

SAFETY DATA SHEET



Revision date: 02-Oct-2013

Version: 3.0

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

Product Identifier

Material Name: Rimadyl (Carprofen) Chewable Tablets

Trade Name: Rimadyl; Rovera
Chemical Family: Mixture

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

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

Details of the Supplier of the Safety Data Sheet

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

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

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

2. HAZARDS IDENTIFICATION

Appearance: 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: Xn
EU Risk Phrases:
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

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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



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.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, the developing fetus.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------|------------|-----------------------|--------------------------------------|---|-----|
| Corn Starch | 9005-25-8 | 232-679-6 | Not Listed | Not Listed | * |
| Carprofen | 53716-49-7 | 258-712-4 | Repr.Cat.3;R63 T;R25 Xn;R48/22 | Acute Tox 3 (H301) Repro 2 (H361d) STOT Re 2 (H373) | 3.3 |
| 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 EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------------------------|--------------|-----------------------|-------------------|--------------------|---|
| 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 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 Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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 / 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.

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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.

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 ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Czech Republic OEL - TWA | 4.0 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |

Carprofen

| | |
|---------------------|------------------------|
| Zoetis OEL TWA 8-hr | 1000 µg/m ³ |
|---------------------|------------------------|

Calcium phosphate dibasic, anhydrous

| | |
|------------------|----------------------|
| Latvia OEL - TWA | 10 mg/m ³ |
|------------------|----------------------|

Sucrose

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|----------------------|
| Lithuania OEL - TWA | 10 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

Magnesium stearate

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

Starch

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

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 Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| Hands: | Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations. |
| Eyes: | Wear safety glasses or goggles if eye contact is possible. |
| Skin: | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. |
| Respiratory protection: | None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|-------------------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Tablet | Color: | Light brown |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solvent Solubility: | No data available | | |
| Water Solubility: | No data available | | |
| pH: | No data available. | | |
| Melting/Freezing Point (°C): | No data available | | |

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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): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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 Oral 5 mg/kg/day NOAEL Gastrointestinal System
13 Week(s) Dog Oral 5 mg/kg/day NOAEL None identified

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Carprofen

Reproductive & Fertility Rat 20 mg/kg/day NOAEL Fetotoxicity, Maternal toxicity
Embryo / Fetal Development Rat 20 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Mouse 40 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rabbit Oral 6 mg/kg/day NOAEL Embryotoxicity, Early embryonic development

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

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.

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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 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

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Liver powder, dehydrated | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Corn Starch | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 232-679-6 |
| Carprofen | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | 258-712-4 |
| Calcium phosphate dibasic, anhydrous | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 231-826-1 |
| Sucrose | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 200-334-9 |
| Lactose NF, monohydrate | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |
| Gelatin | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |

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| | |
|---|------------|
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-554-6 |
| Hydrolyzed vegetable protein | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Magnesium stearate | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 209-150-3 |
| Starch | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 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