



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

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

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**1.1 Product Identifier**

Product name: Carprodolor 50 mg/ml solution for injection

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

Use: Veterinary Medicinal Product

**1.3 Details of the supplier of the safety data sheet**

Registered company name: Le Vet B.V.

Address: Wilgenweg 7, 3421 TV Oudewater, The Netherlands

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

Fax: +31-(0)348-565454

info@levetpharma.com

www.levetpharma.com

**1.4 Emergency telephone number:****+31-(0)6-10203326**

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**SECTION 2: HAZARDS IDENTIFICATION**

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**2.1 Classification of the substance or mixture**GHS classification: Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (repeated exposure): Category 2EU Classification: EU Indication of danger: Harmful  
Toxic to Reproduction: Category 3

EU Symbol: Xn

EU Risk Phrases: R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

**2.2 Label elements**

Signal Word: DANGER

Product identifiers:

CAS53716-49-7 CARPFOPEN

Hazard statements:

H361 Suspected of damaging fertility or 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

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

**2.3 Other hazards**

Short-term: 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.

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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

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**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:**

<i>Ingredient</i>	<i>CAS Number</i>	<i>Amount</i>
Carprofen	53716-49-7	50 mg/ml
Ethanol		
Macrogol 400		
Poloxamer 188		
Ethanolamine		
Water		

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**SECTION 4: FIRST AID MEASURES**

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Skin Contact:	Remove contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get medical attention.
Eye Contact:	Immediately flush eyes with water for at least 15 minutes. 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.

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**SECTION 5: FIREFIGHTING MEASURES**

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**5.1 Extinguishing media****Suitable methods of extinction**

Use carbon dioxide, dry chemical, or water spray.

**5.2 Special hazards arising from the substance or mixture**

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

**5.3 Advice for firefighters**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**6.1 Personal precautions, protective equipment and emergency procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**6.2 Environmental precautions**

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

**6.3 Methods and material for containment and cleaning up**

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**6.4 Reference to other sections**

No data available.

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**SECTION 7: HANDLING AND STORAGE**

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**7.1 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.

**7.2 Conditions for safe storage, including any incompatibilities**

Store in a cool, dry, well-ventilated area. Store as directed by product packaging.

**7.3 Specific end use(s)**

No data available.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**8.1 Control parameters****Occupational exposure limits:**

No data available.

**8.2 Exposure controls****Personal protection measures, such as 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.

**- Eye / face**

Wear safety glasses or goggles if eye contact is possible.

**- Skin**

Wear safety glasses or goggles if eye contact is possible.

**- 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.

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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**9.1 Information on basic physical and chemical properties****General information:**

Physical state: liquid

Colour: Clear, colourless to pale yellow

**Important health, safety and environmental information**

No data available

**9.2 Other information**

No data available.

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**SECTION 10: STABILITY AND REACTIVITY**

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**10.1 Reactivity**

No data available

**10.2 Chemical stability**

This mixture is stable under the recommended handling and storage conditions in section 7.

**10.3 Possibility of hazardous reactions**

No data available

**10.4 Conditions to avoid****10.5 Incompatible materials****10.6 Hazardous decomposition products**

Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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**SECTION 11: TOXICOLOGICAL INFORMATION**

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Harmful if swallowed.

Repeated or prolonged contact with the mixture may cause non-allergic contact dermatitis.

May cause damage to organs in the event of repeated or prolonged exposure.

May affect the unborn child when swallowed during pregnancy.

**11.1.1****Acute toxicity**

Carprofen:

Mouse:	Oral LD50	282 mg/kg
Rat:	Oral LD50	49 mg/kg
Rat (M/F):	SC LD50	230/190 mg/kg
Rat (M/F):	IP LD50	140/110 mg/kg

**Skin irritation**

Irritant

**Eye irritation**

Irritant

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**SECTION 12: ECOLOGICAL INFORMATION**

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**12.1 Toxicity**

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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**SECTION 13: DISPOSAL CONSIDERATIONS**

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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.

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**SECTION 14: TRANSPORT INFORMATION**

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No limitations.

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**SECTION 15: REGULATORY INFORMATION**

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**15.1 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

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**SECTION 16: OTHER INFORMATION**

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Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

More information about this product is in the patient information leaflet that is supplied with the product.