

SAFETY DATA SHEETS

This SDS packet was issued with item:

078862491

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078058247

MATERIAL SAFETY DATA SHEET

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name	METOCLOPRAMIDE HYDROCHLORIDE
Chemical Name	"o-anisamide, 4-amino-5-chloro-N-(2-diethylamino)ethyl-, monohydrochloride"
Synonyms	"4-amino- 5-chloro-N-(2-diethylamino)ethyl)-o-anisamide hydrochloride", "4-amino-5-chloro-N-(2-diethylaminoethyl)-2-methoxybenzamide hydrochloride", "benzamide, 4-amino-5-chloro-N-(2-diethylamino)ethyl)-2-methoxy-, HCl", "N- (diethylaminoethyl)-2-methoxy-4-amino-5-chlorobenzamide hydrochloride", "2-methoxy-5-chloro-procainamide monohydrochloride", Cerucal, Maxolon, Paspertin, Primperan, Reglan, Rimetin, "gastrointestinal agent/ antiemetic"
Molecular Formula	C14-H22-Cl-N3-O2.HCl
Usage	Has central and anti-emetic properties as well as a positive effect on gastro-intestinal motility which appears to depend on the existing tone of the gut. Thought to act by blocking dopamine receptors and by increasing prolactin secretion. Gastric peristalsis increases with an increase in gastric-emptying rate; duodenal peristalsis may also increase and as a result increases intestinal transit. Resting tone of gastroesophageal spincter is also increased. Used as an anti-emetic in some forms of nausea and vomiting and to increase gastro-intestinal motility. May ease intubation procedures and speed radiographic examinations. There may be some benefit in migraine and lactation may be improved. Usually administered by mouth.

Manufacture/supplier identification :

Company	Ipca Laboratories Limited, 48, Kandivli Industrial Estate, Kandivli (West), Mumbai - 400 067 Telephone : 66474747:Telefax 2868 2875
Contact 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 Toxicity (Oral) Category 4
 Reproductive Toxicity Category 2
 Respiratory Sensitizer Category 1
 Skin Sensitizer Category 1



EMERGENCY OVERVIEW

HAZARD

DANGER

Determined by Chemwatch using GHS criteria:

H302	Harmful if swallowed
H334	May cause allergic or asthmatic symptoms or breathing difficulties if inhaled
H317	May cause allergic skin reaction
H361	Suspected of damaging fertility

PRECAUTIONARY STATEMENTS

Prevention

- P-201: Obtain special instructions before use.
- P-202: Do not handle until all safety precautions have been read and understood.
- P-261: Avoid breathing dust/fume/gas/mist/vapours/spray.
- P-264: Wash thoroughly after handling.
- P-270: Do not eat, drink or smoke when using this product.
- P-272: Contaminated work clothing should not be allowed out of the workplace.
- P-280: Wear protective gloves/protective clothing/eye protection/face protection.
- P-281: Use personal protective equipment as required.
- P-285: In case of inadequate ventilation wear respiratory protection.

Response

- P-301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- P-302+352: IF ON SKIN: Wash with plenty of soap and water.
- P-304+341: IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
- P-308+313: IF exposed or concerned: Get medical advice/ attention.
- P-330: Rinse mouth.
- P-333+313: If skin irritation or rash occurs: Get medical advice/attention.
- P-342+311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
- P-363: Wash contaminated clothing before reuse.

Storage

- P-405: Store locked up.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN
Metoclopramide Hydrochloride	7232-21-5

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.

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- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- 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.
- Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
- INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

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 poisons (where specific treatment regime is absent):

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema .
- Monitor and treat, where necessary, for shock.
- Anticipate seizures .
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994.

Treat symptomatically.

Metoclopramide is rapidly absorbed from the gastro-intestinal tract and has been reported to undergo a high degree of first-pass hepatic metabolism. Excreted in the urine as free and as conjugated metoclopramide and its metabolites. Also excreted in breast milk.

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), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY

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

Personal Protective Equipment

Breathing apparatus.

Gas tight chemical resistant suit.

Limit exposure duration to 1 BA set 30 mins.

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.

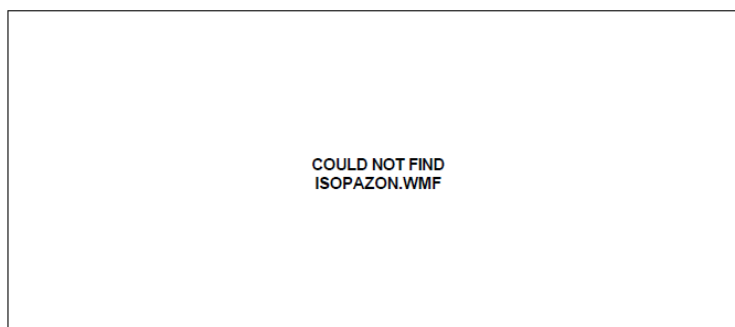
MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert 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.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.

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- Collect recoverable product into labelled containers for recycling.
- Neutralise/decontaminate residue.
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL



From IERG (Canada/Australia)

Isolation Distance 25 mts

Downwind Protection Distance 250 mts

IERG Number 34

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".

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.
- Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

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

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sufficient inert cushioning material in contact with inner and outer packages *.

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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 *.

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* unless the outer packaging is a close fitting moulded plastic box and the substances are not incompatible with the plastic.

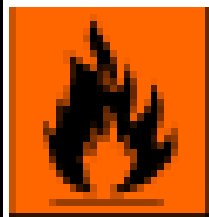
STORAGE INCOMPATIBILITY

- 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..

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



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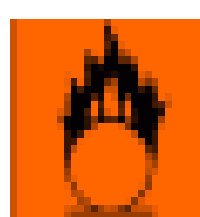
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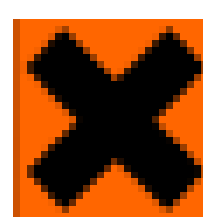
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X



+

+: May be stored together

O: May be stored together with specific precautions

X: Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- Metoclopramide Hydrochloride: CAS:7232- 21- 5 CAS:54143- 57- 6

MATERIAL DATA**METOCLOPRAMIDE 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.

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**

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

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

HANDS/FEET

■ NOTE:

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- The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

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.

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

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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.

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

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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, f/min.),intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5- 1 m/s (100- 200
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1- 2.5 m/s (200- 500 f/min.)

Within each range the appropriate value depends on:

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

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be

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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 or almost white, odourless, crystalline powder; mixes with water (1:0.7), alcohol (1:3), chloroform (1: 55).

PHYSICAL PROPERTIES

Solid

Mixes with water.

State	Divided Solid	Molecular Weight	354.3 (.H ₂ O)
Melting Range (°C)	182-184	Viscosity	Not applicable
Boiling Range (°C)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°C)	Not available	pH (1% solution)	4.5-6.5(10%)
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
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 harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

■ Dopamine receptor antagonists block dopamine receptors. There are five types of dopamine receptor in the human body; these are found in the brain, peripheral nervous system, blood vessels and the kidney.

Side effects of antagonism include:

- parkinsonism (due to effects on the nigrostriatal pathway),
- hyperprolactinaemia (the presence of abnormally high levels of prolactin in the blood) giving rise to hypoestrogenism in woman which may produce infertility decrease or loss of menstruation and loss of libido; in men there may be decreased libido, erectile dysfunction and infertility) and
- tardive dyskinesia (generally after long term use or high doses) which describe involuntary, repetitive, purposeless movements - signs may manifest in grimacing, tongue protrusion, lip smacking, puckering and pursing of the lips and rapid eye blinking; rapid movements of the extremities may occur with impaired movements of the fingers.

Note parkinsonism is characterised by difficult movement whilst tardive dyskinesia is characterised by difficulty in not moving.

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

- The material is not thought to be a skin irritant (as classified by EC Directives using animal models). Abrasive damage however, may result from prolonged exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- 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 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

- Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.
- Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.
- 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.
- Respiratory sensitisation may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping.
- Sensitisation may give severe responses to very low levels of exposure, i.e. hypersensitivity. Sensitised persons should not be allowed to work in situations where exposure may occur.
- Effects of long term exposure include restlessness, sedation, extrapyramidal reactions including dystonia, parkinsonism-like reactions, akathisia, dizziness, anxiety, headache, myoclonus, tardive dyskinesia and rarely mental depression may occur. Nausea and diarrhoea may also. Allergic reactions include urticaria, bronchospasm and angioneurotic oedema. Visual disturbances may include diplopia and nystagmus. Other effects of treatment include urinary frequency and incontinence, convulsive seizures, transient hypertension or hypotension, oedema, neutropenia, leukopenia, agranulocytosis, porphyria, neuroleptic malignant syndrome

and hyperprolactinaemia with galactorrhea, reversible amenorrhea. Nipple tenderness, gynaecomastia and impotence in males has been reported. In animals there is evidence of an increase in the incidence of mammary neoplasms.

TOXICITY AND IRRITATION

METOCLOPRAMIDE HYDROCHLORIDE:

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

TOXICITY

Subcutaneous (rat) LD50: 475 mg/kg
 Oral (rat) LD50: 750 mg/kg Nil Reported
 Intraperitoneal (rat) LD50: 114 mg/kg
 Subcutaneous (rat) LD50: 340 mg/kg
 Intravenous (rat) LD50: 50 mg/kg
 Oral (mouse) LD50: 96 mg/kg

IRRITATION

Nil Reported

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

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

METOCLOPRAMIDE HYDROCHLORIDE:

- DO NOT discharge into sewer or waterways.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persisten Air	Bioaccumulation	Mobility
Metoclopramide Hydrochloride	HIGH		LOW	MED

Section 13 - DISPOSAL CONSIDERATIONS

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product. 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



RISK

Risk Codes	Risk Phrases
R22	■ Harmful if swallowed.
R43	■ May cause SENSITISATION by skin contact.
R62(3)	■ Possible risk of impaired fertility.

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.
S40	■ To clean the floor and all objects contaminated by this material, use water.
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).

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

ANNEX 2: Indications of Danger

Xn Harmful

REGULATIONS

Metoclopramide Hydrochloride (CAS: 7232-21-5, 54143-57-6) is found on the following regulatory lists;

"European Customs Inventory of Chemical Substances (English)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)"

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.

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