

SAFETY DATA SHEETS

This SDS packet was issued with item:

078952661

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078952654

SAFETY DATA SHEET

Vetmedin® oral solution



Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/28/2019	000000054758	Date of first issue: 10/28/2019

SECTION 1. IDENTIFICATION

Product name : Vetmedin® oral solution
Synonyms : with API: Pimobendan

Manufacturer or supplier's details

Company name of supplier : Boehringer Ingelheim AH USA
Address : Satellite Blvd 3239
Duluth GA 30096
Telephone : (404) 678-3000
Prepared by : EHS-Services@Boehringer-Ingelheim.com
Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
24.51 %

Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : inorganic

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him

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If inhaled	: warm.
In case of skin contact	: Move to fresh air.
In case of eye contact	: Wash off immediately with plenty of water.
	: Rinse immediately with plenty of water for at least 15 minutes.
	: Keep eye wide open while rinsing.
If swallowed	: Rinse mouth.
	: Drink plenty of water.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: Observe the summary of product characteristics of proprietary medicinal products
	: Symptomatic treatment (decontamination, vital functions).

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
	Water
	Dry chemical
	Foam
	Carbon dioxide (CO ₂)
Specific hazards during fire-fighting	: In case of fire and/or explosion do not breathe fumes.
	: Can be released in case of fire:
	Carbon oxides
	: Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.
Further information	: Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
	: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus.
	: complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Wear personal protective equipment.
	: Ensure adequate ventilation.
	: High risk of slipping due to leakage/spillage of product.
Environmental precautions	: Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	: Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: No special protective measures against fire required.
	: The product is not flammable.
Advice on safe handling	: Provide sufficient air exchange and/or exhaust in work rooms.
Conditions for safe storage	: No special storage conditions required.
Materials to avoid	: Keep away from food, drink and animal feedingstuffs.
	: Observe joint storage prohibition.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Cateryory	Values	Remark
Pimobendan 74150-27-9	BIEL	3A	30 µg/m3	
	BIPC	1b		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.				

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
Breathing apparatus needed only when aerosol or mist is formed.
Respiratory protection
ABEK2
Use NIOSH approved respiratory protection.

Hand protection

Material : Nitrile rubber
Glove thickness : 0.43 mm
Directive : Protective gloves against chemicals and micro-organisms
Protective index : Class 6

Remarks

: The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.

Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.

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Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: Not applicable
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Bulk density	: Not applicable
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: Not applicable

SECTION 10. STABILITY AND REACTIVITY

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Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	No conditions known that should be avoided.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

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STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

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SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Hydrochloric acid...%	7647-01-0	5000	

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

sodium hydroxide (Solid)	1310-73-2	>= 0 - < 0.1 %
Hydrochloric acid...%	7647-01-0	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

sodium hydroxide (Solid)	1310-73-2	>= 0 - < 0.1 %
Hydrochloric acid...%	7647-01-0	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Hydrochloric acid...%	7647-01-0
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Pennsylvania Right To Know

Wasser	7732-18-5
C*CAVITRON 82006	128446-35-5
Hydrochloric acid...%	7647-01-0

Maine Chemicals of High Concern

ascorbic acid	50-81-7
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Vermont Chemicals of High Concern

ascorbic acid	50-81-7
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Washington Chemicals of High Concern

ascorbic acid

50-81-7

The components of this product are reported in the following inventories:

REACH	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. 4,5-Dihydro-6-(2-(4-methoxyphenyl-1H-benzimidazol-5-yl)-5-methyl-3(2H)-pyridazinone C*CAVITRON 82006
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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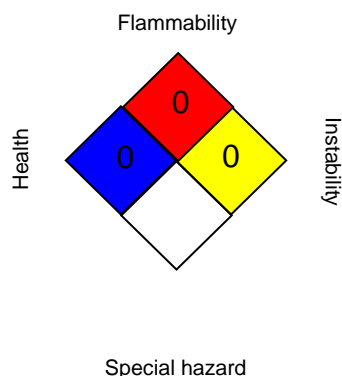


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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations;

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UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Vertical lines in the left hand margin indicate an amendment from the previous version.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 10/28/2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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