Material Safety Data Sheet

Product Name: CAMBIA® Powder for Oral Solution
Effective Date: 12/17/2013
MSDS #: 013

Depomed, Inc encourages and expects you to read and understand the entire MSDS, as there is important information throughout the document. Depomed expects you to follow the precautions identified in this document unless your conditions would necessitate other appropriate methods or actions.

Section 1: Product and Company Identification

Product Identification

Product Name:	CAMBIA®
Active Ingredient	Diclofenac Potassium
Chemical Family	Non-Steroidal Anti-Inflammatory (NSAID)
Chemical Name	1-(aminomethyl)-Cyclohexaneacetic acid,
Synonym(s):	Diclofenac Potassium, Diclofenac
Trademark(s):	CAMBIA®
Chemical characterization:	Mixture of powders

Company Identification

Depomed, Inc.
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Newark, CA 94560
Phone Number: 510-744-8000
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Section 2: Composition/Information on Ingredients

Ingredient Name CAMBIA®	**CAS Number**	**Exposure Limits**
Diclofenac Potassium	15307-81-0	Not established
Inactive Ingredients	N/A	N/A

Section 3: Hazard Identification

Most significant hazards and effects

Human health hazards: Powder may be irritating to the eyes, skin and respiratory system.

Ecological effects: No data.

Physical and chemical hazards: Not hazardous in regular handling.

Human Effects and Symptoms of Overexposure

Skin Hazards

Direct contact may cause contact dermatitis, itching, rash, dry skin, and scaling, especially in sensitive individuals. Although Diclofenac Potassium can be absorbed through the skin, there are no reports of systemic effects by this route.

Eye Hazards

Direct contact may irritate the eyes and cause redness and tearing.

Inhalation Hazards

No hazard is expected from normal clinical use or administration.

Ingestion Hazards

No hazard is expected from normal clinical use or administration. Oral overdose can cause lethargy, drowsiness, nausea, vomiting, epigastric pain, gastrointestinal bleeding, high blood pressure, acute renal failure, respiratory depression, and coma.

Section 4: First Aid Measures

Overdose: Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

Eye: Flush with running water for 20 minutes holding eyelids open. Seek medical attention if adverse effect occurs.

Skin: 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

Flammable Properties: Not available.

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.

NFPA Ratings: Health = 1, Flammability = 1, Instability = 0, Special Hazard = None

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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: Controlled Room Temperature: 25° C (77° F); excursions permitted to 15-30° C (59-86° F)

Handling/Storage Precautions: Avoid breathing powder and avoid contact with eyes.

Section 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

Color and shape: Homogenous white to light yellow powder.
Flammability: Not flammable.

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:	None under normal processing.
Substances to Avoid:	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

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: Transportation 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

Reason for Issue: New (12/17/2013)
Supersedes Date: Not applicable

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