

**Section 1: Identification**

**Product Name** Leflunomide USP  
**Commercial Name** Not available.  
**Product Use** Not available.  
**Restrictions On Use** Not available.  
**Product Code** 50-4520  
**Company** PCCA  
9901 South Wilcrest  
Houston, TX 77099  
Phone: 1-800-331-2498  
Fax: 1-800-874-5760

In case of emergency contact:  
**CHEMTREC (24hr) 1-800-424-9300**

**Section 2: Hazard(s) Identification**

**OSHA Haz Com:** Acute toxicity, oral Category 3 Reproductive toxicity Category 1 specific target organ toxicity repeated exposure Category 1 (liver, Immune system)

**CFR 1910.1200**

**Signal Word** DANGER

**Hazard Statement(s)** Toxic if swallowed.

**Pictogram(s) or Symbol(s)**



**Precautionary Statement(s):**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.

**Storage** Store locked up

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations

**Section 3: Composition/Information on Ingredients**

**Substance/Mixture** Substance  
**Components** Leflunomide USP  
**% By Weight** 100  
**CAS#** 75706-12-6  
**Molecular Weight** 270.21  
**Chemical Formula** C<sub>12</sub>H<sub>9</sub>F<sub>3</sub>N<sub>2</sub>O<sub>2</sub>  
**Synonym(s)** HWA - 486, ARAVA, SU - 101

**Mixtures**

<b>Name</b>	<b>CAS#</b>	<b>% by Weight</b>	<b>TLV/PEL</b>	<b>LC50/LD50</b>
Leflunomide USP	75706-12-6	Not available.	Not available.	Not available.

**Section 4: First-Aid Measures**

<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur
<b>Skin Contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists
<b>Eye Contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Symptoms/Effects</b>	
<b>Acute</b>	Liver damage. Immunosuppression. Reproductive system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects
<b>Delayed</b>	Liver damage. Immunosuppression. Reproductive system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

**Immediate Medical Attention**

Treat symptomatically. An active metabolite of this material has a long half-life, and an 11-day washout treatment with orally administered cholestyramine or activated charcoal may be needed for its elimination. Treatment may include the following: Administer activated charcoal as a slurry or cholestyramine to enhance elimination. 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. Monitor vital signs regularly. 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. The main active metabolite of leflunomide is not dialyzable. [Meditext 2007, USP DI 2007]

**Section 5: Fire-Fighting Measures****Suitable Extinguishing Media**

Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials

**Unsuitable Extinguishing Media**

Not available.

**Products of Combustion**

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**Firefighters Special Equipment and Precautions**

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

**Section 6: Accidental Release Measures**

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Methods and materials for containment and cleaning up: For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

**Section 7: Handling and Storage**

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

**Section 8: Exposure Controls/Personal Protection****Exposure Limits**TWA 0.005 mg/m<sup>3</sup>**Engineering Controls**

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Personal Protection**

**Eye/face protection:** Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. **Skin protection** **Hand protection:** Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. **Other:** Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. **Respiratory protection:** Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls. **Thermal hazards:** Wear appropriate thermal protective clothing, when necessary. **General hygiene considerations:** Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	White powder		
<b>Odor</b>	odorless		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	325.4 - 334.4 °F (163 - 168 °	<b>pH</b>	Not available.
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	Not available.
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	Not available.	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	Not available.	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	Not available.
<b>Flammability</b>	Not available.	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available.
		<b>Upper</b>	Not available.
<b>Solubility(ies)</b>	Practically insoluble in water.		
<b>Other</b>	Acetone: Freely soluble. Chloroform: Freely soluble. Ethanol: Freely soluble. Methanol: Freely soluble Chemical family Isoxazole derivative. Dust explosion properties Minimum ignition energy (MIE) - dust cloud 20 - 32 mJ Molecular formula C <sub>12</sub> H <sub>9</sub> F <sub>3</sub> N <sub>2</sub> O <sub>2</sub> Molecular weight 270.21		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability</b>	Material is stable under normal conditions
<b>Hazardous Polymerization</b>	No dangerous reaction known under conditions of normal use
<b>Conditions to Avoid</b>	Contact with incompatible materials.
<b>Incompatible Materials</b>	Strong oxidizing agents
<b>Hazardous Decomposition Products</b>	F-, NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

**Section 11: Toxicological Information****RTECS** NY2354200**Acute Toxicity**

Toxic if swallowed

**Skin Corrosion/Irritation**

Not available

**Serious Eye Damage/Irritation**

Not available

**Respiratory or Skin Sensitization**

Not available

**Germ Cell Mutagenicity**

Not available

**Carcinogenicity**

Not available

**Reproductive Toxicity**

May damage fertility or the unborn child. Pyrimidine synthesis inhibitors interfere with embryo development and viability at maternally toxic doses in animals.

**Routes of Entry**

Ingestion (liver damage)

**Symptoms Related to Exposure**

Pyrimidine synthesis inhibitors: Gastrointestinal disturbances. Increased liver enzymes. Blood disorders. Hypertension. Headache. Dizziness. Immunosuppression.

**Potential Health Effects**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Target Organ(s)**

Causes damage to organs (Liver, Immune system) through prolonged or repeated exposure

**Section 12: Ecological Information****Ecotoxicity**

Aquatic Algae EC50 Algae 22.42 mg/l, 72 hours Crustacea EC50 Daphnia magna 17 mg/l, 48 hours Fish LC50 Zebra danio (Danio rerio) 3.74 mg/l, 48 hours

**Persistence and Degradability**

Not available.

**Bioaccumulative Potential**

Not available.

**Mobility in Soil**

Not available.

**Other Adverse Effects**

Not available.

**Section 13: Disposal Considerations****Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner

**Disposal of Container**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**Other Considerations**

Not available.

**Section 14: Transport Information****DOT Classification**

DOT UN number: UN2811 UN proper shipping name: Toxic solid, organic, n.o.s. (Leflunomide) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing group III

**Section 15: Regulatory Information****Regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated. Superfund Amendments and Reauthorization Act of 1986 (SARA) Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No Hazard categories SARA 302 Extremely hazardous substance Not listed. Yes SARA 311/312 Hazardous chemical SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins

**Other**

Not available.

**Section 16: Other Information**

The information given in this data sheet is based on the present status of our knowledge, but any conclusions and recommendations are made without liability on our part. Buyers and users should make their own assessment of our product under their own conditions and for their own requirement.