Trimipramine Maleate Salt

sc-213120





Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Trimipramine Maleate Salt

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 Outside the US & Canada: +800 2436 2255 (1–800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C20-H26-N2.C4-H4-O4, "10, 11-dihydro-5-(3-dimethylamino)-2-methylpropyl)-", "5H-dibenz[b, f]azepine maleate (1:1)", "trimeprimine monomaleate", "trimipramine acid maleate", "surmontil maleate"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

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

CANADIAN WHMIS SYMBOLS





EMERGENCY OVERVIEW

Harmful if swallowed.

Possible risk of harm to the unborn child.

Irritating to eyes, respiratory system and skin.

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 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.

EYE

■ This material can cause eye irritation and damage in some persons.

SKIN

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

INHALED

■ The material can cause respiratory irritation in some persons.

The body's response to such irritation can cause further lung damage.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.

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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIE	NTS
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NAME CAS RN % trimipramine maleate 521-78-8 >98

Section 4 - FIRST AID MEASURES

SWALLOWED

· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

FYF

■ 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 fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ For tricyclic antidepressant poisonings: The stomach should be emptied by aspiration and lavage. Activated charcoal as an adjunct to gastric lavage may also be used.

Slowly absorbed from the gastrointestinal tract. Slow gastrointestinal transit time and absorption may be delayed especially in overdose.

Excreted in the urine mainly in the form of metabolites, either free or conjugated. Extensively bound to plasma proteins.

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 (NOx), 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

EXPOSURE CO			TWA		STEL		Peak		
Source	Material	TWA ppm	mg/m³	STEL ppm	mg/m³	Peak ppm	mg/m³	TWA F/CC	Notes
Canada - Ontario Occupational Exposure Limits	trimipramine maleate (Particles (Insoluble or Poorly Soluble) Not Otherwise)		10 (I)						
Canada - British Columbia Occupational Exposure Limits	trimipramine maleate (Particles (Insoluble or Poorly Soluble) Not Otherwise Classified (PNOC))		10 (N)						
Canada - Ontario Occupational Exposure Limits	trimipramine maleate (Specified (PNOS) / Particules (insolubles ou peu solubles) non précisées par ailleurs)		3 (R)						
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	trimipramine maleate (Particulates not otherwise regulated Respirable fraction)		5						
US - California Permissible Exposure Limits for Chemical Contaminants	trimipramine maleate (Particulates not otherwise regulated Respirable fraction)		5						(n)
US - Oregon Permissible Exposure Limits (Z-1)	trimipramine maleate (Particulates not otherwise regulated (PNOR) (f) Total Dust)	-	10						Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated."
US - Michigan Exposure Limits for Air Contaminants	trimipramine maleate (Particulates not otherwise regulated, Respirable dust)		5						
US - Oregon Permissible Exposure Limits (Z-1)	trimipramine maleate (Particulates not otherwise regulated (PNOR) (f) Respirable	-	5						Bold print identifies substances for which the Oregon Permissible Exposure

Fraction)

Limits (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated."

trimipramine US - Wyoming maleate Toxic and (Particulates not Hazardous otherwise Substances regulated Table Z1 Limits (PNOR)(f)for Air Respirable

5

10

trimipramine maleate Canada - Prince (Particles

fraction)

(Insoluble or Poorly Soluble) [NOS] Inhalable particles)

See Appendix B current TLV/BEI Book

ENDOELTABLE

Exposure Limits

Contaminants

Edward Island

Occupational

PERSONAL PROTECTION









RESPIRATOR

· particulate.

■ When handling very small quantities of the material eve 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.

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	410.5
Melting Range (°F)	284- 291	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
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

White, odourless crystalline powder with bitter numbing taste; does not mix well with water. Soluble in chloroform, methanol Trimipramine maleate is prepared as a racemic mixture which can be resolved into levorotatory and dextrorotatory isomers

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

trimipramine maleate

TOXICITY AND IRRITATION

TRIMIPRAMINE MALEATE:

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

TOXICITY	IRRITATION
Oral (rat) LD50: 800 mg/kg	Nil Reported
Intraperitoneal (rat) LD50: 150 mg/kg	
Subcutaneous (rat) LD50: 308 mg/kg	
Intravenous (rat) LD50: 38 mg/kg	
Oral (mouse) LD50: 425 mg/kg	
Intraperitoneal (mouse) LD50: 140 mg/kg	
Subcutaneous (mouse) LD50: 240 mg/kg	
Intravenous (mouse) LD50: 40 mg/kg	

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

Convulsions, respiratory depression, foetotoxicity, foetolethality, specific developmental abnormalities (central nervous system), body temperature decrease recorded.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Semen studies in man (four schizophrenics and nine normal volunteers) revealed no significant changes in sperm morphology. It is recognized that drugs having a parasympathetic effect, including tricyclic antidepressants, may alter the ejaculatory response.

Chronic animal studies showed occasional evidence of degeneration of seminiferous tubules at the highest dose of 60 mg/kg/day.

Trimipramine maleate has shown evidence of embryotoxicity and/or increased incidence of major anomalies in rats or rabbits at doses 20 times the human dose.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient Persistence: Water/Soil Persistence: Air Bioaccumulation Mobility

trimipramine maleate No Data Available No Data Available

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

trimipramine maleate (CAS: 521-78-8) is found on the following regulatory lists;

"Canada - British Columbia Occupational Exposure Limits", "Canada - Ontario Occupational Exposure Limits", "Canada - Prince Edward Island Occupational Exposure Limits", "Canada National Pollutant Release Inventory (NPRI)", "US - California Permissible Exposure Limits for Chemical Contaminants", "US - Michigan Exposure Limits for Air Contaminants", "US - Oregon Permissible Exposure Limits (Z-1)", "US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants", "US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants"

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes trimipramine maleate 521- 78- 8 Mut3; R68 Rep3; R63 Xn; R22 N; R50/53

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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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