

Levomepromazine Maleate

sc-211736

Material Safety Data Sheet



The Power to Question

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

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Levomepromazine Maleate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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EMERGENCY:

ChemWatch
Within the US & Canada: 877-715-9305
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SYNONYMS

C19-H24-N2-O-S.C4-H4-O4, Minozinan, Milezin, Neuractil, Neurocil, Sofmin, Veractil, "maleate of:", levomepromazine, levo-mepromazine, 10H-phenothiazine-10-propanamine, "2-methoxy-N, N-beta-trimethyl-, (R)-", 2-methoxytrimeprazine, "phenothiazine, 10-[3-(dimethylamino)-2-methylpropyl]-2-methoxy-, (-)-", "(R)-2-methoxy-N, N, beta-trimethyl-10H-phenothiazine-10-propanamine", (-)-10-[3-(dimethylamino)-2-methylpropyl]-2-methoxyphenothiazine, 2-methoxy-10-[2-methyl-3-dimethylamino)propyl]phenothiazine, 3-methoxy-10-[3-dimethylamino-2-methylpropyl]phenothiazine, levomeprazine, "10H-phenothiazine-10-propanamine, 2-methoxy-N, N-beta-trimethyl-, (-)-", "phenothiazine (tricyclic)", "tranquilliser/ antipsychotic/ neuroleptic/ ataractic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	3		

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



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

May cause SENSITISATION by skin contact.

May cause harm to the unborn child.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be damaging to the health of the individual.

■ Side effects of tricyclic antidepressants include dry mouth, sour or metallic taste, constipation, retention of urine, blurred vision and changes in focusing, palpitations, and fast heart beat.

Gastrointestinal disturbances (including nausea and vomiting), drowsiness, tremor, low blood pressure when standing, dizziness, sweating, weakness and fatigue, inco-ordination, epilepsy-like seizures, and speech difficulties may occur.

■ Patients of any age with Major Depressive Disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs.

Patients should be closely monitored, especially at the beginning of therapy or when the dose is changed, until such improvement occurs.

■ Antipsychotics (also known as neuroleptics) are a group of psychoactive drugs commonly but not exclusively used to treat psychosis, which is typified by schizophrenia.

Both first generation drugs (typical antipsychotics) and second generation drugs (atypical antipsychotics) tend to block receptors in the brain's dopamine pathways, but antipsychotic drugs encompass a wide range of receptor targets.

■ Antihistamines have side effects such as sedation, stomach upset (nausea, vomiting, diarrhea or constipation), blurred vision, ringing in the ears, mood changes, irritability, nightmares, loss of appetite, difficulty urinating, dry mouth, chest tightness and tingling, heaviness and weakness in the hands, nervousness, restlessness, irritability, feeling of well-being, disturbed eye movements, difficulties moving the face, "pins and needles", palpitations, faintness, increased heart rate, uncommonly irregular heart rhythms, lung swelling, and disturbed sleep and dreaming.

Treatment may cause side effects within 15 minutes including a dry mouth and throat, blocked nose, wheeze, thick phlegm, fever, sweating, smell disturbances, skin flushing, double vision and dilated pupils.

■ Hypotension is more likely with phenothiazine sedatives with an aliphatic (dimethylaminopropyl) side-chain.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

■ The material is not thought to be a skin irritant (as classified using animal models).

Abrasive damage however, may result from prolonged exposures.

■ 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 either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).

Nevertheless, adverse 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.

CHRONIC HEALTH EFFECTS

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

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

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

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.

Antipsychotic drugs have been shown to chronically elevate prolactin levels in rodents. Increases in mammary neoplasms have been

found in rodents after chronic administration of antipsychotic drugs and are considered to be prolactin-mediated. Increased prolactin levels in serum are a secondary consequence of chronic dopamine antagonism of pituitary lactotrophs. The relevance of the increased incidence of prolactin-mediated mammary gland tumours in rats, to human risk, is unknown. Reproductive and developmental toxicity may also result from exposure to dopamine antagonists; these may result from elevation of serum prolactin. Effects may include prolonged oestrus, pre-implantation loss and alterations to the length of the gestational cycle. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with a previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynaecomastia, and impotence have been reported, the clinical significance of elevated serum prolactin levels is unknown for most patients. Oral administration of phenothiazines with an aliphatic side chain, during the first three months of pregnancy, has been associated with malformations amongst offspring. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Chronic constipation and faecal impaction may occur over a long period. Therapeutic use by pregnant women in the first trimester may produce malformations, prolonged jaundice, depressions and hypothermia in the foetus.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
methotrimeprazine maleate	7104-38-3	>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.

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.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

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

■ The management of NMS (Neuroleptic Malignant syndrome) should include:
 · immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy;
 · intensive symptomatic treatment and medical monitoring and
 · treatment of any concomitant serious medical problems for which specific treatments are available.
 · There is no general agreement about specific pharmacological regimes for NMS.
 Following recent ingestion of an overdose of phenothiazine sedatives, the stomach should be emptied by gastric lavage, and aspiration. Management should include intensive symptomatic, and supportive therapy.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

· Foam.
 · Dry chemical powder.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.
 · Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.
 · Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

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

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

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

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

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

MAJOR SPILLS

■ Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
 - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- methotrimeprazine maleate: CAS:7104-38-3

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

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

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

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

HANDS/FEET

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

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

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

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

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

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

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

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

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

OTHER

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

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

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

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	444.5
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Partly miscible

Flash Point (°F)	Not available	pH (1% solution)	4.3 (0.3% sol)
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

Crystalline solid which darkens in light; does not mix well with water (0.3%, 20 C) or alcohol (0.4%).

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

methotrimeprazine maleate

TOXICITY AND IRRITATION

METHOTRIMEPRAZINE MALEATE:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.
 - Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type.
- No significant acute toxicological data identified in literature search.
- Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

‡ Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

methotrimeprazine maleate (CAS: 7104-38-3) is found on the following regulatory lists;

"Canada National Pollutant Release Inventory (NPRI)"

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes methotrimeprazine maleate 7104- 38- 3

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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