

SAFETY DATA SHEETS

This SDS packet was issued with item:

078951652

N/A

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 29Nov18 Date of issue: 29Nov18

Version: 2.0

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

Contact information

General

Dechra Veterinary Products
7015 College Blvd, Suite 525
Overland Park, KS 66211
Phone: (866) 933-2472
www.dechra-us.com



Emergency

telephone number

1-866-933-2472

Product identifier

Carprovet® (carprofen) Sterile Injectable Solution

Synonyms

Carprofen

Trade names

Carprovet® (carprofen) Sterile Injectable Solution

Chemical family

Mixture - contains a substituted carbazole

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

Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product/
mixture packaged in final form for patient use; contains carprofen - a non-steroidal
anti-inflammatory medication.

Note

This SDS is written to address potential worker health and safety issues associated
with the handling of the formulated drug product.

Issue Date

29 November 2018

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

**Drugs in the finished state and intended for the final user are not subject to
labeling in the US, EU or Canada.** Please consult the prescribing/packaging
information. **The classification and labeling listed below is for bulk Carprofen
Sterile Injectable Solution.**

Regulation (EC) 1272/ 2008 [GHS]

Skin Sensitizer - Category 1. Specific Target Organ Toxicity (repeated exposure) -
Category 2.

Directive 67/548/EEC or 1999/45/EC

Xi - R43; Xn - R48/22

Label elements

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

CLP/GHS hazard pictogram



CLP/GHS signal word

Warning

CLP/GHS hazard statements

H317 - May cause allergic skin reaction. H373 - May cause damage to gastrointestinal (GI) tract through prolonged or repeated exposure.

CLP/GHS precautionary statements

P260 - Do not breathe dust. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P314 - Get medical advice/attention if you feel unwell. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger



Risk (R) Phrase(s)

Xi - Irritant; Xn - Harmful

R43 - May cause sensitization by skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Safety Advice

S24 - Avoid contact with skin. S36/37 - Wear suitable protective clothing and gloves.

Other hazards

Contains carprofen - a non-steroidal anti-inflammatory drug (NSAID). Common adverse effects with

therapeutic use of NSAIDs include mild gastrointestinal disturbances. Carprofen has been reported to cause photoallergic contact dermatitis following

Carpovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 29Nov18 Date of issue: 29Nov18

Version: 2.0

occupational exposure.

US Signal word	Warning
US Hazard overview	Contains carprofen. May cause an allergic skin reaction. May cause gastrointestinal tract damage based on animal data.
Note	This mixture is classified as dangerous according to directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US communication regulations. See Section 16 for full text of EU and GHS classifications. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008.

SECTION 3 – COMPOSITION/ INFORMATION ON INGREDIENTS

Ingredient	CAS#	EINECS/ELINCS	Amount	EU Classification	GHS Classification
Carprofen	53716-49-7	N/A	<10%	Toxic - T: R25, R48/22; Irritant - Xi: R43	ATO3: H301; STOT-R1:H372; SS1: H317

Note	The ingredient(s) listed above are considered dangerous/hazardous or are the active ingredient. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.
-------------	--

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 29Nov18 Date of issue: 29Nov18

Version: 2.0

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed

No. If exposed or concerned: Get medical advice/attention.

Eye Contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin Contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Protection of first aid responders

See Section 8 for Exposure Controls/Personal Protection recommendations.

Most important symptoms and effects, both acute and delayed

See Sections 2 and 11.

Indication of immediate medical attention and special treatment needed, if necessary

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, hydrochloric acid, or other chlorine-, magnesium-, and sodium-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/spray.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	Surround spill with absorbents and place a damp cloth or towel over the area. Capture spilled liquid onto spill absorbents. Gather and pick up all pieces of broken glass using a cloth or towel. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Avoid breathing mist/spray.
Conditions for safe storage including any incompatibilities	Store under refrigeration 2°-8°C (36°-46°F), Once broached, product may be stored at 25°C (77°F) for 28 days. Protect from freezing.

Specific end use(s)	No information identified.
----------------------------	----------------------------

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Carprofen	--	--	--

Exposure/Engineering controls

None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. High-energy operations should be done within an approved emission control or containment system.

Respiratory protection

None required for normal handling of packaged product. If handling bulk formulation: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.

Hand protection

None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact with formulated mixture is possible. Double gloves may be considered.

Skin protection

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

Other protective measures

Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid
Color	No information identified.
Odor	No information identified.
Odor threshold	No information identified.
pH	No information identified.
Melting point/ freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	No information identified.
Solvent solubility	No information identified.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

Partition coefficient (*n-octanol/water*) No information identified

Auto-ignition temperature No information identified

Decomposition temperature No information identified

Viscosity No information identified.

Explosive properties No information identified.

Oxidizing properties No information identified.

Other information

Molecular weight Not applicable (Mixture).

Molecular formula Not applicable (Mixture).

SECTION 10 - STABILITY AND REACTIVITY

Reactivity No information identified.

Chemical stability Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid No information identified.

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note Data for the mixture were limited. Therefore, data describing the active ingredient(s) and/or the individual ingredients were included where applicable.

Information on toxicological effects

Route of entry None likely for packaged product. Bulk solution may be absorbed by inhalation, skin contact and ingestion.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Carprofen	LD ₅₀	Oral	Mice	282 mg/kg
	LD ₅₀	Oral	Rats	149 mg/kg

Irritation/Corrosion Carprofen is non-irritating to rabbits.

Sensitization Carprofen is considered a dermal sensitizer, based on effects reported following occupational exposure. It was not a sensitizer in guinea pigs.

STOT-single exposure No data identified.

STOT-repeated exposure/Repeat-dose toxicity In oral rat studies ≥ 6 months duration, doses of 10 mg/kg/day caused mortality, intestinal ulceration, and peritonitis. The NOAEL in a 2-year rat study was 1 mg/kg/day.

Reproductive Toxicity Carprofen caused no adverse effects in a number of laboratory species. Details were not identified

Developmental Toxicity Carprofen was not teratogenic or fetotoxic in animal studies. Details were not identified.

Genotoxicity Carprofen was non-mutagenic in the Ames bacterial mutagenicity assay, in mammalian cell mutagenicity assays, and *in vivo* mutagenicity assays. It was non-clastogenic in an *in vitro* mammalian cell assay.

Carcinogenicity Carprofen was non-carcinogenic in 2-year rat and mouse studies. No components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

Human health data See "Section 2 - Other Hazards"

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 29Nov18 Date of issue: 29Nov18

Version: 2.0

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound
Carprofen

Type
--

Species
--

Concentration
--

Persistence and Degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

Not performed.

Other adverse effects

No data available.

Note

The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
Chemical safety assessment	Not conducted.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

SECTION 16 - OTHER INFORMATION

OSHA Hazardous	Yes. Warning. Contains carprofen. May cause an allergic skin reaction. May cause gastrointestinal tract damage based on animal data.
WHMIS classification	Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.
Full text of R phrases and EU Classifications	T - Toxic. R25 - Toxic if swallowed. Xi - Irritant. R43 - May cause sensitization by skin contact. Xn - Harmful. R48/22 - Danger of serious damage to health by prolonged exposure.
Full text of H phrases, P phrases and GHS classification	ATO3 - Acute Toxicity (Oral) Category 3. H301 - Toxic if swallowed. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. H372 - Causes damage to GI tract through prolonged or repeated exposure. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. H373 - May cause damage to GI tract through prolonged or repeated exposure. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction.

Carprovet® (carprofen) Sterile Injectable Solution

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 29Nov18

Date of issue: 29Nov18

Version: 2.0

Sources of data

Information from published literature and internal company data.

Abbreviations

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

Revision Date

29Nov18.

Disclaimer

This information provided in this Safety Data Sheet has been compiled by Dechra Limited using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Limited makes no warranties express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.

The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and and/or suitable for the user's proposed method of use and application.

Copyright, 2018, Dechra Limited. All rights reserved.

Copying and/or downloading of this information for the purpose of properly utilising Dechra Limited products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Limited, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.