# Clomipramine hydrochloride

# sc-203898

**Material Safety Data Sheet** 



The Power to Oscotion

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

# Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

# **PRODUCT NAME**

Clomipramine hydrochloride

# STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

# HEALTH AZARD INST BLITY

# **SUPPLIER**

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

# EMERGENCY:

ChemWatch

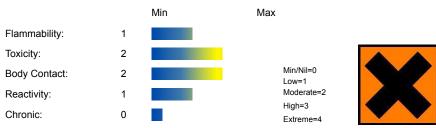
Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

# **SYNONYMS**

C19-H23-CI-N2, "chlorimipramine hydrochloride", "3-chloro-5-(3-(dimethylamin)propyl)-10, 11-dihydro-5H-dibenz[b, ", f]azepine.HCl, "3-chloroimipramine hydrochloride", "chloroimipramine monohydrochloride", Anafranil, A-34586, Anaphranil, Placil, "tricyclic antidepressant"

# **Section 2 - HAZARDS IDENTIFICATION**

# **CHEMWATCH HAZARD RATINGS**



# **CANADIAN WHMIS SYMBOLS**



# **EMERGENCY OVERVIEW**

#### risk

Harmful by inhalation, in contact with skin and if swallowed

## **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.

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■ 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.

There has been a long-standing concern that some antidepressants may have a role in the emergence of suicidality in some patients. The possible risk of increased suicidality in patients applies to all classes of antidepressant medicines, as available data are not adequate to exclude this risk for any antidepressant. Therefore, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms. Generally, when stopping an antidepressant, doses should be tapered rather than stopped abruptly

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania and mania, have been reported in adult and paediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.

Mania and Bipolar Disorder: A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with any antidepressant alone may increase the likelihood of a mixed-manic episode in patients at risk for bipolar disorder. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder.

## 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. <\p>.

## SKIN

- Skin contact with the material may be harmful; systemic effects may resultfollowing absorption.
- The material is not thought to be a skin irritant (as classified using animal models). Abrasive damage however, may result from prolonged exposures.

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- 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**

- Inhalation of dusts, generated by the material, during the course of normalhandling, may be harmful.
- The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
- 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 the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course.

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 INGREDIENTS

NAME	CAS RN	%
clomipramine hydrochloride	17321-77-6	>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:

#### 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 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.

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Readily absorbed from the gastrointestinal tract. Slow gastrointestinal transit time and absorption may be delayed especially in overdose. Extensively demethylated in the liver producing the primary active metabolite desmethylclomipramine. Excreted in the urine mainly as free or conjugated metabolites. Reported plasma half-life range from 17 to 28 hours. Extensively bound to plasma and tissue protein.

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**

- · Water spray or fog.
- · Foam.

## **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), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

May emit poisonous 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**

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
US - California Permissible Exposure Limits for Chemical Contaminants	clomipramine hydrochloride (Particulates not otherwise regulated Respirable fraction)		5						(n)
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	clomipramine hydrochloride (Particulates not otherwise regulated Respirable fraction)		5						
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	clomipramine hydrochloride (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)		5						
US - Michigan Exposure Limits for Air Contaminants	clomipramine hydrochloride (Particulates not otherwise regulated, Respirable dust)		5						
Canada - Prince Edward Island Occupational Exposure Limits	clomipramine hydrochloride (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable		10						See Appendix B current TLV/BEI Book

#### **ENDOELTABLE**

## 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

- 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.

Mixes with water.

mixed man mater.			
State	Divided solid	Molecular Weight	351.3
Melting Range (°F)	377.6	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
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; mixes with water (1:8), alcohol (1:5), chloroform (1:3).

# 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

CLOMIPRAMINE HYDROCHLORIDE

# **TOXICITY AND IRRITATION**

CLOMIPRAMINE HYDROCHLORIDE:

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

TOXICITY	IRRITATION
Oral (rat) LD50: 914 mg/kg	Nil Reported
Intraperitoneal (rat) LD50: 135 mg/kg	
Subcutaneous (rat) LD50: 1750 mg/kg	
Intravenous (rat) LD50: 26 mg/kg	
Oral (mouse) LD50: 470 mg/kg	
Intraperitoneal (mouse) LD50: 90 mg/kg	
Subcutaneous (mouse) LD50: 400 mg/kg	I
Intravenous (mouse) LD50: 22 mg/kg	

Oral (dog) LD50: 383 mg/kg

Convulsions, increased pulse rate, cyanosis, foetolethality, effects on newborn recorded.

# Section 12 - ECOLOGICAL INFORMATION

No data

# **GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles**

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg), C2=Acutemammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation& corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic, I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floater, S=Sinking

substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

# 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

clomipramine hydrochloride (CAS: 17321-77-6) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)", "US - Maine Chémicals of High Concern List"

# **Section 16 - OTHER INFORMATION**

## ND

Substance CAS Suggested codes clomipramine hydrochloride 17321-77-6

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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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