

## Safety Data Sheet

**Product Name: Carprofen Chewable Tablets**

**Strength : 25, 50, and 100 mg**

**Revision No.: 00**

### Emergency Overview

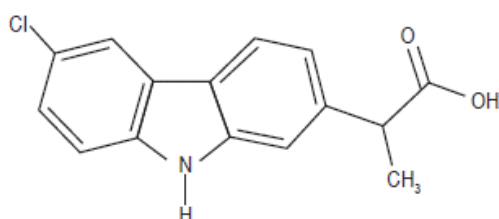
Federal law restricts this drug to use by or on the order of a licensed veterinarian. For personal protection, see section 8 of the SDS.

### Section 1: Identification

**Product Name:** Carprofen Chewable Tablets

**Formula:** C<sub>15</sub>H<sub>12</sub>ClNO<sub>2</sub>

**Chemical Name:** carbazole, 6-chloro- $\alpha$ -methyl-9H-carbazole-2-acetic acid



**Molecular Weight:** 273.72 g/mol

**Description:** Carprofen is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class that includes ibuprofen, naproxen, and ketoprofen. Carprofen is the nonproprietary designation for a substituted carbazole, 6-chloro- $\alpha$ -methyl-9H-carbazole-2-acetic acid. The empirical formula is C<sub>15</sub>H<sub>12</sub>ClNO<sub>2</sub> and the molecular weight 273.72.

Carprofen is a white, crystalline compound. It is freely soluble in ethanol, but practically insoluble in water at 25°C.

**Dosage forms and strengths:** Carprofen chewable tablets are scored, and contain 25 mg, 75 mg or 100 mg of carprofen per tablet. Each tablet size is packaged in bottles containing 30, 60 or 180 tablets.

Product Name	Strength	Pack count	NDC
Carprofen Chewable Tablets	25 mg	HDPE bottle of 30 tablets	8611700903
		HDPE bottle of 60 tablets	8611700905
		HDPE bottle of 180 tablets	8611700909
	75 mg	HDPE bottle of 30 tablets	8611701003
		HDPE bottle of 60 tablets	8611701005
		HDPE bottle of 180 tablets	8611701009
	100 mg	HDPE bottle of 30 tablets	8611701103
		HDPE bottle of 60 tablets	8611701105
		HDPE bottle of 180 tablets	8611701109

### Manufacturer / supplier identification

**Company** Zyodus Animal Health and Investments Limited,

Ahmedabad, India

**Contact for information** Tel.: +91 2717-683954

**Emergency Telephone No** Tel.: +91 2717-683951

**Distributed by:** ZyVet Animal Health Inc.

Pennington, NJ 08534



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**Section 2: Hazard (s) Identification**

<b>2.1 Classification of the substance or mixture</b>	
NFPA 704 Diamond	
	
<b>2.2 Label Elements</b>	
<b>Hazard Pictogram:</b>	
<b>Signal Word:</b>	<b>WARNING</b>
<b>Hazard statement(s):</b>	
H302 Harmful if swallowed H317 May cause an allergic skin reaction H412 Harmful to aquatic life with long lasting effects	
<b>Supplementary Statement(s):</b>	
	Not applicable
<b>Precautionary Statement(s) Prevention:</b>	
	P270 Do not eat, drink or smoke when using this product
<b>Precautionary Statement(s) Response:</b>	
	P302+P352 IF ON SKIN: Wash with plenty of water P332+P313 If skin irritation occurs: get medical advice/ attention
<b>Precautionary Statement(s) Storage:</b>	
	P405 Store locked up
<b>Precautionary Statement(s) Disposal:</b>	
	P501 Dispose of contents/ container in accordance with local regulations
<b>2.3 Other Hazard Information</b>	
Not applicable.	

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<b>SECTION 3: INFORMATION ON THE INGREDIENTS</b>		
<b>3.1 Substances</b>		
See section below for composition of mixtures		
<b>3.2 Mixtures</b>		
<ul style="list-style-type: none"><li>• CAS No</li><li>• EC Number</li><li>• Index Number</li><li>• REACH Number</li></ul>	<b>% Weight</b>	<b>Name</b>
9004-34-6	10-30	cellulose
53716-49-7	1-10	carprofen
557-04-0	1-10	Magnesium stearate
Other ingredients	Not indicated	Ingredients determined not to be hazardous

<b>SECTION 4: FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
<b>Ingestion:</b>	If swallowed, seek medical advice without delay and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth. Induce vomiting if medical attention is not immediately available.

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<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>Eye contact:</b>	Not expected to cause eye irritation.
<b>Skin contact:</b>	May cause skin irritation.
<b>Ingestion:</b>	Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
See Section 11 for more detailed information	
<b>4.3 Indication of immediate medical attention and special treatment needed</b> Patients should be managed by symptomatic and supportive care following NSAIDs overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 grams 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).	

## SECTION 5: FIRE FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable:</b>	Select extinguishing media suitable for surrounding area
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used

### 5.2 Special hazards arising from the substance or mixture

<b>Fire incompatibility:</b>	None known
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### 5.3 Special protective actions for fire-fighters:

<b>Firefighting:</b>	Use water delivered as a fine spray to control fire and cool adjacent area. <b>Do not</b> approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
<b>Fire / explosion hazard:</b>	Extremely high temperatures such as encountered in a fire may produce hazardous fumes.

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<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8	
<b>6.2 Environmental Precautions</b>	
See section 12	
<b>6.3 Methods and material for containment and cleaning up</b>	
Spills are unlikely due to the nature of the product and how it is packaged	
<b>Minor Spills:</b>	Small spills should be cleaned up and placed in a closed container for disposal.
<b>Major Spills:</b>	Large spills should be diked and contained and then absorbed with no reactive materials and place in disposal drums.
<b>SECTION 7: HANDLING AND STORAGE</b>	
<b>7.1 Precautions for safe handling</b>	
<b>Safe Handling:</b>	Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Store at room temperature Keep out of the reach and sight of children.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	
<b>Suitable Container:</b>	Store in original HDPE market container with child resistant cap
<b>Storage incompatibility:</b>	No known incompatibilities.
<b>7.3 Specific end uses</b>	
Not available	

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**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

**DERIVED NO EFFECT LEVEL – DNEL (EU)**

Not Available

**PREDICTED NO EFFECT LEVEL – PNEC (EU)**

Not Available

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA**

Not Available

**EMERGENCY LIMITS (US):**

<b>Ingredient</b>	<b>Material Name</b>	<b>TEEL-1</b>	<b>TEEL-2</b>	<b>TEEL-3</b>
Not available				

<b>Ingredient</b>	<b>Original IDLH</b>	<b>Revised IDLH</b>
Not available		

**8.2 Exposure controls**

<b>Appropriate engineering controls:</b>	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
<b>Personal protection:</b>	Non required
<b>Eye and face protection:</b>	Non required
<b>Skin protection:</b>	Non required
<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities.
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	No special equipment needed when handling small quantities
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable

**8.3 Environmental exposure controls**

See Section 12

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
<b>9.1 Information on basic physical and chemical properties</b>	
<p><b>Appearance:</b> Round, tan colored tablets with single bisect on one side, “C” logo on the other side  <b>Container:</b> Store in original HDPE market container with child resistant cap  <b>Physical state:</b> Tablet  <b>Odor:</b> Odor of beef and liver  <b>Melting point / freezing point (degrees C):</b> Not applicable <b>Initial boiling point and boiling range:</b> Not applicable <b>Flash Point:</b> Not applicable  <b>Evaporation rate</b> Not applicable  <b>Flammability:</b> Not available  <b>Upper/lower flammability or explosive limits:</b> Not available  <b>Vapour pressure:</b> Not applicable  <b>Specific Gravity:</b> Not available  <b>Solubility in water and solvents (mg/l):</b> Not available <b>Auto ignition temperature (degrees C):</b> Not available <b>Decomposition temperature (degrees C):</b> Not available <b>Viscosity: (degrees C):</b> Not available  <b>Explosive properties:</b> Not available  <b>Oxidising properties:</b> Not available  <b>Partition Coefficient:</b> Not available <b>Taste:</b> Not applicable  <b>Surface tension:</b> Not available <b>Volatile component:</b> Not available <b>Gas group:</b> Not applicable  <b>pH:</b> Not available  <b>VOC g/L:</b> Not applicable</p>	
<b>9.2 Other information</b>	
Not Available	

SECTION 10: STABILITY AND REACTIVITY	
<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Product is considered stable. Hazardous polymerisation will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid:</b>	Protect from light.
<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

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### SECTION 11: TOXICOLOGICAL INFORMATION

<b>Inhalation:</b>	Not expected to cause any irritation of the respiratory tract	
<b>Ingestion:</b>	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain. Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma	
<b>Skin contact:</b>	May cause skin irritation	
<b>Eye contact:</b>	Not expected to cause any eye irritation	
<b>Chronic:</b>	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby. Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools.	
<b>Carprovet Chewable Tablets:</b>	<b>Toxicity</b>	<b>Irritation</b>
	Not available	Not available
<b>Cellulose</b>	<b>Toxicity</b>	<b>Irritation</b>
	Dermal (rabbit) LD50: >2000mg/kg[2] Oral (rat) LD50: >5000 mg/kg[2]	Not available
<b>Carprofen</b>	<b>Toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: 74 mg/kg[2]	Not available
<b>Magnesium stearate</b>	<b>Toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: >2000 mg/kg[2]	Not available

*1. \* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*

**Skin corrosion/irritation:**

May cause skin irritation.

**Serious eye damage/irritation:**

Not expected to cause any eye irritation



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<b>Respiratory or skin sensitization:</b>
Not expected to be a respiratory or skin sensitization.
<b>Germ cell mutagenicity:</b>
Not available
<b>Carcinogenicity:</b>
Not expected to be carcinogenic.
<b>Reproductive toxicity:</b>
There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby.
<b>STOT – single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Carprovet Chewable Tablets	Not available	Not available	Not available	Not available	Not available
cellulose	LC50	96	Fish	9160000mg/l	3
	EC50	96	Algae or other aquatic plants	340000000mg/l	3
carprofen	LC50	96	Fish	22.941 mg/l	3
	EC50	496	Algae or other aquatic plants	35.413mg/l	3

**DO NOT** discharge into sewer or waterways.

#### 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
cellulose	LOW	LOW
carprofen	HIGH	HIGH

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<b>12.3 Bioaccumulative potential</b>	
<b>Ingredient</b>	<b>Bioaccumulative Potential</b>
cellulose	LOW (LogKOW = -5.1249)
carprofen	LOW (LogKOW = 3.7888)
<b>12.4 Mobility in Soil</b>	
<b>Ingredient</b>	<b>Mobility</b>
cellulose	LOW (KOC = 10)
carprofen	LOW (KOC = 816.3)
<b>12.5 Results of PBT and vPvB assessment</b>	
Not Available	
<b>12.6 Other adverse effects</b>	
Not Available	

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

<b>Product packaging disposal:</b>	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

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<b>SECTION 14: TRANSPORT INFORMATION</b>	
<b>Labels required:</b>	
<b>Marine pollutant:</b>	NO
<b>Land transport (US: DOT / TDG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable</b>	

<b>SECTION 15: REGULATORY INFORMATION</b>
<b>15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture</b>

<b>CELLULOSE IS FOUND IN THE FOLLOWING REGULATORY LISTS:</b> USA: OEL/ TLV/ WEELs/ TSCA/ RELs/ PELs
<b>CARPROFEN IS FOUND IN THE FOLLOWING REGULATORY LISTS:</b> USA: IATA/ IMDG Code/ DOT/ USPS

<b>FEDERAL REGULATIONS:</b>	
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Section 311/312 Hazard Categories</b>	
Immediate (acute) health hazard	NO
Delayed (chronic) health hazard	NO
Fire hazard	NO
Pressure hazard	NO
Reactivity hazard	NO
<b>US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)</b> None reported	

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<b>STATE REGULATIONS:</b>	
<b>US. CALIFORNIA PROPOSITION 65</b>	
None reported	
<b>National Inventory</b>	<b>Status</b>
Australia - AICS	Yes
Canada - DSL	No (carprofen)
Canada - NDSL	No (carprofen)
China - IECSC	No (carprofen)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (carprofen, cellulose)
Korea - KECI	No (carprofen)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (carprofen)
USA - TSCA	No (carprofen)
Taiwan – TCSI	Yes
Mexico – INSQ	No (carprofen)
Vietnam – NCI	Yes
Russia – ARIPS	No (carprofen)
<b>Legend:</b>	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)</i>

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**SECTION 16: OTHER INFORMATION**

**References:** Nil.

**Issue date:** 25-01-2023

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product