

Section 1 - Identification of The Material and Supplier

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Product Name: Carproflam 50mg/mL Injection
APVMA Codes: 90599
Product Use: Non-steroidal, anti-inflammatory and analgesic for use in dogs, cats and horses
Other Names: Carprofen

Creation Date: 3rd January 2024

Revision Date: 2nd January 2028

Poisons Information

Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Appearance: Clear Colourless to pale yellow liquid

Classification of the substance or mixture:

GHS Classification:

REPRODUCTIVE TOXICITY - Category 2

SPECIFIC TARGET ORGAN SYSTEMIC TOXICITY - REPEATED EXPOSURE: Category 2

Label Element:

Hazard Pictogram:



Signal Word:

WARNING

Hazard Statement:

H361 - Suspected of damaging fertility or the unborn child.

H373 – May causes damage to organs through prolonged or repeated exposure.

Precautionary statements:

Prevention:

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe vapour.

P280 - Wear protective gloves, protective clothing, eye protection, face protection, or hearing protection.

Response:

P308 + P313 - IF exposed or concerned: Get medical advice or attention.

Other Hazards

Short Term:

There have been anecdotal reports that workers handling this material have experienced skin irritation and/or sensitivity reactions.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, the developing fetus.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and

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warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 - Composition/Information on Ingredients

Hazardous

Ingredients	CAS No	Conc, %	GHS Classification
Glycocholic acid	475-31-0	*	Not Listed
Benzyl Alcohol	100-51-6	*	Acute Tox. 4(H302) Acute Tox. 4(H332)
Hydrogen chloride	7647-01-0	**	STOT SE 3 (H335) Skin Corr. 1A(H314) Press. Gas Acute Tox. 3(H331)
Sodium hydroxide	1310-73-2	**	Skin Corr. 1A(H314)
Carprofen	53716-49-7	5	Acute Tox 3 (H301)Repro 2 (H361d) STOT Re 2 (H373)

Ingredients	CAS No	Conc, %	GHS Classification
Lecithin	8002-43-5	*	Not Listed
Water for injection	7732-18-5	*	Not Listed

Additional Information: * Proprietary
 ** to adjust pH
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 4 - First Aid Measures

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

Eye contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Most important symptoms and effects, acute and delayed

Symptoms and

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Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions

Aggravated by

Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Section 5 - Fire Fighting Measures

Extinguishing Media: Use dry chemical, water spray, carbon dioxide.

Specific hazards arising from the substance or mixture.

Hazardous Combustion

Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire / Explosion Hazards: Not applicable.

Advice for Fire-Fighters: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration

for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7 - Handling and Storage

Precautions for safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment

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should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities.

Storage Conditions: Store in a cool, dry, well-ventilated area. Store as directed by product packaging.

Incompatible Materials: None known.

Section 8 - Exposure Controls and Personal Protection

Control parameters

Refer to available public information for specific member state.

Occupational exposure limits

Ingredient name	Exposure limits
Hydrogen Chloride Australia Peak	5 ppm 7.5 mg/ m ³
Sodium Hydroxide Australia Peak	2mg/ m ³
Carprofen	1000µg/m ³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective

Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

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Section 9 - Physical and Chemical Properties:

Physical state:	Liquid.
Colour:	Clear, colourless to pale yellow.
Odour:	No data available
Odour threshold:	No data available.
pH:	7.0 – 7.4
Melting point/freezing point(°C):	Not available.
Boiling point (°C):	Not available.
Evaporation rate(gram/s):	Not available.
Flammability:	Not available.
Autoignition temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash point (Liquid) (°C):	No data available
Upper explosive limits (Liquid) (% by Vol.):	No data available
Lower explosive limits (Liquid) (% by Vol.):	No data available
Vapor pressure (kPa):	No data available.
Vapor density(g/ml):	No data available
Relative density:	Not available.
Solvent solubility:	Not available.
Solubility in water:	Not available.
Partition coefficient (Method, pH, End point, value):	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Molecular formula:	Mixture
Molecular weight:	Mixture
Polymerization:	Will not occur.

Section 10 - Stability and Reactivity

Reactivity:	No data available.
Chemical stability:	Stable under normal condition of use.
<u>Possibility of hazardous reactions</u>	
Oxidizing properties:	None.
Conditions to avoid:	None known.
Incompatible materials:	None known.
Hazardous decomposition products:	
	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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Section 11 - Toxicological Information

Information on toxicological effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Carprofen

Mouse	Oral	LD50	282 mg/kg
Rat	Oral	LD50	149mg/kg
Rat (M/F)	SC	LD50	230/190mg/kg
Rat (M/F)	IP	LD50	140/110 mg/kg

Lecithin

Rat	Oral	LD50	> 8 ml/kg
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Benzyl Alcohol

Rat	Oral	LD50	1230 mg/kg
Rat	Para-periosteal	LD50	53mg/kg
Rat	Inhalation	LC50	>4.178mg/L

Sodium hydroxide

Mouse	IP	LD50	40 mg/kg
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Hydrogen chloride

Rat	Sub-tenon injection (eye)	LC50 1H	3,124 ppm
Mouse	Inhalation	LC50 1H	1,108ppm
Mouse	Oral	LD50	900mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Carprofen

Eye Irritation	Rabbit	Non-irritating
Skin Irritation	Rabbit	Non-irritating
Skin Sensitization - GPMT	Guinea Pig	Negative
Antigenicity- Delayed skin reaction	Guinea Pig	No effect

Benzyl Alcohol

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Moderate
Skin Irritation	Guinea Pig	Moderate
Sodium hydroxide		
Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Sodium Hydroxide

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Carprofen

13 Week(s)	Rat	Oral 5 mg/kg/day	NOAEL	Gastrointestinal System
13 Week(s)	Dog	Oral 5 mg/kg/day	NOAEL	None identified

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Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Carprofen

Reproductive & Fertility Embryo /Fetal Development	Rat 20 mg/kg/day	NOAEL	Fetotoxicity, Maternal toxicity
Prenatal & Postnatal Development	Rat 20 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Mouse 40 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rabbit Oral 6 mg/kg/day	NOAEL	Embryotoxicity, Early embryonic development

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Carprofen

Bacterial Mutagenicity (Ames)		Salmonella	Negative
In Vivo Micronucleus	Mouse	Negative	

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Carprofen

2 Year(s)	Rat	Oral	10 mg/kg/day	NOAEL	Not carcinogenic, Gastrointestinal system
2 Year(s)	Dog	Oral	25 mg/kg/day	NOAEL	Not carcinogenic, No effects at maximum dose

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Hydrogen chloride IARC: Group 3 (Not Classifiable)

Section 12 - Ecological Information

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities use a commercial waste disposal service.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under IATA, ADG or IMDG regulations.

Section 15 - Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Benzyl Alcohol

Australia (AICS): Present

Lecithin

Australia (AICS): Present

Water for injection

Australia (AICS): Present

Hydrogen chloride

Australia (AICS): Present

Sodium hydroxide

Australia (AICS): Present

Carprofen

Australia (AICS): Present

Poison Schedule: Schedule 4

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, rawmaterial suppliers, or from the published literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase

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SUSMP
UN Number

Standard for the Uniform Scheduling of Medicines & Poisons
United Nations Number

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