

Name: CARPORAL 40 MG TABLETS



SAFETY DATA SHEET

(REACH regulation no. 1907/2006 and 453/2010)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product Identifier**

Product name: Carporal 40 mg tablets

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use: Non Steroidal Anti-Inflammatory Drug (NSAID) for veterinary use

1.3 Details of the supplier of the safety data sheet

Registered company name: Le Vet Beheer B.V.

Address: Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Telephone: +31-(0)348-565858.

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1.4 Emergency telephone number:**+31-(0)6-10203326****SECTION 2: HAZARDS IDENTIFICATION****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:** H302 – Harmful if swallowed

H361d - Suspected of damaging the unborn child

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

Precautionary Statements: P201 – Obtain special instructions before use

P202 – Do not handle until all safety precautions have been read and understood

P280 – Wear protective gloves/protective clothing/eye protection/face protection

P260 – Do not breathe dust/fume/gas/mist/vapors/spray

P264 – Wash hands thoroughly after handling

P270 – Do not eat, drink or smoke when using this product

P308 + P313 – IF exposed or concerned: Get medical attention/advice

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.
Known Clinical Effects:	Typical undesirable effects associated with NSAIDs are vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

No substances fulfill the criteria set forth in annex II section A of the REACH regulation (EC) no. 1907/2006

3.2 Mixtures**Composition:**

Ingredient	CAS-no.	Quantity
Carprofen	53716-49-7	40.0 mg
Lactose monohydrate	10039-26-6	Classified
Sodium starch glycolate	9063-38-1	Classified
Maize starch	9005-25-8	Classified
Purified talc	14807-96-6	Classified
Cellulose, powdered	9004-34-6	Classified
Pregelatinized maize starch	9057-07-2	Classified
Colloidal anhydrous silica	7631-86-8	Classified
Calcium behenate	3578-72-1	Classified
Yeast, deactivated	-	Classified
Chicken flavour	-	Classified

SECTION 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.
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Medical Conditions

Aggravated by Exposure:	None known
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Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media: SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam.
Do not use water jet.**Special hazards arising from the substance or mixture****Hazardous Combustion****Products:** May be combustible at high temperature. Products of combustion are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).**Fire/Explosion Hazards:** Not applicable**Advice for firefighters**

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

SECTION 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 spill with absorbent material. 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.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. 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

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Specific end use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters**Occupational****Exposure Limits:** No data available.**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.**Personal Protective****Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).**Hands:** None**Eyes:** None**Skin:** None

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Round and convex flavoured tablet with a cross-shaped break line on one side.**Odor:** Odourless**Colour:** Light brown with brown spots**Molecular formula:** Mixture**Molecular weight:** Mixture**Solvent Solubility:** Not applicable**Water Solubility:** Not applicable**pH:** Not applicable**Melting/Freezing Point:** No data available**Boiling Point (°C):** No data available**Partition Coefficient:** No data available**Evaporation Rate:** No data available**Vapor Pressure:** No data available**Vapor Density:** No data available**Viscosity:** No data available**Flammability:****Autoignition Temperature (Solid):** No data available**Flammability (Solids):** No data available**Flash Point (Liquid):** No data available**Upper Explosive Limits (Liquid):** No data available**Lower Explosive Limits (Liquid):** No data available

SECTION 10: STABILITY AND REACTIVITY**Reactivity**

No data available

Chemical stability

Stable under normal conditions of use.

Possibility of hazardous reactions

No data available

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

No data available

SECTION 11: TOXICOLOGICAL INFORMATION**Information on Toxicological Effects****General Information:**

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: ingestion, eye contact, skin contact.

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

Mouse	Oral	LD ₅₀	282 mg/kg
Rat	Oral	LD ₅₀	149 mg/kg
Rat (M/F)	SC	LD ₅₀	230/190 mg/kg
Rat (M/F)	IP	LD ₅₀	140/110 mg/kg

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

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

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> 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.

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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

SECTION 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.

SECTION 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.

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Particular provisions: Veterinary medicinal product, under the scope of 2001/82/EC as amended

Chemical safety assessment: No data available

SECTION 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 SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.