# This SDS packet was issued with item:

078447367

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078447227 078447243 078447268 078447284 078447300 078447326 078447383 078447409 078915955 078915956 078915957

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).



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

**Product Identifier** 

Material Name: Rimadyl (Carprofen) Chewable Tablets

Rimadyl; Rovera **Trade Name:** 

**Chemical Family:** Mixture

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

Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid) Intended Use:

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: Emergency telephone number:** 

CHEMTREC (24 hours): 1-800-424-9300

**Contact E-Mail:** VMIPSrecords@zoetis.com International CHEMTREC (24 hours): +1-703-527-3887

# 2. HAZARDS IDENTIFICATION

Appearance: Light brown tablets

Classification of the Substance or Mixture

**GHS - Classification** 

Reproductive Toxicity: Category 2

Specific target organ systemic toxicity (repeated exposure): Category 2

**EU Classification:** 

EU Indication of danger: Harmful

EU Symbol: EU Risk Phrases:

Xn

R22 - Harmful if swallowed.

**Label Elements** 

Signal Word: Warning

**Hazard Statements:** H361d - Suspected of damaging the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure

Material Name: Rimadyl (Carprofen) Chewable Tablets

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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

P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

**Short Term:** Not an eye irritant; Not a skin irritant (based on animal data). There have been anecdotal

reports that workers handling this material have experienced skin irritation and/or sensitivity

reactions.

Repeat-dose studies in animals have shown a potential to cause adverse effects on Long Term:

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

i iazai uous					
Ingredient	CAS Number	EU	<b>EU Classification</b>	GHS	%
_		EINECS/ELINCS		Classification	
		List			
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*
Carprofen	53716-49-7	258-712-4	Repr.Cat.3;R63	Acute Tox 3 (H301)	3.3
			T;R25	Repro 2 (H361d)	
			Xn;R48/22	STOT Re 2 (H373)	
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU	EU Classification	GHS	%
		EINECS/ELINCS		Classification	
		List			
Wheat germ	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Liver powder, dehydrated	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	Not Listed	*
Hydrolyzed vegetable protein	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

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Additional Information: \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

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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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

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 May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride

**Products:** and other chlorine-containing compounds.

Fire / Explosion Hazards: Not applicable

**Advice for Fire-Fighters** 

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

# 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 / Contain the source of spill if it is safe to do so. Collect spilled material by a method that

Collecting: controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

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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.

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# 7. HANDLING AND STORAGE

### **Precautions for Safe Handling**

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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 as directed by product packaging.

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.

#### Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m³
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m³
OSHA - Final PELS - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>

### Carprofen

**Zoetis OEL TWA 8-hr** 1000 μg/m<sup>3</sup>

### Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 mg/m<sup>3</sup>

### **Sucrose**

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>

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# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Starch

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> **Australia TWA** 10 ma/m<sup>3</sup> **Belgium OEL - TWA** 10 mg/m<sup>3</sup> **Bulgaria OEL - TWA** 10.0 mg/m<sup>3</sup> 4.0 mg/m<sup>3</sup> Czech Republic OEL - TWA 10 mg/m<sup>3</sup> **Greece OEL - TWA**  $5 \text{ mg/m}^3$ Ireland OEL - TWAs 10 mg/m<sup>3</sup>  $4 \text{ mg/m}^3$ **OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> Portugal OEL - TWA 10 ma/m<sup>3</sup> Slovakia OEL - TWA 4 mg/m<sup>3</sup> Spain OEL - TWA 10 mg/m<sup>3</sup> **Switzerland OEL -TWAs** 3 mg/m<sup>3</sup>

**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

Refer to applicable national standards and regulations in the selection and use of personal

**Equipment:** 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:TabletColor:Light brownOdor:No data available.Odor Threshold:No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility:
Water Solubility:
PH:
No data available
No data available
No data available.
No data available.
No data available

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Material Name: Rimadyl (Carprofen) Chewable Tablets

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# 9. PHYSICAL AND CHEMICAL PROPERTIES

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):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
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:** Fine particles (such as dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition** 

**Products:** 

# 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

ingredients.

No data available

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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

**Sucrose** 

Rat Oral LD50 29.7 g/kg

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

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.

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# 11. TOXICOLOGICAL INFORMATION

### 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

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

### Carprofen

13 Week(s) Rat Oral5 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 Rabbit Prenatal & Postnatal Development Oral 6 mg/kg/day Embryotoxicity, Early embryonic development NOAEL

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

### Sucrose

Bacterial Mutagenicity (Ames) Salmonella Negative

### 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.

Material Name: Rimadyl (Carprofen) Chewable Tablets

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# 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

# 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

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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



Wheat germ

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# **15. REGULATORY INFORMATION**

232-679-6

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Liver powder, dehydrated

CERCLA/SARA 313 Emission reporting

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

**Corn Starch** 

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the obligations of Register:

Not Listed

Not Listed

Not Listed

Not Listed

Present

EU EINECS/ELINCS List

Carprofen

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 258-712-4

Calcium phosphate dibasic, anhydrous

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Present

231-826-1

Sucrose

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

Present

obligations of Register:

EU EINECS/ELINCS List 200-334-9

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Gelatin

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Not Listed
Present

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Material Name: Rimadyl (Carprofen) Chewable Tablets

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15. REGULATORY INFORMATION

Australia (AICS): Present EU EINECS/ELINCS List 232-554-6

Hydrolyzed vegetable protein

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Magnesium stearate

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Eisted

Not Listed

Not

Starch

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the obligations of Register:

Not Listed

Present

Present

Present

EU EINECS/ELINCS List 232-679-6

# **16. OTHER INFORMATION**

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

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

T - Toxic

Toxic to Reproduction: Category 3

Xn - Harmful

R25 - Toxic if swallowed.

R63 - Possible risk of harm to the unborn child.

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 8 - Exposure Controls / Personal

Protection.

**Prepared by:** Toxicology and Hazard Communication

Zoetis Global Risk Management

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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** 



1. Identification

**Product identifier** Rimadyl (Carprofen) Chewable Tablets

Other means of identification

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

Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid) Recommended use

**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

Zoetis Belgium S.A. Company Name (EU)

> Mercuriusstraat 20 1930 Zaventem

**Emergency telephone** 

number

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

VMIPSrecords@zoetis.com **Contact E-Mail** 

2. Hazard(s) identification

Not classified. Physical hazards

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

May cause an allergic skin reaction. Suspected of damaging the unborn child. May cause damage **Hazard statement** 

to organs (digestive system) through prolonged or repeated exposure by ingestion.

**Precautionary statement** 

Obtain special instructions before use. Do not handle until all safety precautions have been read Prevention

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.

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

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

reuse.

Storage Store locked up.

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**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, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash. if swallowed:

Indication of immediate medical attention and special treatment needed

**General information** 

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.

No unusual fire or explosion hazards noted. General fire hazards

### 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.

### **Environmental precautions**

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

### 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 Components	Туре	Value	
Carprofen (CAS 53716-49-7)	TWA	1000 μg/m3	
US. OSHA Table Z-1 Limits for Air		-	_
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.
,		10 mg/m3	Total

Biological limit values

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

Control banding approach Appropriate engineering 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

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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.

Flammability limit - upper

(%)

Not available.

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)

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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.

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#### **IMDG**

Not regulated as dangerous goods.

Transport in bulk according to N

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

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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 country(s).

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

Issue date 10-02-2013 **Revision date** 06-01-2017

Version # 04

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

**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.

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

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