# SAFETY DATA SHEET



1. Identification

Product identifier Rimadyl (Carprofen) Chewable Tablets

Other means of identification

Synonyms Rimadyl \* Rovera \* RIMADYL® CHEWABLE TABLETS \* Rimadyl Chewable Tablets

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 Sensitization, skin Category 1B

Reproductive toxicity (the unborn child) Category 2

Specific target organ toxicity, repeated

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement May cause an allergic skin reaction. 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 dust/fume/gas/mist/vapors/spray. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye

Category 2 (digestive system)

protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of water. If

skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before

reuse.

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

None.

# 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Carprofen	·	53716-49-7	***
Corn Starch		9005-25-8	*
Magnesium stearate		557-04-0	*
Sucrose		57-50-1	*

**Composition comments** 

\*\*\* 25, 50, 75 or 100 mg per tablet

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

#### 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,

Indication of immediate medical attention and special treatment needed

**General information** 

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. Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

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

Unsuitable extinguishing media

Water spray. Foam. Powder. Carbon dioxide (CO2).

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

Specific methods

equipment/instructions

Use water spray to cool unopened containers.

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 touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and 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. Avoid release to the environment.

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. Avoid discharge into drains, water courses or onto the ground.

# **Environmental precautions**

# 7. Handling and storage

# Precautions for safe handling

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

# Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep away from heat and sources of ignition. Store in original tightly closed container. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. Protect from moisture.

# 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
Componente

Components	Туре	Value				
Carprofen (CAS 53716-49-7)	TWA	1000 μg/m3				
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)						
Components	Туре	Value	Form			
Corn Starch (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.			
,		15 mg/m3	Total dust.			
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.			
		15 mg/m3	Total dust.			
US. ACGIH Threshold Limit Value	s					
Components	Туре	Value				
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m3				
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3				
Sucrose (CAS 57-50-1)	TWA	10 mg/m3				
US. NIOSH: Pocket Guide to Cher	nical Hazards					
Components	Туре	Value	Form			
Corn Starch (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.			
		10 mg/m3	Total			
Sucrose (CAS 57-50-1)	TWA	5 mg/m3	Respirable.			

# **Biological limit values**

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

Control banding approach 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

10 mg/m3

Total

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

Not available.

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact Hand protection

with drug product is possible and for bulk processing operations.

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable Other

coveralls, etc.) in both production and laboratory areas.

No personal respiratory protective equipment normally required. In case of insufficient ventilation. Respiratory protection

wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.

Not applicable. Thermal hazards

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. Contaminated work clothing should not be allowed out of the workplace.

# 9. Physical and chemical properties

Tablet. (Chewable tablet). **Appearance** 

Physical state Solid. Solid. **Form** 

Light brown. Color Not available. Odor **Odor threshold** Not available. Not available. Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Not available.

Flammability limit - upper

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available. Not available. Vapor pressure Vapor density Not available. Relative density Not available.

Solubility(ies)

Not available. Solubility (water) Not available. Partition coefficient

(n-octanol/water)

**Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity** Not available.

Other information

Not explosive. **Explosive properties 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. Moisture.

Incompatible materials

Strong oxidizing agents. Acids.

**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.

**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.

Carprofen Species: Rabbit

Severity: Non-irritating

Eye contact Carprofen Direct contact with eyes may cause temporary irritation.

Species: Rabbit Severity: Non-irritating

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational

exposure.

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) Chewable Tablets

Acute Oral

ATE 4545 mg/kg

Components Species Test Results

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)

Components Species Test Results

Magnesium stearate (CAS 557-04-0)

Acute Inhalation

LC50 Rat > 2000 mg/m3

Oral

LD50 Rat > 2000 mg/kg

Sucrose (CAS 57-50-1)

Acute Oral

LD50 Rat 29.7 g/kg

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

Corrosivity

Carprofen Species: Rabbit

Severity: Non-irritating

Serious eye damage/eye

irritation

Direct contact with eyes may cause temporary irritation.

**Eye Contact** 

Carprofen Species: Rabbit Severity: Non-irritating

Respiratory or skin sensitization

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** May cause an allergic skin reaction. 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

Sucrose Bacterial Mutagenicity (Ames)

Result: Negative Species: Salmonella

Carprofen 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

Not listed.

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.

Anecdotal reports from facilities handling RIMADYL caplets have indicated a potential for workers **Further information** 

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.

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.

SDS US

#### **IMDG**

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

# 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)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

## SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

No

chemical

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

# Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

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

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)
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.

### **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)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region Inventory name On inventory (yes/no)\*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

\*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

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

 Issue date
 10-02-2013

 Revision date
 06-01-2017

Version # 04

country(s).

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.

Material name: Rimadyl (Carprofen) Chewable Tablets

270 Version #: 04 Revision date: 06-01-2017 Issue date: 10-02-2013 9 / 9