Annora

SAFETY DATA SHEET

Section 1: Identification		
Material	Diclofenac Potassium for Oral Solution USP 50 mg	
Recommended use	Pharmaceutical Product	
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)	
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854	
Section 2: Hazard(s) Identification		
Human health hazards	Powder may be irritating to the eyes, skin and respiratory	
Ecological effects	No data	
Physical and chemical hazards	Not hazardous in regular handling.	
Section 3: Composition/Information on Ingredients		
CAS	Diclofenac Potassium	15307-81-0
Section 4: First-Aid Measures		
Eye	Flush with running water for 20 minutes holding eyelids open. Seek medical attention if adverse effect occurs.	
Skin Contact	Wash contaminated area with soap and water. Seek medical attention if adverse effect occurs.	
Inhalation	No specific treatment is necessary since this product is not likely to be hazardous by inhalation. Seek medical attention if adverse effect occurs	
Ingestion	Get medical attention immediately overdoes is suspected or if person has adverse symptoms.	
Section 5: Fire-Fighting Measures		
Suitable extinguishing media	Use carbon dioxide, dry chemical, or alcohol type foam extinguishers or water fog.	
Unsuitable extinguishing media	Not applicable.	
Special Exposure Hazards	This product may decompose and produce irritating fumes and toxic gases when involved in a fire	

Decomposition Products	Thermal decomposition may result in the emission of carbon oxides, nitrogen oxides, and potassium oxides
Section 6: Accidental Release Measures	
Spill Procedure	Using appropriate protective equipment, wipe up and containerize spilled material. Avoid generation of mists or sprays during cleanup. Ignition sources should be identified and eliminated prior to cleanup beginning. Avoid contamination of sewers and waterways. Dispose of spilled material according to local regulations
Section 7: Handling and Storage	
Storage Temperature	Store at 20º to 25ºC (68º to 77ºF); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].
Handling/Storage Precautions	Avoid breathing powder and avoid contact with eyes
8. Exposure controls / personal protection	
Engineering Guidelines: This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.	
Engineering Controls	Not necessary.
Protective equipment	Not necessary
Section 9: Physical and Chemical Properties	
Physical State	Powder
Description	Diclofenac potassium for oral solution 50 mg, is a white to off-white, buffered, flavored powder for oral solution, supplied as individual dose packets. Each individual packet is designed to deliver a dose of 50 mg diclofenac potassium when mixed in water. Boxes of nine (9) diclofenac potassium for oral solution Packets - NDC 31722-046-32

Section 10: Stability and Reactivity	
Stability	Stable under normal temperature and pressure
Reactivity	Not hazardous under normal use conditions
Incompatible Materials	No information available
Hazardous Decomposition Products	Carbon monoxide, Carbon dioxide, nitrogen oxides, oxides of potassium, hydrogen chloride.
Possibility of Hazardous Reactions: **Substances to Avoid**	None under normal processing. May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)

Section 11: Toxicological Information

Therapeutic Side Effects:

Individuals sensitive to Diclofenac Potassium, other NSAIDS, aspirin, or any other ingredient in this product may have an allergic reaction upon ingestion of this product. The most frequently reported adverse effects include abdominal pain, constipation, diarrhea, indigestion, nausea, vomiting, dizziness, headaches, sleepiness, itching, increased sweating.

Human Data:

There are no data for Diclofenac Potassium. The following data are for the Anhydrous Diclofenac.

DICLOFENAC:

TDLo (Oral-Man) 29 mg/kg: Blood: changes in serum composition (e.g.TP, bilirubin, cholesterol) TDLo (Oral-Human) 6 mg/kg: Blood: change in clotting factors TDLo (Oral-Human) 10 mg/kg/10 days-intermittent: Skin and Appendages: dermatitis, allergic (after systemic exposure) Immunological Including; Allergic: hypersensitivity delayed TDLo (Skin-Human) 6.4 mg/kg/30 days-intermittent: Skin and Appendages: dermatitis, allergic(after systemic exposure), dermatitis, irritative (after systemic exposure) TDLo (Intramuscular-Man) 1070 µg/kg: Skin and Appendages: dermatitis, other (after systemic exposure) TDLo (Intramuscular-Man) 5.4 mg/kg/5 days-intermittent: Gastrointestinal: ulceration or bleeding from stomach; Blood: other hemolysis with or without anemia; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: dehydrogenases TDLo (Rectal-Human) 0.65 mg/kg: Blood: hemorrhage TDLo (Multiple Routes-Human) 4.2 mg/kg/2 days-intermittent: Behavioral: analgesia, Metabolism (Intermediary): effect on inflammation or mediation of inflammation TDLo (Intravenous-Human) 0.96 mg/kg: Skin and Appendages: dermatitis, other (after systemic exposure) TDLo (Unreported-Human) 1.07 mg/kg: Behavioral: analgesia

Section 11: Toxicological Information

Oral Toxicity: Oral overdose can cause lethargy, drowsiness, nausea, vomiting, epigastric pain, gastrointestinal bleeding, anemia, adverse cardiovascular effects, high blood pressure, acute renal failure, respiratory depression, adverse effects on liver and kidneys (including failure), life-threatening skin reactions, life-threatening allergic reactions, triggering of asthma, and coma. There are no data for Diclofenac Potassium. The following data are for the Anhydrous Diclofenac.

ANHYDROUS DICLOFENAC:

LD50 (Oral-Rat) 62,500 µg/kg

LD50 (Oral-LD50) (Oral-Mouse) 170 mg/kg

LD50 (Intraperitoneal-Mouse) 345 mg/kg

Dermal Toxicity: Although Diclofenac Potassium can be absorbed through the skin, there are no reports of systemic effects by this route.

Inhalation Toxicity: No well-controlled studies have been performed on product.
Carcinogenicity: Long-term carcinogenicity studies in rats given diclofenac sodium up to 2 mg/kg/day (or 12 mg/m2/day, 0.2-fold an adult human daily dose of 100 mg/day) have revealed no significant increase in tumor incidence. A 2-year carcinogenicity study conducted in mice employing diclofenac sodium at doses up to 0.3 mg/kg/day (0.9 mg/m2/day, 0.014-fold an adult human daily dose of 100 mg/day) in males and 1 mg/kg/day (3 mg/m2/day, 0.04-fold an adult human daily dose of 100 mg/day) in females did not reveal any oncogenic potential.

Mutagenicity: Diclofenac sodium did not show mutagenic activity in in vitro point mutation assays in mammalian (mouse lymphoma) and microbial (yeast, Ames) test systems and was non-mutagenic in several mammalian in vitro and in vivo tests, including dominant lethal and male germinal epithelial chromosomal aberration studies in Chinese hamsters.

Section 12: Ecological Information

Diclofenac potassium is not an ecotoxicological toxin. No data available for this product.

Section 13: Disposal Considerations

Waste disposal Method	Disposal must be in accordance with applicable federal, state, and local laws and regulations. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14: Transport Information

Ground Regulations:

UN Classification: Not classified as dangerous materials (Nonflammable).

UN Number : Not regulated

Packing Group: Not Applicable

Section 15: Regulatory Information

CAMBIA® Powder for Oral Solution is regulated under the Federal Food, Drug and Cosmetic Act of the United State of America.

OSHA (Occupational Safety & Health Administration):

This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

OSHA PSM (Process Safety Management):

Not listed (29 CFR 1910.119, Appendix A).

NJ TCPA (Toxic Catastrophe Prevention Act):

This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.

TSCA (Toxic Substance Control Act): Not applicable

CERCLA (Comprehensive Response Compensation & Liability Act): Not listed

SARA Title III (Superfund Amendments & Reauthorization Act):

Section 302 Extremely Hazardous Substances: Not listed

Section 311/312 Hazard Categories: Not applicable

Section 313 Reportable Ingredients: Not listed

RCRA (Resource Conservation & Recovery Act): Not listed

Other State Regulatory Information:

New Jersey: NJ RTK Threshold Planning Quantity = 10,000 lb.

California Proposition 65:

The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. This product contains no chemicals known to the State of California to cause cancer or reproductive toxicity.

Canada:

WHMIS Ingredient Disclosure List: Not listed

WHMIS Classification: D2A:

Other Toxic Effects: Acute Effects/Chronic Effects

Section 16: Other Information, including date of preparation or last revision

Issue Date: 12-12-2022

Version: 00

Further information

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.