# Tizanidine • HCI

# sc-200148

# **Material Safety Data Sheet**



The Power to Questi

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

# Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

#### **PRODUCT NAME**

Tizanidine • HCI

# STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

# NFPA FLAME BILITY 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

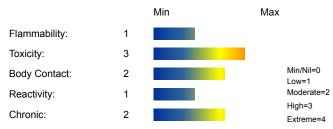
Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

# **SYNONYMS**

C9-H8-Cl-N5-S.HCl, "5-chloro-N-(4, 5-dihydro-1H-imidazol-2-yl)-2, 1, 3-benzothiadiazol-4-", "amine hydrochloride", "5-chloro-4-(2-imidazolin-2-ylamino)-2, 1, 3-benzothiadiazole", hydrochloride, AB-021, DS-103-282, Sirdalud, Ternelin, Zanaflex, "skeletal muscle relaxant"

# **Section 2 - HAZARDS IDENTIFICATION**

# **CHEMWATCH HAZARD RATINGS**



# **CANADIAN WHMIS SYMBOLS**



# EMERGENCY OVERVIEW RISK

Harmful if swallowed.

Possible risk of harm to the unborn child.

Irritating to eyes, respiratory system and skin.

Inhalation may produce serious health damage\*.

Cumulative effects may result following exposure\*.

\* (limited evidence).

#### 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.
- Skeletal muscle relaxants (called spasmolytics or antispasmodics) may have the following side-effects: sedation, drowsiness, blurred or double vision, constipation or diarrhoea, impairment of mental or physical abilities required for driving or operating hazardous machinery, dizziness and drowsiness, nervousness and confusion, an unpleasant taste in the mouth, dry mouth, recurrent stomach pain, fatigue, headache, heartburn, hiccups and nausea, sleep problems, stomach cramps, and dependence following long-term use.

#### 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.
- 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.

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.

■ Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may produce serious damage to the health of the individual.

# **CHRONIC HEALTH EFFECTS**

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Prolonged cessation of breathing may follow exposure to competitive or depolarising muscle relaxants.

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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS			
NAME	CAS RN	%	
Tizanidine • HCI	64461-82-1	>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:

- Immediately hold eyelids apart and flush the eye continuously with 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.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

#### **INHALED**

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor, without delay.

#### **NOTES TO PHYSICIAN**

■ for poisons (where specific treatment regime is absent):

#### BASIC TREATMENT

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

#### \_\_\_\_\_

# ADVANCED TREATMENT

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

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

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

	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.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog Large fires only.

#### **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.

When any large container (including road and rail tankers) is involved in a fire,

consider evacuation by 800 metres in all directions.

#### GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- 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.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary 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)
- When processed with flammable liquids/vapors/mists,ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable
  mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required
  to ignite dust clouds MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture
  will be lower than the individual LELs for the vapors/mists or dusts
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to
  damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust
  layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted
  from chain reactions of this type.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-meter/sec
- A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or
  pressure, may result in ignition especially in the absence of an apparent ignition source
- One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours).
- Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride, phosgene, nitrogen oxides (NOx), sulfur oxides (SOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

#### FIRE INCOMPATIBILITY

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

# **Section 6 - ACCIDENTAL RELEASE MEASURES**

#### MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labelled container for waste disposal.

#### MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Neutralise/decontaminate residue (see Section 13 for specific agent).
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

#### **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.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
- Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be
  given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA
  Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.
- Do not use air hoses for cleaning.
- Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used.
- Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition.
- Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance.
- Do not empty directly into flammable solvents or in the presence of flammable vapors.
- The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic
  bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges.

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

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

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):

- Removable head packaging;
- Cans with friction closures and
- low pressure tubes and cartridges

may be used.

- ´

Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages \*.

In addition, where inner packagings are glass and contain liquids of packing group I and II there must be sufficient inert absorbent to absorb any spillage \*.

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

All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

#### 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.

# Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

# **EXPOSURE CONTROLS**

The following materials had no OELs on our records

• tizanidine hydrochloride: CAS:64461-82-1

# PERSONAL PROTECTION









# **RESPIRATOR**

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

#### **EYE**

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

- Chemical googles
- 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], [AS/NZS 1336 or national equivalent]

# HANDS/FEET

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

- 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, AS/NZS 2161.1 or national equivalent).

- 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, AS/NZS 2161.10.1 or national equivalent) 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, AS/NZS 2161.10.1 or national equivalent) 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, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.
- Wash hands immediately after removing gloves.
- Protective shoe covers. [AS/NZS 2210]
- Head covering.

#### **OTHER**

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

#### **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)  Within each range the appropriate value depends on:	1-2.5 m/s (200-500 f/min.)
Lower end of the range	Upper end of the range

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**

#### **PHYSICAL PROPERTIES**

Toxic or noxious vapours/gas.

State	Divided Solid	Molecular Weight	290.2
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)	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 Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

# **APPEARANCE**

Fine crystalline powder, which is odorless or with a faint characteristic odor. Tizanidine is slightly soluble in water and methanol; solubility in water decreases as the pH increases. mixes with water.

# **Section 10 - CHEMICAL STABILITY**

#### CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

#### STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents

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

# **Section 11 - TOXICOLOGICAL INFORMATION**

tizanidine hydrochloride

# **TOXICITY AND IRRITATION**

TIZANIDINE HYDROCHLORIDE:

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

TOXICITY IRRITATION

Oral (Rabbit) LD50: 98 mg/kg

Oral (Rat) LD50: 414 mg/kg

Subcutaneous (Rat) LD50: 282 mg/kg

Intravenous (Rat) LD50: 35 mg/kg

Oral (Mouse) LD50: 235 mg/kg

#### Intravenous (Mouse) LD50: 48 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.

Carcinogenesis, Mutagenesis and Impairment of Fertility

No evidence for carcinogenicity was seen in two dietary studies in rodents. Tizanidine was administered to mice for 78 weeks at doses up to 16 mg/kg, which is equivalent to 2 times the maximum recommended human dose on a mg/m2 basis. Tizanidine was also administered to rats for 104 weeks at doses up to 9 mg/kg, which is equivalent to 2.5 times the maximum recommended human dose on a mg/m2 basis. There was no statistically significant increase in tumors in either species.

Tizanidine was not mutagenic or clastogenic in the following in vitro assays: the bacterial Ames test and the mammalian gene mutation test and chromosomal aberration test in Chinese hamster cells. It was also negative in the following in vivo assays: the bone marrow micronucleus test in mice, the bone marrow micronucleus and cytogenicity test in Chinese hamsters, the dominant lethal mutagenicity test in mice, and the unscheduled DNA synthesis (UDS) test in mice.

Tizanidine did not affect fertility in male rats at doses of 10 mg/kg, approximately 2.7 times the maximum recommended human dose on a mg/m2 basis, and in females at doses of 3 mg/kg, approximately equal to the maximum recommended human dose on a mg/m2 basis; fertility was reduced in males receiving 30 mg/kg (8 times the maximum recommended human dose on a mg/m2 basis) and in females receiving 10 mg/kg (2.7 times the maximum recommended human dose on a mg/m2 basis). At these doses, maternal behavioral effects and clinical signs were observed including marked sedation, weight loss, and ataxia.

Reproduction studies performed in rats at a dose of 3 mg/kg, equal to the maximum recommended human dose on a mg/m2 basis, and in rabbits at 30 mg/kg, 16 times the maximum recommended human dose on a mg/m2 basis, did not show evidence o teratogenicity. Tizanidine at doses that are equal to and up to 8 times the maximum recommended human dose on a mg/m2 basis increased gestation duration in rats. Prenata and postnatal pup loss was increased and developmental retardation occurred. Post implantation loss was increased in rabbits at doses of 1 mg/kg or greater, equal to or greate than 0.5 times the maximum recommended human dose on a mg/m2 basis.

#### **Section 12 - ECOLOGICAL INFORMATION**

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

#### **Ecotoxicity**

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
tizanidine hydrochloride	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.

- 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. In most instances the supplier of the material should be consulted.

- 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 - TRANSPOR	RTATION INFORMATION	
DOT:			
Symbols:	None	Hazard class or Division:	6.1
Identification Numbers:	UN3249	PG:	II
Label Codes:	6.1	Special provisions:	T3, TP33
Packaging: Exceptions:	153	Packaging: Non-bulk:	212
Packaging: Exceptions:	153	Quantity limitations: Passenger aircraft/rail:	5 kg
Quantity Limitations: Cargo aircraft only:	5 kg	Vessel stowage: Location:	С
Vessel stowage: Other:	40		
Hazardous materials descriptions Medicine, solid, toxic, n.o.s. <b>Air Transport IATA:</b>	and proper shipping names:		
ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None
UN/ID Number:	3249	Packing Group:	II
Special provisions:	A3		
Cargo Only			
Packing Instructions:	676	Maximum Qty/Pack:	100 kg
Passenger and Cargo		Passenger and Cargo	
Packing Instructions:	669	Maximum Qty/Pack:	25 kg
Passenger and Cargo Limited Quantity		Passenger and Cargo Limited Quantity	
Packing Instructions:	Y644	Maximum Qty/Pack:	1 kg
Shipping name:MEDICINE, SOLII Maritime Transport IMDG:	D, TOXIC, N.O.S.(contains tizanidi	ne hydrochloride)	
IMDG Class:	6.1	IMDG Subrisk:	None
UN Number:	3249	Packing Group:	II
EMS Number:	F-A,S-A	Special provisions:	221
Limited Quantities: 500 g Shipping name:MEDICINE, SOLID, TOXIC, N.O.S.(contains tizanidine hydrochloride)			

# **Section 15 - REGULATORY INFORMATION**



# tizanidine hydrochloride (CAS: 64461-82-1) is found on the following regulatory lists;

"Canada Substances in Products Regulated Under the Food and Drugs Act (F&DA) That Were In Commerce between January 1, 1987 and September 13, 2001 (English)"

# **Section 16 - OTHER INFORMATION**

#### LIMITED EVIDENCE

- Inhalation may produce serious health damage\*.
- Cumulative effects may result following exposure\*.
- \* (limited evidence).
- 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.
- For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:

OSHA Standards - 29 CFR:

1910.132 - Personal Protective Equipment - General requirements

1910.133 - Eye and face protection

1910.134 - Respiratory Protection

1910.136 - Occupational foot protection

1910.138 - Hand Protection

Eye and face protection - ANSI Z87.1

Foot protection - ANSI Z41

Respirators must be NIOSH approved.

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www.Chemwatch.net

Issue Date: Dec-16-2009 Print Date:Mar-13-2012