

SECTION 01 – PRODUCT AND COMPANY INFORMATION

Belcher Pharmaceuticals, Inc.
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Product Name: Carprofen Caplets.

Synonyms: Vetprofen™.

Therapeutic Use: Non-narcotic, non-steroidal anti-inflammatory drug (NSAID) with characteristic analgesic and antipyretic activity approximately equipotent to indomethacin in animal models.

Description: Orange Caplets debossed "25 MG" or "75 MG" or "100 MG" with bisect on one side and debossed "BP-CAR" on the other side.

SECTION 02 – COMPOSITION AND INFORMATION ON INGREDIENTS

<u>Hazardous Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Carprofen	53716-49-7	Trade Secret
Microcrystalline Cellulose	9004-34-6	Trade Secret
Croscarmellose Sodium	7811-65-7	Trade Secret
Magnesium Stearate	557-04-0	Trade Secret
Purified Stearic Acid	57-11-4	Trade Secret
Yellow # 6	2783-94-0	Trade Secret

SECTION 03 – HAZARDOUS IDENTIFICATION

Statements of Hazard: MAY BE HARMFUL IF SWALLOWED. ACCIDENTAL OR INCIDENTAL INGESTION OF THIS MATERIAL MAY CAUSE GASTROINTESTINAL TOXICITY.

Eye:

Short Term Effects: None known or expected.

Long Term Effects: None known or expected.

Skin:

Short Term Effects: None known or expected.

Long Term Effects: None known or expected.

Inhalation:

Short Term Effects: None known or expected.

Long Term Effects: None known or expected.

Ingestion:

Short Term Effects: 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.

Long Term Effects: Not known; see short term effects above.

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 carbon dioxide, dry chemical, or water spray.

Flash Point: Not known.

Autoignition: 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

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 03 and 08 proceeding with the clean up. 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 CAPLETS 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.

Temperature Range: 15°C – 30°C (59°F – 86°F).

SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

<u>Hazardous Ingredient</u>	<u>Type</u>	<u>Value</u>
Carprofen	TWA-8	1 mg / m ³
Microcrystalline Cellulose	TWA-8	10 mg / m ³
Croscarmellose Sodium	TWA-8	Not available
Magnesium Stearate	TWA-8	10 mg / m ³
Purified Stearic Acid	TWA-8	10 mg / m ³
Yellow # 6	TWA-8	Not available

- Exposure Information:** See exposure limits for components listed above.
- Ventilation:** General room ventilation is adequate unless the process generates airborne dust or fumes.
- Eye Protection:** None required under normal and foreseeable conditions of use.
- Skin Protection:** None required under normal and foreseeable conditions of use.
- Hand Protection:** None required under normal and foreseeable conditions of use.
- 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:** Caplets.
- Color:** Orange.
- Odor:** Odorless.
- Molecular Weight:** Not applicable.
- Molecular Formula:** Not applicable.
- pH:** Not applicable.
- Melting Point:** Not applicable.
- Vapor Pressure:** Not applicable.
- Water Solubility:** Not applicable.
- Solvent Solubility:** Not applicable.

SECTION 10 – STABILITY AND REACTIVITY

- Reactivity:** Stable.
- Conditions to Avoid:** None known.
- Incompatibilities:** None known.
- Hazardous Polymerization:** Will not occur.
- Hazardous Decomposition Products:** No data available. See section 05 under Hazardous Combustion Products.

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 03 – HAZARDOUS IDENTIFICATION.

Skin: No data available. See Section 03 – HAZARDOUS IDENTIFICATION.

Inhalation: No data available. See Section 03 – HAZARDOUS 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 *S. typhimurium* 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: The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment options.

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 Caplets.

General Shipping Instructions: Non-regulated.

SECTION 15 – REGULATORY INFORMATION

TSCA: No.

SARA Section 302: No.

SARA Section 313: No.

SECTION 16 – OTHER INFORMATION

Summary: Not applicable.

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