


Section 1: Identification

Common Name/Trade Name	URSODIOL 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) NSW Poisons Information Centre: 131 126 (24 hours)
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)	Ursodeoxycholic acid. 3 α ,7 β -Dihydroxy-5 β -cholan-24-oic acid 7 β -Hydroxylithocholic acid 5 β -Cholan-24-oic acid-3 α ,7 β -diol	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Skin corrosion/irritation (Category 2), Serious eye damage/eye irritation (Category 2)	
Signal Word	Warning	
Hazard Statement(s)	H315 H319	Causes skin irritation Causes serious eye irritation
Pictogram(s)		
Precautionary Statement(s)	P264 P280 P302+P352 P305+P351+P338 P332+P313 P337+P313 P362	Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN Wash with soap and water. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. If skin irritation occurs Get medical advice/attention. If eye irritation persists Get medical advice/attention. Take off contaminated clothing and wash before reuse.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Ursodeoxycholic acid
Common Name	Ursodiol
CAS Number	128-13-2
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. Consult a physician.
In Case of Skin Contact	Wash off with soap and plenty of water. Consult a physician.
In Case of Eye Contact	Flush eyes with water as a precaution.
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most Important Symptoms and Effects	The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water Foam Carbon dioxide (CO ₂) Dry powder
Special Hazards Arising From the Substance/Mixture	Combustible. Risk of dust explosion. Development of hazardous combustion gases or vapors possible in the event of fire.
Special PPE and/or Precautions for Firefighters	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing. Further information: Prevent fire extinguishing water from contaminating surface water or the groundwater.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Avoid breathing dust.
Methods and Materials Used for Containment	Do not let product enter drains.
Cleanup Procedures	Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Conditions for Safe Storage	Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Exposure controls- Contains no substances with occupational exposure limit values.
Appropriate Engineering Controls	No data available.
PPE - Eye/Face Protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
PPE - Skin Protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
PPE - Body Protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
PPE - Respiratory Protection	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	White Powder
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	202 - 204°C
Solubility	No data available
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	Non flammable
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	No data available
Chemical Stability	No data available
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	No data available
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions. - Carbon oxides. Other decomposition products - no data available

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral - rat – 4,600 mg/kg
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available. Causes serious eye irritation.
Skin Corrosion/Irritation	No data available. Causes skin irritation.
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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	No data available
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	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Waste Treatment Methods Packaging	Dispose of as unused product.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

Regulation under the Occupational Safety and Health Act Harmful Substances Required Permission for Manufacture - Not applicable Harmful Substances Prohibited from Manufacturing - Not applicable Harmful Agents to be kept below Occupational Exposure Limits - Not applicable Controlled Substances Subject to Environment Monitoring - Not applicable Controlled Substances Subject to Health Examination - Not applicable Hazardous substances requiring management - Not applicable. Special Management Materials - Not applicable Act on the Registration and Evaluation, etc. of Chemical Substances, Chemicals Control Act Toxic Chemicals - Not applicable Restricted Chemicals - Not applicable Prohibited Chemicals - Not applicable Accident Precaution Chemicals - Not applicable Dangerous Substances Safety Management Act Not Applicable to Dangerous Materials

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
Revision Date	01/28/2025 12:16

Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.