Material Safety Data Sheet

Telmisartan

sc-204907

Hazard Alert Code

Key:

- EXTREME
- HIGH
- MODERATE
- LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Telmisartan

STATEMENT OF HAZARDOUS NATURE

NFPA

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<th>Min</th>
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<tr>
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Canadian WHMIS Symbols

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<th>Moderate=2</th>
<th>High=3</th>
<th>Extreme=4</th>
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<td>Chronic</td>
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Suppliers
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
C33H30N4O2, "4' -((2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-", 1-yl), "methyl)biphenyl-2-carboxylic acid", "BiBR 277 SE", antihypertensive, "angiotensin II receptor blocker", "ACE inhibitor"
EMERGENCY OVERVIEW

RISK
Harmful 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.
- ACE inhibitors are fairly safe and serious overdoses are rare.
  Overdoses may cause low blood pressure, increased heart rate and reversible kidney failure.
- Harmful if swallowed.

EYE

- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn).
  Slight abrasive damage may also result.

SKIN

- Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models).
  Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
  Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models).
  Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

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

Based on experience with animal studies, there is a possibility that 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.

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.

ACE inhibitors may aggravate kidney and collagen vascular disorders. They may cause injury and death to the foetus late in pregnancy.

There has been low blood pressure of the newborn, kidney failure, underdevelopment of the skull and lungs, insufficient amniotic fluid, and foetal growth retardation and limb contractures. Miscarriage or stillbirth may occur. ACE inhibitors can cause growths in glands, but rarely cause malignant cancer.

Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deepdermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitization (cross-sensitivity).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>telmisartan</td>
<td>144701-48-4</td>
<td>100</td>
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</tbody>
</table>
### 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.

**EYE**
If this product comes in contact with the eyes
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

**SKIN**
If skin or hair contact occurs
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

**INHALED**
- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

### Section 5 - FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Vapor Pressure (mmHG)</td>
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<tr>
<td>Upper Explosive Limit (%)</td>
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<tr>
<td>Specific Gravity (water=1)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

**EXTINGUISHING MEDIA**
- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

**FIRE FIGHTING**
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.

**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.
- 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 vapors, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Combustion products include carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
- May emit poisonous fumes.
- Dusts with Minimum Ignition Energies (MIEs) of less than 10mJ are extremely sensitive to ignition.
- Precautions should be as for flammable liquids and gases. They require that
- plant is grounded
personnel might also need to be grounded
Minimum Ignition Energy 1-3 mJ (24 C).
Slightly sensitive to impact (method drop-weight test; borderline).
Slightly sensitive to friction.

**FIRE INCOMPATIBILITY**
- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

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### 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.

#### MAJOR SPILLS
Moderate hazard.
- CAUTION Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.

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### 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.

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 is suitable for laboratory quantities
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

#### 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.

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### Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

#### EXPOSURE CONTROLS
The following materials had no OELs on our records
- telmisartan  CAS144701-48-4

#### PERSONAL PROTECTION

**RESPIRATOR**
Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, ANSI Z88 or national equivalent)

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 lenses 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
- 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. [AS/NZS 2210]
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
- fluoroelastomer

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.

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.
- 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.

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<th>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</th>
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<th>Melting Range (°F)</th>
<th>Boiling Range (°F)</th>
<th>Flash Point (°F)</th>
<th>Decomposition Temp (°F)</th>
<th>Autoignition Temp (°F)</th>
<th>Upper Explosive Limit (%)</th>
<th>Lower Explosive Limit (%)</th>
<th>Volatile Component (%vol)</th>
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<td>Not applicable</td>
<td>&gt;336</td>
<td>680; 513</td>
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<td>Molecular Weight</td>
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<td>Viscosity</td>
<td>Solubility in water (g/L)</td>
<td>pH (1% solution)</td>
<td>Vapor Pressure (mmHG)</td>
<td>Specific Gravity (water=1)</td>
<td>Relative Vapor Density (air=1)</td>
<td>Evaporation Rate</td>
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APPEARANCE
Powder with a very faint odor; insoluble in water. Glow temperature >435 deg. C.

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 oxidizing agents

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

Section 11 - TOXICOLOGICAL INFORMATION

telmisartan

TOXICITY AND IRRITATION
No data for this material.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

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<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
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<td>No Data Available</td>
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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 cannot 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 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

telmisartan (CAS: 144701-48-4) is found on the following regulatory lists;
“US FDA Maximum Recommended Therapeutic Dose (MRTD) Database”

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Cumulative effects may result following exposure*.
- May possibly be harmful to the foetus/embryo*.
  * (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.
- 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

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