

Revision date: 15-Jun-2010 Version: 2.0 Page 1 of 8

# IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
Street
CT13 9NJ
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Pfizer Ltd,
Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Poison Control Center Phone: 1-866-531-8896 Technical Services Phone: 1-800-366-5288

**Emergency telephone number:** 

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

ChemSafe (24 hours): +44 (0)208 762 8322

# Material Name: Rimadyl (Carprofen) Chewable Tablets

Trade Name: Rimadyl Chemical Family: Mixture

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

# 2. HAZARDS IDENTIFICATION

Appearance: Light brown tablets

Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

**Additional Hazard Information:** 

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.

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

gastrointestinal system, the developing fetus.

EU Indication of danger: Harmful

### **EU Hazard Symbols:**

**EU Risk Phrases:** 

R22 - Harmful if swallowed.

Australian Hazard Classification

(NOHSC):

Hazardous Substance. Non-Dangerous Goods.

**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.

040

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010 Version: 2.0

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

### **Hazardous**

TIGEAT GOGO						
Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%		
Carprofen	53716-49-7	258-712-4	Repr.Cat.3;R63	3.3		
			T;R25			
			Xn;R48/22			
Corn Starch	9005-25-8	232-679-6	Not Listed	*		
Sucrose	57-50-1	200-334-9	Not Listed	*		
Starch	9005-25-8	232-679-6	Not Listed	*		
Magnesium stearate	557-04-0	209-150-3	Not Listed	*		

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

Additional Information: \* Proprietary

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

Page 2 of 8

safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. 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.

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.

# 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride

and other chlorine-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-

contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

Material Name: Rimadyl (Carprofen) Chewable Tablets Page 3 of 8 Revision date: 15-Jun-2010 Version: 2.0

# 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that

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

dry solids. Clean spill area thoroughly.

**Measures for Environmental** 

**Protections:** 

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to

avoid environmental release.

**Additional Consideration for Large** 

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

**General 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 hands and any exposed skin after removal of PPE. 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.

**Storage Conditions:** Store as directed by product packaging.

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Carprofen

Pfizer OEL TWA-8 Hr: 1000 µg/m<sup>3</sup>

Corn Starch

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> TWA **Australia TWA** 10 mg/m<sup>3</sup> **Belgium OEL - TWA** Listed **Bulgaria OEL - TWA** Listed Czech Republic OEL - TWA Listed **Greece OEL - TWA** Listed **Ireland OEL - TWAs** Listed

**OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> total 5 mg/m<sup>3</sup>

Listed Portugal OEL - TWA Spain OEL - TWA Listed

Sucrose

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

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010

Page 4 of 8

Version: 2.0

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA Listed
Lithuania OEL - TWA Listed

OSHA - Final PELS - TWAs: 15 mg/m³ total

5 mg/m<sup>3</sup>

Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA Listed

Starch

10 mg/m<sup>3</sup> TWA **ACGIH Threshold Limit Value (TWA)** 10 ma/m<sup>3</sup> Australia TWA Listed **Belgium OEL - TWA Bulgaria OEL - TWA** Listed Czech Republic OEL - TWA Listed **Greece OEL - TWA** Listed Ireland OEL - TWAs Listed **OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> total 5 mg/m<sup>3</sup>

Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Magnesium stearate

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> TWA 10 mg/m<sup>3</sup> **Australia TWA Belgium OEL - TWA** Listed Ireland OEL - TWAs Listed Listed Lithuania OEL - TWA Portugal OEL - TWA Listed Spain OEL - TWA Listed Sweden OEL - TWAs Listed

Analytical Method:

Engineering Controls:

Analytical method available for Carprofen. Contact Pfizer Inc for further information.

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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental

legislation.

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:** 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.

Page 5 of 8

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010 Version: 2.0

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:TabletColor:Light brownMolecular Formula:MixtureMolecular Weight:Mixture

Polymerization: Will not occur

# 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**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

### 11. TOXICOLOGICAL INFORMATION

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

ingredients.

# 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 149 mg/kg

Rat (M/F) SC LD50 230/190 mg/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.

# 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 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))

646

Page 6 of 8

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010 Version: 2.0

# 11. TOXICOLOGICAL INFORMATION

### 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.

# 12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to

the environment should be avoided.

# 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

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

# 15. REGULATORY INFORMATION

EU Symbol: Xn EU Indication of danger: Harmful

**EU Risk Phrases:** 

R22 - Harmful if swallowed.

**EU Safety Phrases:** 

Page 7 of 8

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010 Version: 2.0

# 15. REGULATORY INFORMATION

S36 - Wear suitable protective clothing.

S22 - Do not breathe dust. S24 - Avoid contact with skin.

### **OSHA Label:**

**WARNING** 

Harmful if swallowed.

### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



### Carprofen

Australia (AICS): Listed
Standard for the Uniform Scheduling Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 258-712-4

Corn Starch

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

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

obligations of Register:

EU EINECS/ELINCS List 232-679-6

Sucrose

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

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

obligations of Register:

EU EINECS/ELINCS List 200-334-9

Calcium phosphate dibasic, anhydrous

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

Australia (AICS):

EU EINECS/ELINCS List

Listed
231-826-1

Starch

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

Australia (AICS):

REACH - Annex IV - Exemptions from the

Present

obligations of Register:

EU EINECS/ELINCS List 232-679-6

Material Name: Rimadyl (Carprofen) Chewable Tablets

Revision date: 15-Jun-2010

Page 8 of 8

Version: 2.0

Version 2

# 15. REGULATORY INFORMATION

Gelatin

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

Australia (AICS):

EU EINECS/ELINCS List

232-554-6

Lactose NF, monohydrate

Australia (AICS): Listed

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)ListedAustralia (AICS):ListedEU EINECS/ELINCS List209-150-3

# 16. OTHER INFORMATION

# Text of R phrases mentioned in Section 3

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.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 -

Regulatory Information. Updated Section 13 - Disposal Considerations.

Prepared by: Product Stewardship Hazard Communications

Pfizer Global Environment, Health, and Safety Operations

Pfizer 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** 

\_\_\_\_\_