

Leflunomide 3-Isomer: sc-211731



The Power to Question

MATERIAL SAFETY DATA SHEET

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Leflunomide 3-Isomer
Product Number: sc-211731
Supplier: Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, CA 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

SECTION 2 – HAZARD INFORMATION

EMERGENCY OVERVIEW – Toxic. Reproductive Hazard. Irritant.

This material is an isomer of leflunomide. Information on the chemical, physical and toxicological properties is not readily available. For reference, health hazard information on leflunomide is provided. It is not known if this material causes the same effects.

Adverse Effects: Adverse effects of leflunomide may include congestion; difficulty breathing; loss of appetite; nausea or vomiting; yellow eyes or skin; dizziness; headache; cough; fever; sneezing; sore throat; bloody or cloudy urine; difficult, burning, or painful urination; frequent urge to urinate; unusual tiredness or weakness; chest pain; stomach or abdominal pain; indigestion; fast or pounding heartbeat; burning, prickling, or tingling sensations in fingers and/or toes; joint or muscle pain; hair loss; back pain; heartburn; skin rash; red or irritated eyes; dry mouth; itching skin, and runny nose. It is not known if this material has the same effects. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, bone marrow dysplasia, severe immunodeficiency, severe or uncontrolled infections, impaired liver or kidney function including hepatitis B or C, and history of blood abnormalities.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Leflunomide Related Compound C

Formula: C₁₂H₉F₃N₂O₂

Synonym: n/f

Chemical Name: N-(3-trifluoromethylphenyl)-5-methylisoxazol-4-carboxamid

CAS: 61643-23-0

RTECS Number: n/f

Chemical Family: n/f

Therapeutic Category: n/f

Composition: Pure Material

SECTION 4 – FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. Perform gastric lavage soon after ingestion. Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first.
3. Monitor vital signs regularly.
4. For mild/moderate asymptomatic hypertension (no end organ damage), treatment is generally not necessary. For agitated patients with hypertension and tachycardia, sedate with benzodiazepines. For severe hypertension, administer nitroprusside. Labetalol, nitroglycerin, and phentolamine are alternatives.
5. The main active metabolite of leflunomide, M1, is not dialyzable. [Meditext 2007]

SECTION 5 – FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

SECTION 7 – HANDLING AND STORAGE

Handling: As a general rule when handling, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container. This material should be handled and stored per label instructions to ensure product integrity. Store in a refrigerator.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Exposure Limits: n/f

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Melting Range: n/f

Boiling Point: n/f

Specific Gravity: n/f

Vapor Pressure: n/f

Percent Volatile: n/f

Vapor Density: n/f

Solubility in Water: n/f

Appearance and Odor: Fine yellowish-white powder.

Evaporation Rate: n/f

Reactivity in Water: n/f

Properties as indicated on the MSDS are general.

Odor Threshold: n/f

pH: n/f

Flash Point: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Fat Solubility: n/f

Other Solubility: n/f

Partition Coefficient: n-octanol/water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Molecular Weight: 270.21

Formula: C₁₂H₉F₃N₂O₂

Autoignition Temperature: n/f

Stable? Yes

Conditions to Avoid: Avoid exposure to light and heat.

Incompatibilities: Strong oxidizing agents

Decomposition Products: When heated to decomposition material emits toxic fumes of NO_x and HF. Emits toxic fumes under fire conditions.

Hazardous Polymerization? No

SECTION 10 – STABILITY AND REACTIVITY

Oral Rat: LD50: n/f

Oral Mouse: LD50: n/f

NTP: No **IARC:** No **OSHA:** No

Listed as a Carcinogen by:

Irritancy Data: Rabbit/eye: slight (leflunomide); Rabbit/skin: non-irritant (leflunomide)

SECTION 11 – TOXICOLOGICAL PROPERTIES

Other Toxicity Data: n/f

Corrosivity: n/f

Sensitization Data: Guinea Pig: negative (leflunomide)

Other Carcinogenicity Data: The risk of malignancy, especially lymphoproliferative disorders, is increased with use of some immunosuppression, though no apparent increase in the incidence of malignancies or lymphoproliferative disorders were reported in clinical trials.

There was no evidence of carcinogenicity in a 2-year study in rats given oral leflunomide at doses up to 6 mg/kg. Male mice administered 15 mg/kg for two years exhibited an increased incidence of lymphoma, and female mice, in the same study, exhibited a dose-related increased incidence of bronchoalveolar adenomas and carcinomas combined beginning at 1.5 mg/kg.

Mutagenicity Data: Leflunomide was not mutagenic in the Ames test, the unscheduled DNA synthesis assay, or in the HGPRT gene mutation assay. A minor metabolite of leflunomide, 4-trifluoromethylamine (TFMA), was mutagenic in the Ames test and the HGPRT gene mutation assay. There was no evidence of clastogenicity with leflunomide or TFMA in the in vivo mouse micronucleus assay or in the cytogenic test in Chinese hamster bone marrow cells. There was no evidence of clastogenic activity with TFMA in the in vitro assay for chromosome aberration in the Chinese hamster cells.

Reproductive and Developmental Effects: Leflunomide has caused death, growth retardation, and malformations in rats and rabbits.

The no-effect level for both species was 1 mg/kg.

Therapeutic use of leflunomide is considered contraindicated in pregnancy. In a study of leflunomide-exposed pregnancies, out of 63 pregnancies there were six miscarriages (9.7%). Of the 54 reported live births, two babies were born with structural defects (3.7%) and two with microcephaly (3.7%). The rate of babies with structural defects in a disease-matched comparison group was 4.2% and in a non-diseased comparison group was 3.7%. In 14 reported live births from another leflunomide-exposed group, there were no structural defects and one report of hearing loss in the infants. (Organization of Teratology Information Specialists, 2006)

SECTION 12 – ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 -TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 – REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

SECTION 16 – OTHER INFORMATION

The above information is believed to be correct but does not purport to be complete and should be used only as a guide. The burden of safe use of this material rests entirely with the user.

10/13/2010