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 5 ppm
Sodium hydroxide (CAS 1310-73-2)	PEL	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 5 ppm
Sodium hydroxide (CAS 1310-73-2)	Ceiling	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: Salmonella In 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: Rat 40 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic Result: NOAEL Species: Mouse 6 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)	500 mg/L, 72 Hours
	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).

Disclaimer Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.

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