


Section 1: Identification

Common Name/Trade Name	KETOPROFEN MICRONIZED USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	Ketoprofen	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 3), Skin irritation (Category 2), Eye irritation (Category 2), Specific target organ toxicity - single exposure (Category 3) Respiratory system	
Signal Word	Danger	
Hazard Statement(s)	H301 H315 H319 H335	Toxic if swallowed Causes skin irritation Causes serious eye irritation May cause respiratory irritation
Pictogram(s)		
Precautionary Statement(s)	P261 P301+P310 P305+P351+P338 P321 P405 P501	Avoid breathing dust/fume/gas/mist/vapours/spray. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. Specific treatment (see on this label). Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Ketoprofen
Common Name	Ketoprofen Micronized USP
CAS Number	22071-15-4
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If Inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Seek immediate medical advice.
In Case of Skin Contact	In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
In Case of Eye Contact	Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, Consult an eye specialist
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician
Most Important Symptoms and Effects	Information for doctor: Treat symptomatically and supportively. The following symptoms may occur: Eye contact: Inflammation of the eye is characterized by redness, watering, and itching. Skin contact: Inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable extinguishing agents: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. For safety reasons unsuitable extinguishing agents: Water jet: - this may increase fire intensity.
Special Hazards Arising From the Substance/Mixture	Carbon dioxide (CO ₂) Carbon monoxide (CO)
Special PPE and/or Precautions for Firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment.
Methods and Materials Used for Containment	Prevent further leakage or spillage if safe to do so. Do not let product enter drains
Cleanup Procedures	Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Conditions for Safe Storage	Requirements to be met by storerooms and receptacles: Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Information about storage in one common storage facility: Keep away from incompatibles such as oxidizing agents Further information about storage conditions: Store receptacle in a well ventilated area. Keep container tightly sealed.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Ingredients with limit values that require monitoring at the workplace: Not required.
Appropriate Engineering Controls	Additional information about design of technical facilities: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. General protective and hygienic measures: Provide good ventilation and /or an exhaust system in the work area. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.
PPE - Eye/Face Protection	Tightly sealed goggles
PPE - Skin Protection	Protective gloves The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation $\hat{A}??\hat{A}?$ Material of gloves The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. $\hat{A}??\hat{A}?$ Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
PPE - Body Protection	Protective gloves The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation $\hat{A}??\hat{A}?$ Material of gloves The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. $\hat{A}??\hat{A}?$ Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
PPE - Respiratory Protection	In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Section 9: Physical and Chemical Properties

Appearance	Form: Solid (Crystalline powder) Colour: White to Off-white
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless
Vapor Pressure	at 25°C: 3.32E-08 hPa
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	93-97°C
Solubility	Solubility in / Miscibility with water at 25°C: 0.5 mg/ml Insoluble
Initial Boiling Point and Boiling Range	431.3°C (at 760 mm Hg)
Flash Point	147°C
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	React with oxidizing agent.
Chemical Stability	Stable under recommended storage condition.
Possibility of Hazardous Reactions	React with oxidizing agent.
Conditions to Avoid	Keep away from excess heat Protect from moisture.
Incompatible Materials	Incompatible with oxidizing materials.
Hazardous Decomposition Products	Carbon monoxide Carbon dioxide

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Oral LD50 - 62.4 mg/kg (rat)
Acute Toxicity - Inhalation	Inhalative LC50 (8hrs) - 100 mg/litre (rat)
Acute Toxicity - Dermal	Dermal LD50 - 2000 mg/kg (rabbit)
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	Irritant to skin and mucous membranes.
Serious Eye Damage/Irritation	Strong irritant with the danger of severe eye injury.
Respiratory or Skin Sensitization	May be sensitizing.
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No data available
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	No data available
Carcinogenicity OSHA	No data available
Reproductive Toxicity	No data available
Specific Target Organ Toxicity - Single Exposure	May cause respiratory irritation.
Specific Target Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Observe all federal, state, and local environmental regulations. Must not be disposed together with household garbage. Do not allow product to reach sewage system. European waste catalogue 07 05: Wastes from the manufacture, Supply, Formulation and Use (MFSU) of pharmaceuticals.
Waste Treatment Methods Packaging	Disposal must be made according to official regulations.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	2811
UN Proper Shipping Name	Toxic Solid, Organic, N.O.S. (Ketoprofen)
Transport Hazard Class(es)	6.1
Packaging Group	III
Environmental Hazards	No data available

Section 15: Regulatory Information

Labelling according to Regulation (EC) No 1272/2008 Hazard pictograms Please refer section 2 Signal word Danger Hazard statements Please refer section 2 Precautionary statements Please refer section 2 Labelling according to EU guidelines: Risk phrases: Please refer section 2 Chemical safety assessment A Chemical Safety Assessment has not been carried out and shall be available at the time of REACH registration. A Chemical Safety Assessment has not been carried out. National regulations: Other regulations, limitations and prohibitive regulations Substances of very high concern (SVHC) according to REACH, Article 57 The substance is not listed as SVHC.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
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