

Section 1 - Identification of the Substance/Mixture and Supplier

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Product Identifier:	Rimadyl® Injection
APVMA Approval No:	51605
Other names:	None
Chemical family:	Injectable Carprofen in a saline solution
Recommended Use:	Non-steroidal, anti-inflammatory and analgesic for use in dogs, cats and horses
Restrictions on use	For veterinary use only
Emergency Phone:	1800 814 883 (all hours)

Section 2 - Hazards Identification

Appearance: Clear, colorless 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 Elements

Signal Word: Warning

Hazard Statements: H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up



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

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statements and 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

Description of First Aid Measures

Eye Contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Remove contaminated clothing and shoes. Wash skin with soap and water. 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.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

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Symptoms and 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 carbon dioxide, dry chemical, or water spray.

Special 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 labeled, 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 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

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Specific end use(s): No data available

Section 8 - Exposure Controls and Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Hydrogen chloride	
Australia PEAK	5 ppm 7.5 mg/m ³
Sodium hydroxide	
Australia PEAK	2 mg/m ³
Carprofen	
Zoetis OEL TWA 8-hr	1000 µg/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.

Section 9 - Physical and Chemical Properties:

Physical State:	Liquid	Color:	Clear, colorless to pale yellow
Odor:	No data available	Odor Threshold:	No data available
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	7.0-7.4		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available		
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available		
Decomposition Temperature (°C):	No data available		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		

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Viscosity: No data available

Flammability:

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

Polymerization: Will not occur

Section 10 - Stability and Reactivity

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use

Possibility of Hazardous Reactions

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.

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

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

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)

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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

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

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

Reproductive & Fertility	Rat	20 mg/kg/day	NOAEL	Fetotoxicity, Maternal toxicity
Embryo / Fetal 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)	<i>Salmonella</i>	Negative
<i>In Vivo</i> 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

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Mobility in Soil: No data available

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, raw material 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
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

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This version issued: 1 October 2016 and is valid for 5 years from this date

Supersedes: Revision issued 30 April 2015

Revision History:

Date of Revision	Reason
17 Nov 2014	Update to GHS
30 Apr 2015	Revision for consistency with Zoetis organisation
01 Oct 2016	Corrections to the ingredient listing

Contact Points:

Zoetis	1800 814 883
Police and Fire Brigade:	Dial 000

If ineffective:

**Dial Poisons Information Centre
(13 11 26 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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End of Safety Data Sheet

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