



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc	Emergency telephone	1-800-228-5635
Animal Health Group	Hours of operation	24 Hours
812 Springdale Drive	Telephone	1-800-877-6250
Exton, PA 19341		

Product name	Carprofen caplets
Synonyms	RIMADYL-V® caplets; Carprofen caplets
Chemical family	Carbazole derivative
Therapeutic use	Non-steroidal, anti-inflammatory drug (NSAID)
Description	Yellow orange, capsule shaped, biconvex caplets imprinted on front with "RIMADYL" and scored on back and imprinted with "25, 75 or 100".

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Hazardous Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Lactose hydrous	64044-51-5	Trade Secret
Carprofen	53716-49-7	Trade Secret
Starch, pregelatinized NF	9005-25-8	Trade Secret
Sodium starch glycolate	9063-38-1	Trade Secret
Talc	14807-96-6	Trade Secret

SECTION 3 - HAZARDS IDENTIFICATION

CERCLA ratings (scale 0-3) Health=0 Fire=0 Reactivity=0

NFPA ratings (scale 0-4) Health=0 Fire=0 Reactivity=0

Signal word **CAUTION!**

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

SECTION 3 - HAZARDS IDENTIFICATION continued

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 4 - 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.

SECTION 5 - 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.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds.
Flash point	Not known
Autoignition	Not known
Minimum explosive concentration for dust/vapor	Not known
Flammability limits	Not known

SECTION 6 - 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 Section 3 and 8 before 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 absorbant material and transfer to labeled

SECTION 6 - ACCIDENTAL RELEASE MEASURES continued

container for treatment and disposal. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

SECTION 7 - HANDLING AND STORAGE

General handling	Keep away from heat. Avoid creating dust when handling. Use with adequate ventilation. IF TABLETS OR CAPSULES 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 8.
Storage	Store out of direct sunlight in a well ventilated area at ambient temperature.
Temperature range	15 - 30 °C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits	Hazardous Ingredient	OEL	Type	Value
	Carprofen	Pfizer	TWA-8	1 mg/m ³
	Starch, pregelatinized NF	ACGIH	TWA-8	10 mg/m ³ (total dust)
		OSHA	TWA-8	5 mg/m ³ (respirable fraction)
		OSHA	TWA-8	15 mg/m ³ (total dust)
	Talc	ACGIH	TWA-8	2 mg/m ³ (particulate)
Exposure information	See exposure limits for components listed above.			
Measurement method	Carprofen: CAM-KAS-97-08 (contact Pfizer for additional details)			
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. Use dust mask for dusty conditions.			

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Caplets
Color	Yellow orange
Odor	Odorless.
Molecular weight	Not applicable
Molecular formula	Not applicable
pH	Not applicable
Melting point	Not applicable
Pour point	Not applicable
Vapor pressure	Not applicable
Water solubility	No data available
Solvent solubility	No data available

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES continued

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable.
Conditions to avoid	None known.
Incompatibilities	None known.
Hazardous decomposition products	No data available. See Section 5 - under Hazardous combustion products.
Hazardous polymerization	Will not occur.
Oxidizing properties	No data available.
Explosive properties	None known or expected.

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity	Type	Route	Species	Dosage
	LD50	Oral	Mouse	282 mg/kg
	LD50	Oral	Rat	149 mg/kg
Eye	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Skin	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Inhalation	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
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 changes in blood enzyme levels. In dogs, daily oral doses of 2 and 7 mg/kg for 1 year were well-tolerated.			
Chronic effects/ Carcinogenicity	No long-term toxicity studies to evaluate the carcinogenic potential of this material have been done in laboratory animals.			
OSHA carcinogen	No			
NTP carcinogen	Not classified			
IARC 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).			

SECTION 11 - TOXICOLOGY INFORMATION continued

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.

SECTION 13 - DISPOSAL INFORMATION

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 options.

SECTION 14 - TRANSPORTATION INFORMATION

Proper shipping name Carprofen caplets
General shipping instructions Non-regulated

SECTION 15 - REGULATORY INFORMATION

TSCA status No
SARA section 302 No
SARA section 313 No
California proposition 65 No

SECTION 16 - OTHER

Summary Not applicable
Disclaimer **Pfizer 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.**