can be exquisitely sensitive to at least some of this class of compounds. Although some SSRIs are extremely potent, others have almost no effect, which possibly makes the approach of assessing ecologic risk on a class-by-class basis infeasible.

Concentration of SSRIs plays a complicated role with respect to effects. For example, while injected fluoxetine induced significant metamorphosis in a gastropod, 10^{-4} M induced less metamorphosis than 10^{-6} M.

Simple extrapolations of effects from higher concentrations do not necessarily have any relevance to effects at lower concentrations.

The potential for SSRIs to elicit subtle effects on aquatic life is further extended by serotonin reuptake mechanisms that also are a factor in snails and squids, particularly in the regulation of aggression. Yet another example of a subtle effect that would go unnoticed is the fighting behavior of lobsters, in which serotonin causes behavior reversal by stimulating subordinates to engage in fighting against dominants by reducing their propensity to retreat.

- DO NOT discharge into sewer or waterways.

Section 13 - DISPOSAL CONSIDERATIONS

- 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 or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION



Ippca Laboratories Limited

RISK

Risk Codes	Risk Phrases
------------	--------------

R50	■ Very toxic to aquatic organisms.
-----	------------------------------------

R63(3)	■ Possible risk of harm to the unborn child.
--------	----------------------------------------------

SAFETY

Safety Codes	Safety Phrases
--------------	----------------

S51	■ Use only in well ventilated areas.
-----	--------------------------------------

S09	■ Keep container in a well ventilated place.
-----	----------------------------------------------

S53	■ Avoid exposure - obtain special instructions before use.
-----	------------------------------------------------------------

S401	■ To clean the floor and all objects contaminated by this material, use water and detergent.
------	----------------------------------------------------------------------------------------------

S35	■ This material and its container must be disposed of in a safe way.
-----	----------------------------------------------------------------------

S13	■ Keep away from food, drink and animal feeding stuffs.
-----	---------------------------------------------------------

S46	■ If swallowed, IMMEDIATELY contact Doctor or Poisons Information Centre. (show this container or label).
-----	-----------------------------------------------------------------------------------------------------------

S57	■ Use appropriate container to avoid environmental contamination.
-----	-------------------------------------------------------------------

S61	■ Avoid release to the environment. Refer to special instructions/Safety data sheets.
-----	---------------------------------------------------------------------------------------

S60	■ This material and its container must be disposed of as hazardous waste.
-----	---------------------------------------------------------------------------

ANNEX 2: Indications of Danger

N	Dangerous for the environment
---	-------------------------------

Xn	Harmful
----	---------

REGULATIONS

paroxetine hydrochloride (CAS: 78246-49-8) is found on the following regulatory lists; "EU Directive 96/61/EC concerning integrated pollution prevention and control, Annex III", "Scotland Pollution Inventory"

This safety data sheet is in compliance with the following EU legislation and its adaptations – as far as applicable - : 67/548/EEC, 1999/45/EC, 76/769/EEC, 98/24/EC, 92/85/EEC, 94/33/EC, 91/689/EEC, 1999/13/EC, as well as the following British legislation:

- The Control of Substances Hazardous to Health Regulations (COSHH) 2002
- COSHH Essentials

- The Management of Health and Safety at Work Regulations 1999

Section 16 - OTHER INFORMATION

Text of H-code(s) and P-sentence(s) are mentioned in Section 3

The information given in the safety data sheet is believed to be accurate and is based on our present knowledge .We take no guarantee with respect to such information and assume no liability resulting from its use.

Issue Date:

03-09-2010