

SAFETY DATA SHEETS

This SDS packet was issued with item:

078925884

N/A

SECTION 01 – IDENTIFICATION

Belcher Pharmaceuticals, LLC.
12393 Belcher Road, Suite # 420A
Largo, FL 33773

Telephone: 1-727-471-0850
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Product Name: Carprofen Flavored Tablets, 25 mg or 75 mg or 100 mg.

Synonyms: Vetprofen Flavored Tab.

Therapeutic Use: Carprofen Flavored Tablets is a non-narcotic, non-steroidal anti-inflammatory agent with characteristic analgesic and antipyretic activity approximately equipotent to indomethacin in animal models. It is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Restrictions on Use: For oral use in dogs only. Carprofen Flavored Tablets should not be used in dogs exhibiting previous hypersensitivity to Carprofen.

Description: Light peach color, round tablets debossed "F 25 MG" or "F 75 MG" or "F 100 MG" with bisect on one side and debossed "BP-CAR" on the other side.

SECTION 02 – HAZARD(S) IDENTIFICATION

Hazard Statement: As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity.

Signal Word: Warning.

Eye: None known or expected.

Skin: None known or expected.

Inhalation: None known or expected.

Ingestion: Ingestion of this material may cause gastrointestinal effects including stomatitis (inflammation of the mouth), anorexia, nausea, abdominal discomfort and pain, diarrhea, and indigestion. May also cause dizziness, drowsiness, headache, blood system changes. Itching, rash, ringing in the ear, and edema.



SECTION 03 – COMPOSITION AND INFORMATION ON INGREDIENTS

Ingredients	CAS Number	Amount
Carprofen	53716-49-7	25 mg or 75 mg or 100 mg
Inactive Ingredients	CAS Number	Amount
Microcrystalline Cellulose, NF	9004-34-6	Trade Secret
Croscarmellose Sodium, NF	74-811-65-7	Trade Secret
Magnesium Stearate, NF	557-04-0	Trade Secret
Purified Stearic Acid, NF	57-11-4	Trade Secret
FD&C Yellow # 6	2783-94-0	Trade Secret
Artificial Powdered Beef Flavor	Trade Secret	Trade Secret

SECTION 04 – FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin: Wash skin with soap and water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention.

Inhalation: Remove to fresh air. If not breathing, start basic life support. Get medical attention immediately.

Ingestion: If swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person or animal.

SECTION 05 – FIRE FIGHTING MEASURES

General Hazard: Toxic or corrosive emissions may be given off in a fire. See Hazardous Combustion Products below, and Hazardous Decomposition Products in Section 10 - STABILITY AND REACTIVITY.

Fire Fighting Instructions: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Extinguisher to Use: Use foam, dry powder, carbon dioxide, fog, or water spray.

Flash Point: Not known.

Auto-Ignition: Not known.

Flammability Limits: Not known.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen products chloride and other chlorine-containing compounds.

Minimum Explosive Concentration for Dust / Vapor: Not known.

SECTION 06 – ACCIDENTAL RELEASE MEASURES

Protective Equipment: Personnel involved in clean-up should wear appropriate equipment (see section 08). Minimize exposure.

Occupational Spill: Contain the source of spill or leak. Scoop spilled material into a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.

Clean-up – Large Spill: Review Sections 02 and 08 proceeding with the cleanup. Contain the source of the spill or leak. Eliminate possible ignition sources and follow appropriate grounding procedures. Scoop or shovel spilled material into a labeled container for recovery or disposal. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

SECTION 07 – HANDLING AND STORAGE

General Handling: Keep away from heat. Avoid creating dust when handling. Use with adequate ventilation. If Tablets are crushed and/or broken, avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use proper personal protective equipment specified in Section 08.

Storage: Store out of direct sunlight in a well-ventilated area at controlled room temperature.

Incompatible Materials: None Known.

Temperature Range: Store at controlled room temperature 15°C – 30°C (59°F – 86°F).

SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA's Permissible Exposure Limits (PELs):

Hazardous Ingredient	(PEL) Value (Total Dust)
Carprofen	Not available
Microcrystalline Cellulose, NF	15 mg / m ³
Croscarmellose Sodium, NF	Not available
Magnesium Stearate, NF	15 mg / m ³
Purified Stearic Acid, NF	15 mg / m ³
FD&C Yellow # 6	Not available
Artificial Powdered Beef Flavor	Not available

ACGIH Threshold Limit Values (TLVs):

Hazardous Ingredient	Type	Value
Carprofen	TWA-8	Not available
Microcrystalline Cellulose, NF	TWA-8	10 mg / m ³
Croscarmellose Sodium, NF	TWA-8	Not available
Magnesium Stearate, NF	TWA-8	10 mg / m ³
Purified Stearic Acid, NF	TWA-8	10 mg / m ³
FD&C Yellow # 6	TWA-8	Not available
Artificial Powdered Beef Flavor	TWA-8	Not available

Engineering Controls: No specific measures necessary. Good general room ventilation is expected to be adequate.

Personal Protective Equipment: Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. Refer to below recommended protection.

Eye Protection: Chemical goggles and/ or face shield.

Skin Protection: Body covering to minimize skin contact.

Hand Protection: Chemical – resistant gloves.

Respiratory Protection: None required under normal and foreseeable conditions of use. Use dust mask for dusty condition.

SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Tablets.
Color: Light Peach.
Odor: Odorless.
Molecular Weight: 273.72
Molecular Formula: Not applicable.
pH: Not applicable.
Melting Point: Not applicable.
Vapor Pressure: Not applicable.
Water Solubility: Insoluble in water at 25°C.
Solvent Solubility: Not applicable.

SECTION 10 – STABILITY AND REACTIVITY

Chemical Stability: Stable under recommended storage conditions.
Reactivity: None Known.
Conditions to Avoid: None known.
Incompatibilities: None known.
Hazardous Polymerization: Will not occur.
Hazardous Decomposition Products: Produces toxic fumes of carbon monoxide under fire condition.
Oxidizing Properties: No data available.
Explosive Properties: None known or expected.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity:	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
	LD50	Oral	Mouse	282 mg / kg
	LD50	Oral	Rat	149 mg / kg
Eye:	No data available. See Section 02 – HAZARD(S) IDENTIFICATION.			
Skin:	No data available. See Section 02 – HAZARD(S) IDENTIFICATION.			
Inhalation:	No data available. See Section 02 – HAZARD(S) IDENTIFICATION.			
Ingestion:	The acute oral LD50s for the active ingredient are listed above in the table. While this formulation has not been tested as a whole, it would be expected to be harmful orally based on the amount of active ingredient in the mixture.			
Mutagenicity:	No evidence of mutagenicity was observed for this material in the Ames test when tested in 5 strains of <i>S. typhimurium</i> with or without metabolic activation.			
Subchronic Effects:	Subchronic oral toxicity studies for Carprofen were conducted in rats and dogs for 13 weeks. In rats, daily administration of this material at dose of 5 mg/kg was well tolerated. In dogs, daily administration of this material at dose levels of 5 and 25 mg/kg showed a slight change in serum enzyme values at the high dose (25 mg/kg); no signs of toxicity were seen at 5 mg/kg.			
Chronic Toxicity:	Chronic oral toxicity studies for Carprofen were conducted in rats and dogs. In rats, oral administration of daily doses of 1, 3, and 10 mg/kg for 2 years showed increased mortality rate, intestinal lesions, and change in blood enzyme levels. In dogs, daily doses of 2 and 7 mg/kg for 1 year were well tolerated.			
OSHA Carcinogen:	No.			
NTP Carcinogen:	Not classified.			
LARC Carcinogen:	Not classified.			
Reproductive Effects:	Carprofen was administered to pregnant mice at daily oral doses of 10, 20 or 40 mg/kg from day 7 to day 16 of gestation. No impairment of reproduction and no indication of embryo or fetotoxicity was seen.			
Teratogenicity:	No evidence of teratogenicity was observed in rats for Carprofen when administered at daily oral doses of 2, 6, and 20 mg/kg. Slightly prolonged gestation, which was associated with an increased number of dead pups at birth, was observed (this is a common finding among non-steroidal, anti-inflammatory drugs).			
Chronic Effects / Carcinogenicity:	No long term toxicity studies to evaluate the carcinogenic potential of this material have been done in laboratory animals.			
At Increased Risk from Exposure:	Individuals who have shown hypersensitivity to this material and individuals with heart conditions and impaired kidney and/or liver functions may be more susceptible to toxicity in cases of overexposure.			

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: No ecological information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Procedure: Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal.

SECTION 14 – TRANSPORT INFORMATION

Proper Shipping Name: Carprofen Flavored Tablets, 25 mg or 75 mg or 100 mg.

General Shipping Instructions: Non-regulated.

SECTION 15 – REGULATORY INFORMATION

No Data Available.

Labeling on Container to Include: Product Name, Batch Number, Expiry Date, Storage Conditions, Company Name and Address.

SECTION 16 – OTHER INFORMATION

Disclaimer: Belcher Pharmaceuticals, LLC. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.