**SAFETY DATA SHEET**

Revision date: 06-Oct-2013

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

<table>
<thead>
<tr>
<th>Product Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Name: Carprofen caplets</td>
</tr>
<tr>
<td>Trade Name: RIMADYL(R) Caplets</td>
</tr>
<tr>
<td>Chemical Family: Mixture</td>
</tr>
</tbody>
</table>

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

**Zoetis Belgium S.A.**

| Mercuriusstraat 20 |
| 1930 Zaventem |
| Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887 |

**2. HAZARDS IDENTIFICATION**

**Appearance:**

Yellow orange, capsule shaped, biconvex caplets imprinted on front with "RIMADYL" and scored on back and imprinted with "25, 75 or 100"

**Classification of the Substance or Mixture**

<table>
<thead>
<tr>
<th>GHS - Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Toxicity: Category 2</td>
</tr>
<tr>
<td>Specific target organ systemic toxicity (repeated exposure): Category 2</td>
</tr>
</tbody>
</table>

**EU Classification:**

EU Indication of danger: Not classified

**Label Elements**

<table>
<thead>
<tr>
<th>Signal Word: Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements:</td>
</tr>
<tr>
<td>H361d - Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H373 - May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautionary Statements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>P201 - Obtain special instructions before use</td>
</tr>
<tr>
<td>P202 - Do not handle until all safety precautions have been read and understood</td>
</tr>
<tr>
<td>P260 - Do not breathe dust/fume/gas/mist/vapors/spray</td>
</tr>
<tr>
<td>P280 - Wear protective gloves/protective clothing/eye protection/face protection</td>
</tr>
<tr>
<td>P308 + P313 - IF exposed or concerned: Get medical attention/advice</td>
</tr>
<tr>
<td>P405 - Store locked up</td>
</tr>
<tr>
<td>P501 - Dispose of contents/container in accordance with all local and national regulations</td>
</tr>
</tbody>
</table>
Other Hazards

**Short Term:**
Not expected to cause eye irritation. Not expected to cause skin irritation. (based on components). May cause allergic skin reaction. Anecdotal reports from facilities handling RIMADYL caplets have indicated a potential for workers to develop rashes upon exposure to dusts of the material.

**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):**

**Note:**
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carprofen</td>
<td>53716-49-7</td>
<td>258-712-4</td>
<td>Repr.Cat.3;R63T;R25Xn;R48/22</td>
<td>Acute Tox 3 (H301) Repro 2 (H361d) STOT Re 2 (H373)</td>
<td>2</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Yellow lake blend</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

**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**
4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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: 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.

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
7. HANDLING AND STORAGE

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.

Storage Temperature: 15 - 30 °C

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.

Starch, pregelatinized

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

Carprofen

Zoetis OEL TWA 8-hr 1000 µg/m³

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
6.0 mg/m³
3.0 mg/m³
Czech Republic OEL - TWA 2.0 mg/m³
10 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
2 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
0.8 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**Magnesium Stearate**

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

**Colloidal silicon dioxide**

- Australia TWA: 2 mg/m³
- Austria OEL - MAKs: 4 mg/m³
-                               : 0.3 mg/m³
- Czech Republic OEL - TWA: 0.1 mg/m³
-                                       : 4.0 mg/m³
- Estonia OEL - TWA: 2 mg/m³
- Finland OEL - TWA: 5 mg/m³
- Germany - TRGS 900 - TWAs: 4 mg/m³
- Germany (DFG) - MAK: 4 mg/m³
- Ireland OEL - TWAs: 6 mg/m³
-                               : 2.4 mg/m³
- Latvia OEL - TWA: 1 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
-                               : Listed
- Slovakia OEL - TWA: 4.0 mg/m³
- Switzerland OEL - TWAs: 4 mg/m³
-                               : 0.3 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Not required for the normal use of this product. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Caplets</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>Will not occur</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
- Oxidizing Properties: None
- Conditions to Avoid: None known
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: See Section 5 - under Hazardous combustion 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)
11. TOXICOLOGICAL INFORMATION

Talc (non-asbestiform)
Rat  Oral  LD50  > 1600 mg/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.

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)

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. See below

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. 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
### 15. REGULATORY INFORMATION

**Lactose hydrous**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

**Starch, pregelatinized**
- 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

**Sodium starch glycolate**
- 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: Not Listed

**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

**Talc (non-asbestiform)**
- 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: 238-877-9

**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

**Colloidal silicon dioxide**
- 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: 231-545-4

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00104A
15. REGULATORY INFORMATION

Yellow lake blend
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

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

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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet