


Section 1: Identification	
Common Name/Trade Name	KETOPROFEN USP
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au
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), Acute toxicity, dermal (Category 3), Skin corrosion/irritation (Category 2), Serious eye damage/eye irritation (Category 2A)
Signal Word	Danger
Hazard Statement(s)	H301 Toxic if swallowed H311 Toxic in contact with skin H315 Causes skin irritation H319 Causes serious eye irritation
Pictogram(s)	
Precautionary Statement(s)	P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. P302+P352 IF ON SKIN Wash with soap and water. P302+P352 IF ON SKIN Wash with soap and water. P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. P312 Call a POISON CENTER or doctor/physician if you feel unwell. P330 Rinse mouth. P332+P313 If skin irritation occurs Get medical advice/attention. P337+P313 If eye irritation persists Get medical advice/attention. P361 Remove/Take off immediately all contaminated clothing. P362 Take off contaminated clothing and wash before reuse. P363 Wash contaminated clothing before reuse. P405 Store locked up. P501 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 USP Micronized
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	Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician
Most Important Symptoms and Effects	Skin contact with chemical is toxic and causes skin irritation. Eye contact causes eye irritation. Toxic effects if swallowed. Treat symptomatically.

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 firefighting 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 a tightly closed container. Keep away from incompatibles such as oxidizing agents.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No data available.
Appropriate Engineering Controls	Local exhaust ventilation required plus good work practice. Safety shower. Eye fountain. Handle in accordance with good industrial hygiene and safety practice. Contaminated clothing should be thoroughly cleaned. 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. Material of gloves: The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. 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 work clothing.
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: 3.72E- 07 mmHg
Odor Threshold	No data available
Vapor Density	Density at 22°C: 1.198 g/cm ³
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	94°C
Solubility	Solubility in / Miscibility with water at 25°C: 51 mg/ml
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	(n-octanol/water): 3.12 log POW
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No further relevant information available.
Chemical Stability	Keep away from excess heat. Protect from moisture. Stable under recommended storage condition.
Possibility of Hazardous Reactions	React with oxidizing agent.
Conditions to Avoid	No further relevant information available.
Incompatible Materials	Incompatible with oxidizing materials.
Hazardous Decomposition Products	Hazardous decomposition products: Carbon monoxide Carbon dioxide

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Toxic if swallowed. Oral LD50 - 62.4 mg/kg (rat)
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	Toxic in contact with skin. Dermal 550 mg/kg (mouse)
Acute Toxicity - Eye	No data available. Causes serious eye irritation. The test chemical causes swollen, pain and irritated eye when tested in human.
Skin Corrosion/Irritation	Causes skin irritation. The test chemical causes erythema or other skin discoloration when tested in human
Serious Eye Damage/Irritation	Causes serious eye irritation. The test chemical causes swollen, pain and irritated eye when tested in human.
Respiratory or Skin Sensitization	When tested in Hartley albino guinea pigs produced no sensitization reaction.
Germ Cell Mutagenicity	The substance is non-mutagenic.
Carcinogenicity IARC	Based on available data, the classification criteria are not met.
Carcinogenicity ACGIH	Based on available data, the classification criteria are not met.
Carcinogenicity NTP	Based on available data, the classification criteria are not met.
Carcinogenicity OSHA	Based on available data, the classification criteria are not met.
Reproductive Toxicity	In fertility studies, in rats, effects of ketoprofen on male and female reproduction functions were observed with a NOEL of 3 mg/kg/day.
Specific Target Organ Toxicity - Single Exposure	Based on available data, the classification criteria are not met.
Specific Target Organ Toxicity - Repeated Exposure	Based on available data, the classification criteria are not met.
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	Biodegradation in water: Half-life = 15 days (predicted). Result: Readily biodegradable
Bio-accumulative Potential	Bioaccumulation factor: BEF=3.2 (predicted) Result: Non-bioaccumulative
Mobility in Soil	Soil absorption coefficient=390 (Estimated) result: The test chemical is moderately mobile in soil.
Other Adverse Effects	Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Section 13: Disposal Considerations

Waste Treatment Methods Product	Observe all federal, state, and local environmental regulations. Must not be disposed of 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	Marine pollutant: No

Section 15: Regulatory Information

Other regulations, limitations and prohibitive regulations: Japan MITI listed. NZio C-Listed. AICS-Listed, PICCS-Listed. Canada- DSL-Listed. US TSCA-Listed. The substance is not listed as SVHC. A Chemical Safety Assessment has not been carried out.

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
Revision Date	07/19/2023 15:25

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