

SAFETY DATA SHEETS

This SDS packet was issued with item:

078447425

N/A

SAFETY DATA SHEET



Revision date: 02-Oct-2013

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Rimadyl®(Carprofen) Injectable Solution

Trade Name: Rimadyl
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid)
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

US OSHA Specific - Classification

EU Classification:

EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Symbol: Xn
EU Risk Phrases:

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

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

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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.
 Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Glycocholic acid	475-31-0	207-494-9	Not Listed	Not Listed	*
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	*
Hydrogen chloride	7647-01-0	231-595-7	T; R23 C; R35	STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**
Carprofen	53716-49-7	258-712-4	Repr.Cat.3;R63 T;R25 Xn;R48/22	Acute Tox 3 (H301) Repro 2 (H361d) STOT Re 2 (H373)	5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
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Lecithin	8002-43-5	232-307-2	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

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

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

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

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

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.

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

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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.

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

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Hydrogen chloride

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	5 ppm
	8 mg/m ³
Belgium OEL - TWA	5 ppm
	8 mg/m ³
Bulgaria OEL - TWA	8.0 mg/m ³
	5 ppm
Cyprus OEL - TWA	5 ppm
	8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm
	8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³
Germany (DFG) - MAK	2 ppm
	3.0 mg/m ³
Greece OEL - TWA	5 ppm
	7 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm
	8 mg/m ³
Italy OEL - TWA	5 ppm
	8 mg/m ³
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m ³
Latvia OEL - TWA	5 ppm
	8 mg/m ³
Lithuania OEL - TWA	5 ppm
	8 mg/m ³
Luxembourg OEL - TWA	5 ppm
	8 mg/m ³
Malta OEL - TWA	5 ppm
	8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Poland OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 ppm
	8 mg/m ³
Slovakia OEL - TWA	5 ppm
	8.0 mg/m ³
Slovenia OEL - TWA	5 ppm
	8 mg/m ³
Spain OEL - TWA	5 ppm
	7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm
	3.0 mg/m ³
Sodium hydroxide	
ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³
Carprofen	
Zoetis OEL TWA 8-hr	1000 µg/m ³

Exposure Controls

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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		
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	

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

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products:

Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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)

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

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11. TOXICOLOGICAL INFORMATION

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) *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)

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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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Glycocholic acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	207-494-9

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Lecithin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-307-2
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Hydrogen chloride	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	231-595-7
Sodium hydroxide	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
	454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-185-5
Carprofen	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	258-712-4

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

C - Corrosive
Toxic to Reproduction: Category 3
T - Toxic
Xn - Harmful

R23 - Toxic by inhalation.
R25 - Toxic if swallowed.
R35 - Causes severe burns.
R63 - Possible risk of harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis 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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET



1. Identification

Product identifier	Rimadyl® (Carprofen) Sterile Injectable Solution
Other means of identification	
Synonyms	RIMADYL® INJECTABLE SOLUTION * Rimadyl® Injection * Carprofen injectable solution
Recommended use	Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid)
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	Category 2
	Specific target organ toxicity, repeated exposure	Category 2 (digestive system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	Suspected of damaging the unborn child. May cause damage to organs (digestive system) through prolonged or repeated exposure by ingestion.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

Supplemental information May cause an allergic skin reaction. May cause eye and skin irritation.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Carprofen		53716-49-7	5
Benzyl Alcohol		100-51-6	1
Hydrochloric Acid		7647-01-0	**
Sodium hydroxide		1310-73-2	**

Composition comments ** to adjust pH

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. if swallowed: Nausea, vomiting. Abdominal pain. Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Wear appropriate personal protective equipment. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Do not taste or swallow. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. Refrigeration recommended. @ 2 - 8°C (36 - 46°F). Do not allow material to freeze. Store in a tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components****Type****Value**

Carprofen (CAS
53716-49-7)

TWA

1000 µg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value**

Hydrochloric Acid (CAS
7647-01-0)

Ceiling

7 mg/m³

Sodium hydroxide (CAS
1310-73-2)

PEL

5 ppm
2 mg/m³

US. ACGIH Threshold Limit Values**Components****Type****Value**

Hydrochloric Acid (CAS
7647-01-0)

Ceiling

2 ppm

Sodium hydroxide (CAS
1310-73-2)

Ceiling

2 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value**

Hydrochloric Acid (CAS
7647-01-0)

Ceiling

7 mg/m³

Sodium hydroxide (CAS
1310-73-2)

Ceiling

5 ppm
2 mg/m³

US. Workplace Environmental Exposure Level (WEEL) Guides**Components****Type****Value**

Benzyl Alcohol (CAS
100-51-6)

TWA

44.2 mg/m³

10 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Not available.

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Color	Clear, colorless to pale yellow.

Odor Not available.

Odor threshold Not available.

pH 7 - 7.4

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Heat, flames and sparks. High temperatures. Protect from freezing.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Hydrochloric Acid Severity: Irritant

Skin contact Prolonged skin contact may cause temporary irritation. There have been anecdotal reports that workers handling this material have experienced skin irritation and/or sensitivity reactions.
Hydrochloric Acid Severity: Severe

Benzyl Alcohol Species: Guinea Pig
Severity: Moderate

Species: Rabbit
Severity: Minimal

Carprofen Species: Rabbit
Severity: Non-irritating

Sodium hydroxide Species: Rabbit
Severity: Severe

Eye contact Direct contact with eyes may cause temporary irritation.
Hydrochloric Acid Severity: Severe

Carprofen Species: Rabbit
Severity: Non-irritating

Benzyl Alcohol Species: Rabbit
Severity: Severe

Sodium hydroxide Species: Rabbit
Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Hydrochloric Acid Severity: Irritant

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. if swallowed: Nausea, vomiting. Abdominal pain. Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Product	Species	Test Results
Rimadyl® (Carprofen) Sterile Injectable Solution		
Acute		
Oral		
ATE		2860 mg/kg
Components	Species	Test Results
Benzyl Alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LC50	Rat	> 4.178 mg/L 1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rat	1230 mg/kg
Carprofen (CAS 53716-49-7)		
Acute		
Intraperitoneal		
LD50	Rat	140 - 110 mg/kg (M/F)
Oral		
LD50	Mouse	282 mg/kg
	Rat	149 mg/kg
Subcutaneous		
LD50	Rat	230 - 190 mg/kg (M/F)
Chronic		
Oral		
NOAEL	Dog	25 mg/kg/day, 2 years (Not carcinogenic; No effects at maximum dose)
	Rat	10 mg/kg/day, 2 years (Not carcinogenic, Gastrointestinal system effects)
Subchronic		
Oral		
NOAEL	Dog	5 mg/kg/day, 13 weeks (Target organs: None identified)
	Rat	5 mg/kg/day, 13 weeks (Target organs: Gastrointestinal System)
Sodium hydroxide (CAS 1310-73-2)		
Acute		
Intraperitoneal		
LD50	Mouse	40 mg/kg
Skin corrosion/irritation		
Prolonged skin contact may cause temporary irritation.		
Corrosivity		
Hydrochloric Acid		Severity: Corrosive
Carprofen		Species: Rabbit Severity: Non-irritating
Serious eye damage/eye irritation		
Direct contact with eyes may cause temporary irritation.		
Eye Contact		
Hydrochloric Acid		Severity: Severe

Eye Contact

Carprofen

Species: Rabbit
Severity: Non-irritating

Benzyl Alcohol

Species: Rabbit
Severity: Severe

Sodium hydroxide

Species: Rabbit
Severity: Severe**Respiratory or skin sensitization****Respiratory sensitization**

Not a respiratory sensitizer.

Skin sensitization

Due to partial or complete lack of data the classification is not possible. Not a skin sensitizer in experimental animals. However, workers handling Rimadyl tablets have developed red and blotchy patches on their hands and faces.

Skin sensitization

Carprofen

GPMT
Species: Guinea Pig
Severity: Negative**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Carprofen

Bacterial Mutagenicity (Ames)
Result: Negative
Species: SalmonellaIn Vivo Micronucleus
Result: Negative
Species: Mouse**Carcinogenicity**

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrochloric Acid (CAS 7647-01-0)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Suspected of damaging the unborn child.

Developmental effects

Carprofen

20 mg/kg/day Embryo / Fetal Development, Not Teratogenic
Result: NOAEL
Species: Rat40 mg/kg/day Prenatal & Postnatal Development, Not
Teratogenic
Result: NOAEL
Species: Mouse6 mg/kg/day Prenatal & Postnatal Development,
Embryotoxicity, Early embryonic development
Result: NOAEL
Species: Rabbit
Organ: Oral**Reproductivity**

Carprofen

20 mg/kg/day Reproductive & Fertility, Fetotoxicity, Maternal
toxicity
Result: NOAEL
Species: Rat**Specific target organ toxicity -
single exposure**

Not classified.

Specific target organ toxicity - repeated exposure	May cause damage to organs (digestive system) through prolonged or repeated exposure by ingestion.
Aspiration hazard	Not an aspiration hazard.
Further information	Anecdotal reports from facilities handling RIMADYL caplets have indicated a potential for workers to develop rashes upon exposure to dusts of the material.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test Results
Benzyl Alcohol (CAS 100-51-6)	EC50	Daphnia magna (Water Flea)
		230 mg/L, 48 Hours
		66 mg/L, 21 Day(s) Reproduction
		Pseudokirchneriella subcapitata (Green Alga)
LC50	Pimephales promelas (Fathead Minnow)	460 mg/L, 96 Hours
Aquatic		
Fish	LC50	Bluegill (Lepomis macrochirus)
10 mg/l, 96 hours		
Hydrochloric Acid (CAS 7647-01-0)		
Aquatic		
Fish	LC50	Western mosquitofish (Gambusia affinis)
282 mg/l, 96 hours		
Sodium hydroxide (CAS 1310-73-2)		
Aquatic		
Crustacea	EC50	Water flea (Ceriodaphnia dubia)
34.59 - 47.13 mg/l, 48 hours		
Fish	LC50	Western mosquitofish (Gambusia affinis)
125 mg/l, 96 hours		

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available for this product. Not expected to bioaccumulate.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.**15. Regulatory information****US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)Hydrochloric Acid (CAS 7647-01-0) Listed.
Sodium hydroxide (CAS 1310-73-2) Listed.**SARA 304 Emergency release notification**

Hydrochloric Acid (CAS 7647-01-0) 5000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories** Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Hydrochloric Acid	7647-01-0	5000	500		

SARA 311/312 Hazardous chemical No**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Hydrochloric Acid (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Hydrochloric Acid (CAS 7647-01-0)

Safe Drinking Water Act (SDWA) Not regulated.**Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number**

Hydrochloric Acid (CAS 7647-01-0) 6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Hydrochloric Acid (CAS 7647-01-0) 20 %WV

DEA Exempt Chemical Mixtures Code Number

Hydrochloric Acid (CAS 7647-01-0) 6545

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**Hydrochloric Acid (CAS 7647-01-0)
Sodium hydroxide (CAS 1310-73-2)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 06-03-2017

Version # 01

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

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Revision information This document has undergone significant changes and should be reviewed in its entirety.