SAFETY DATA SHEETS

This SDS packet was issued with item:

078693996

N/A

Ipca Laboratories Limited

MATERIAL SAFETY DATA SHEET

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name	METOPROLOL TARTRATE
Chemical Name	"2-propanol, 1-(isopropylamino)-3-[p-(2-methoxyethyl)phenoxy]-, (+/-)-, ",
Synonyms	"tartrate (2:1)", (+/-)-1-(isopropylamino)-3-[p-(2 methoxyethyl)phenoxy]-2-propanol, hemi-L-tartrate, "2- propanol, 1-[4-(2-methoxyethyl)phenoxy]-3-[(1-methylethyl)amino]-, ", "(+/-)-, [R-(R*, R*)]-2, 3- dihydroxybutanedioate (2:1)", Beloc, Betaloc, H-93/26, Lopresor, "Metoprolol hemitartrate", "Metoprolol tartrate (2:1)", Seloken, "Slow Lopresor", "beta-adrenoreceptor blocker", "anti-adrenergic (beta-receptor)", antihypertensive, antianginal, "antiarrhythmic (class II)"
Molecular Formula	C15-H25-N-O3.1/2C4-H6-O6
Usage	A beta-adrenoreceptor blocking agent used in the treatment of hypertension and angina pectoris. Normally given by mouth. Classified as cardioselective. and reported to lack intrinsic sympathomimetic and membrane stabilising ability. The usual adult oral dose is 100 mg per day in single or divided doses initially, the dosage being increased at one week intervals up to a maximum of 450 mg per day if neccesary. The principle effect of beta-adrenoreceptor blockade is to reduce cardiac activity by reducing the rate and force of contraction.

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	
		Min/Nil=0 Low=1 Moderate=2

Flammability:	1	High=3
Toxicity:	2	Extreme=4
Body Contact:	2	
Reactivity:	1	
Chronic:	2	

GHS Classification
Acute Toxicity (Oral) Category 4
Eye Irritation Category 2B
Skin Corrosion/Irritation Category 3

EMERGENCY OVERVIEW
HAZARD
WARNING
Determined by Chemwatch using GHS criteria:
H302 H316 H320
Harmful if swallowed
Causes mild skin irritation
Causes eye irritation

PRECAUTIONARY STATEMENTS

Prevention
P264: Wash thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.

Response
P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330: Rinse mouth.

P332+313: If skin irritation occurs: Get medical advice/ attention.
P337+313: If eye irritation persists: Get medical advice/attention.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
metoprolol tartrate	56392-17-7	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
• IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
• 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 or hair 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 dust is inhaled, remove from contaminated area.
• Encourage patient to blow nose to ensure clear passage of breathing.
• If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN
■ Following a recent overdosage with a beta-blocker the stomach should be emptied by gastric lavage. Emesis should not be used. Severe bradycardia and hypotension may respond to atropine 1 to 2 mg or more intravenously. Where response is inadequate, the treatment of choice is high-dose glucagon, initially as a bolus dose of 5 to 10 mg, followed if necessary by intravenous infusion of 1 to 5 mg per hour or more depending on response; the rate of infusion should be reduced as the patient improves. Dobutamine or isoprenaline have been used for the management of hypotension; large doses of the latter may be required to overcome competitive blockade of beta-adrenoreceptors. The use of adrenalin has been suggested but precautions must be observed. Intravenous aminophylline or inhaled or intravenous salbutamol may be of benefit in bronchospasms. MARTINDALE; The Extra Pharmacopoeia, 29th Edition. Readily and completely absorbed from the gastrointestinal tract and subject to considerable first pass metabolism with metabolites excreted in the urine the metabolism of metoprolol is reported to exhibit genetic polymorphism; the half-life in fast metabolisers is about 3-4 hours whereas in poor metabolisers it is about 7 hours. Crosses the blood-brain barrier.
Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If not breathing give artificial respiration; if breathing give oxygen.
For treatment of overdose the following supportive and symptomatic measures may be utilised:
Induce vomiting or gastric lavage to decrease further absorption.
For bradycardia:
Use intravenous atropine sulfate to induce vagal blockage. If bradycardia persists, intravenous isoproterenol or dobutamine may be administered with caution. Intravenous epinephrine or a transvenous pacemaker may be used if necessary.
For hypotension:
Trendelburg position and intravenous fluids. If needed intravenous vasopressors such as epinephrine, dobutamine, dopamine or norepinephrine may be used. Intravenous glucagon may be useful in treating bradycardia and hypotension.
For bronchospasm:
Isoproterenol and/or a theophylline derivative may be used.
For acute cardiac failure:
Therapy with digitalis, diuretics and oxygen. Treat premature ventricular contractions with intravenous lidocaine or phenytoin. Avoid the use of quinidine, procainamide or disopyramide. Treat seizures with intravenous diazepam or lorazepam or if necessary, phenytoin [US DI 14th ed. 1994]

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 are 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 (NOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes
May emit corrosive 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

Glasses:	Respirator:
Safety Glasses.	Particulate

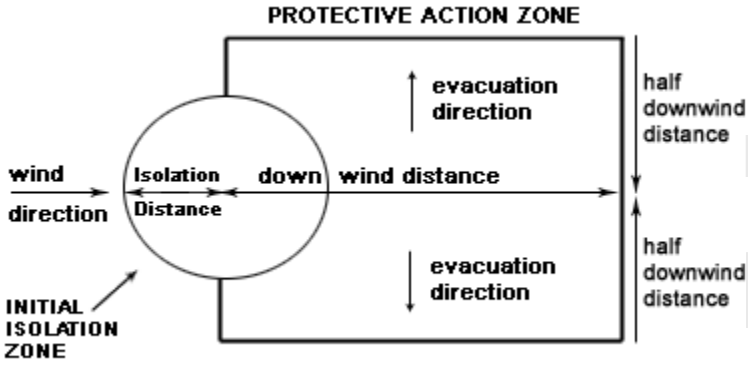
Section 6 - ACCIDENTAL RELEASE MEASURES

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

• Dampen with water to prevent dusting before sweeping.
• Place in suitable containers for disposal.

MAJOR SPILLS
■ Moderate hazard.
• CAUTION: Advise personnel in area.
• Alert Emergency 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 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

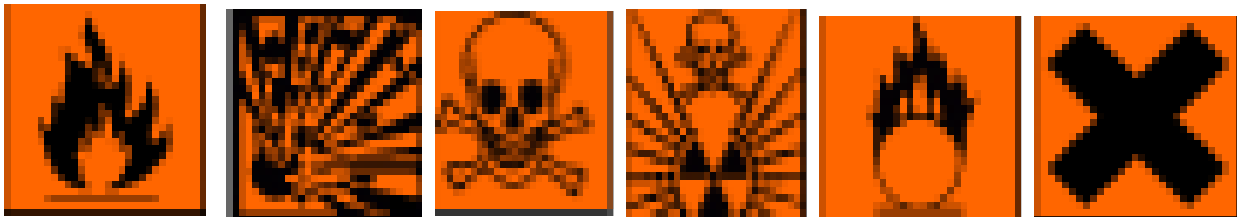
PROCEDURE FOR HANDLING
• Avoid all personal contact, including inhalation.
• Wear protective clothing when risk of exposure occurs.
• Use in a well-ventilated area.
• Prevent concentration in hollows and sumps.
• DO NOT enter confined spaces until atmosphere has been checked.
• DO NOT allow material 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.

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.

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

• Metoprolol Tartrate CAS:56392- 17- 7 CAS:55250- 54- 9 CAS:60168- 92- 5 CAS:74220- 04-5

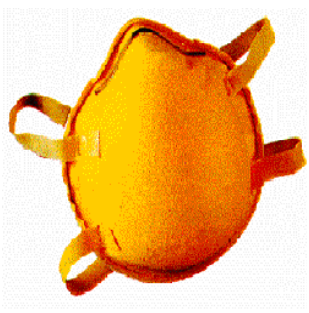
MATERIAL DATA

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

HANDS/FEET
■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
• frequency and duration of contact,
• chemical resistance of glove material,
• glove thickness and
• dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
• When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
• When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
• Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly.

Application of a non-perfumed moisturiser is recommended.
• Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
• Double gloving should be considered.
• PVC gloves.
• Protective shoe covers.
• Head covering.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
• polychloroprene
• nitrile rubber
• butyl rubber
• fluorocaoutchouc

• polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

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

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.

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.)

Within each range the appropriate value depends on:

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

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

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; mixes with water, alcohol, chloroform, methylene chloride.

PHYSICAL PROPERTIES
Solid.
Mixes with water

State	Divided solid	Molecular Weight	342.41
Melting Range (°C)	Not available	Viscosity	Not applicable
Boiling Range (°C)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°C)	Not available	pH (1% solution)	Not available
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 (air=1)	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.
■ Side effects from beta-blocking agents include nausea, vomiting, disturbance of the gastrointestinal tract, fatigue and dizziness. The nervous system may be involved, causing depression, delirium, stoppage of breathing, confusion, psychosis, motor abnormalities, coma, visual disturbance and insomnia. Cardiovascular effects include slowing of pulse, low blood pressure, and heart failure. Other adverse effects include blood disorders, and allergic reactions characterised by skin rash. Other effects include sexual dysfunction, allergic reactions, weight

gain, hair loss, muscle disorders, dry eyes and inflammation of the mouth cavity. The signs of overdose usually appear rapidly (within 1-2 hours) and sometimes death occurs.
■ Salts of tartaric acid (including Rochelle salt and Seidlitz powder) and the acid itself have all produced serious poisonings or fatalities in man. Gastrointestinal symptoms are marked and include violent vomiting, diarrhoea, abdominal pain and thirst followed by cardiovascular collapse and/or kidney failure.

EYE
■ There is some evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Moderate inflammation may be expected with redness; conjunctivitis may occur with prolonged exposure.
■ Eye absorption of beta blockers can reduce the pressure in the eye and cause systemic toxicity.

SKIN
■ There is some evidence to suggest that the material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED
■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
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
■ Substance accumulation, in the human body, may occur and may cause some concern following repeated or longterm occupational exposure.
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.
Prolonged use of beta blockers can result in dry mouth, taste distortion, heartburn, stomach pain, nausea, vomiting, loss of appetite, bloating, flatulence, and diarrhoea or constipation. The

nervous system may be affected by fatigue, headache, dizziness, lethargy, depression, "pins and needles", reduced or increased sensation, anxiety, nervousness, poor concentration, sleep loss and nightmares or bizarre dreams. Eye effects include irritation, discomfort, drying, burning sensation, inflammation of the conjunctiva, impaired vision and reduction in eye pressure. Cardiovascular effects include a tight chest pain, heart failure, heart block, claudication and stroke, with chest pain, pallor, shortness of breath, flushing and fainting. Respiratory system effects include blocked nose, cough, crackling sounds, wheezing and lung scarring. Other effects recorded include renal and mesenteric arterial thrombosis, renal failure, ischaemic colitis, f acute pancreatitis, enlarged liver, elevated liver enzymes, altered blood lipids, high blood glucose, impotence or diminished sex drive, painful urination, urination at night, and urinary retention or frequent urination.
Allergic reactions include fever, inflammation of the pharynx, sore throat, throat spasms and respiratory arrest. Effects on the skin include itchiness, pigmentation, necrosis and a purple colour.
The safe use of beta-adrenergic blocking agents is not fully established. Some studies in rats given very large doses of metoprolol showed decreased neonatal survival, but no evidence of teratogenicity has been established.
[FDA Pregnancy Category C - USP DI 14th ed. 1994]

TOXICITY AND IRRITATION
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY
Oral (human) TDLo: 160 mg/kg
Oral (rat) LD50: 5500 mg/kg
Intraperitoneal (rat) LD50: 219 mg/kg
Intravenous (rat) LD50: 90 mg/kg
Oral (mouse) LD50: 1500 mg/kg
Intraperitoneal (mouse) LD50: 202 mg/kg
Subcutaneous (mouse) LD50: 510 mg/kg
Intravenous (mouse) LD50: 90 mg/kg
Oral (dog) LD50: 1090 mg/kg
Oral (rabbit) LD50: 604 mg/kg
Intravenous (rabbit) LD50: 28.7 mg/kg

IRRITATION
Skin: Irritant *
Eye: Irritant *

■ The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
Subcutaneous (rat) 1150 mg/kg Lowered blood pressure, cyanosis, altered sleep time, somnolence, convulsions, reproductive system tumours, hyperglycaemia, foetotoxicity, foetolethality, effects on newborn, specific developmental abnormalities (musculoskeletal system) recorded.

* [United States Pharmacopeial Convention Inc.]

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

METOPROLOL TARTRATE:
■ DO NOT discharge into sewer or waterways..

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.

SAFETY

Safety Codes	Safety Phrases
S22	■ Do not breathe dust.
S25	■ Avoid contact with eyes.
S36	■ Wear suitable protective clothing.
S40	■ To clean the floor and all objects contaminated by this material, use water.
S13	■ Keep away from food, drink and animal feeding stuffs.
S26	■ In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S46	■ If swallowed, IMMEDIATELY contact Doctor or Poisons Information Centre. (show this container or label).

ANNEX 2: Indications of Danger

Xn	Harmful

REGULATIONS

Metoprolol tartrate (CAS: 56392-17-7,55250-54-9,60168-92-5,74220-04-5) 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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