

Product name: Pimobendan

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product

Product name: **PIMOBENDAN**

Usage: Active pharmaceutical ingredient for medical use.

Supplier identifier

Saneca Pharmaceuticals a.s, Nitrianska 100, 920 27 HLOHOVEC, Slovakia

Company reg. No: 46 833 323

Emergency telephone number

Saneca Pharmaceuticals a.s, Nitrianska 100, 920 27 HLOHOVEC,

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E-mail: reach@saneca.com

National Toxicological Information Centre (NTIC): FNsP Bratislava Limbová 5, 833 05 Bratislava 37, Slovakia

tel.: +421 (02)54774166; Cell: +421 911 166066; fax: +421 (02) 54774605

e-mail: ntic@ntic.sk ; web: www.ntic.sk

2. Hazard identification

CLP (GHS07, GHS08) labeling

Acute toxicity, oral, cat.4 H302

Acute toxicity, inhalation, cat.4 H332

Rep. toxicity , cat. 2 H361



Warning

H302 Harmful if swallowed.

H332 Harmful if inhaled.

H361 Suspected of damaging fertility or the unborn child .

P201 Obtain special instructions before use.

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

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash with soap thoroughly after handling.

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

P271 Use only outdoors or in a well-ventilated area.

P281 Use personal protective equipment as required.

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

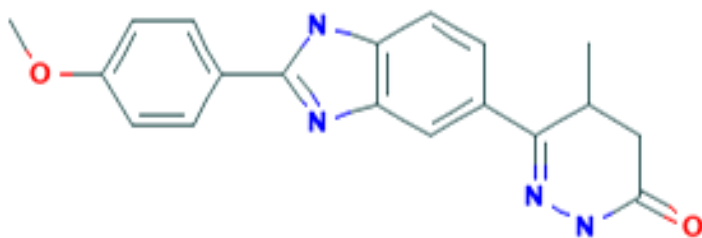
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P405 Store locked up.

P501 Dispose of contents/container to waste unit .wash

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3. Composition/information on ingredients



IUPAC name

4,5-Dihydro-6-[2-(4-methoxyphenyl)-1H-benzimidazol-5-yl]-5-methyl-3(2H)-pyridazinone

Synonyms

4,5-Dihydro-6-[2-(p-methoxyphenyl)-5-benzimidazolyl]-5-methyl-3(2H)-pyridazinone

6-[2-(4-methoxyphenyl)-1H-1,3-benzodiazol-5-yl]-5-methyl-2,3,4,5-tetrahydropyridazin-3-one

Molecular formula:	$C_{19}H_{18}N_4O_2$	CAS-No.:	74150-27-9
Molar mass:	334.37	EC-No:	640-420-7
		RTECS:	

4. First aid measures

Description of first aid measures

General information

Instantly remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- After inhalation Supply fresh air or oxygen; call for doctor.
- After skin contact Instantly wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for several minutes (10 - 15) under running water.
- After swallowing

Instantly call for doctor.

Administer medicinal carbon

Rinse out mouth and then drink plenty of water (200 - 300 ml).

Most important symptoms and effects, both acute and delayed

CNS depression

Dizziness

Dyspnoea, wheezing, respiratory depression

Drowsiness/fatigue

Restlessness, irritability

Agitation/excitement

Nausea, vomiting

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Irritating in the respiratory tract.

Bronchospasmus

Information for doctor Pharmacological group:

Indication of any immediate medical attention and special treatment needed

If swallowed, gastric irrigation with added, activated carbon.

Possibly oxygen respiration treatment

5. Fire-fighting measures

Extinguishing media**Suitable extinguishing agents**

CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents Do not use a heavy water stream.

Special hazards arising from the substance or mixture

Can be released in case of fire

Nitrogen oxides (NO_x)

Vapours heavier than air.

Advice for firefighters**Protective equipment:**

Wear self-contained breathing apparatus.

Do not inhale explosion gases or combustion gases.

Wear full protective suit.

Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment (described in section 8). Keep unprotected persons away.

Do not inhale fumes/aerosol.

Avoid contact with substance.

Environmental precautions:

Do not allow product to reach sewage system or water bodies.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

Dispose of contaminated material as waste according to item 13.

7. Handling and storage

Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

- Storage

- Requirements to be met by storerooms and containers: No special requirements.

- Information about storage in one common storage facility: Not required.

- Further information about storage conditions:

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Keep container tightly closed.

Store in cool, dry conditions in well sealed containers.

Store in a locked cabinet or with access restricted to technical experts or their assistants.

8. Exposure controls/personal protection

Control parameters

- Components with limit values that require monitoring at the workplace: Not required.
- DNELs (Derived no-effect level) No information available
- PNECs (predicted no effect concentration) No information available
- Additional information: OEL: No information available

Exposure controls

- Personal protective equipment

- General protective and hygienic measures

The usual precautionary measures should be adhered to general rules for handling chemicals.

Keep away from foodstuffs, beverages and food.

Wash hands during breaks and at the end of the work.

Do not inhale fumes

- Breathing equipment: Use breathing protection if fumes/aerosols are formed.

- Recommended filter device for short term use: Combination filter ABEK (DIN 3181)

- Protection of hands: Protective gloves (EN 374).

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection: Safety glasses

9. Physical and chemical properties

Form:	White hygroscopic powder
Colour:	White or slightly yellowish
Odour:	odourless
Melting temperature: °C	around 242 °C
Boiling temperature: °C	N/A
Ignition temperature: °C	N/A
Flash temperature: °C	N/A
Explosion limits lower:	N/A
Upper:	N/A

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Density: kg/m^3	N/A
pH	N/A
Solubility in	freely soluble in dimethylformamide, dimethylsulfoxid , slightly soluble in acetone
Water:	practically insoluble in water
Ethanol:	
Thermal decomposition:	N/A
Other properties:	N/A

10. Stability and reactivity

Reactivity No further relevant information available.

Chemical stability
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known

Conditions to avoid No further relevant information available.

Incompatible materials No further relevant information available.

Hazardous decomposition products No dangerous decomposition products known

11. Toxicological Information

Organism	Test Type	Route	Reported Dose (Normalized Dose)	Effect	Source
monkey	LD50	oral	> 2gm/kg (2000mg/kg)		Iyakuin Kenkyu. Study of Medical Supplies. Vol. 25, Pg. 815, 1994.
mouse	LD50	oral	> 2gm/kg (2000mg/kg)		Oyo Yakuri. Pharmacometrics. Vol. 43, Pg. 561, 1992.
rat	LD50	intravenous	72mg/kg (72mg/kg)	LUNGS, THORAX, OR RESPIRATION: ACUTE PULMONARY EDEMA GASTROINTESTINAL: OTHER CHANGES	Oyo Yakuri. Pharmacometrics. Vol. 43, Pg. 561, 1992.
rat	LD50	intravenous	75mg/kg (75mg/kg)		Oyo Yakuri. Pharmacometrics. Vol. 43, Pg. 561, 1992.
rat	LD50	oral	950mg/kg (950mg/kg)	LUNGS, THORAX, OR RESPIRATION: OTHER CHANGES ENDOCRINE: OTHER CHANGES	Oyo Yakuri. Pharmacometrics. Vol. 43, Pg. 561, 1992.
rat	LD50	subcutaneous	> 300mg/kg (300mg/kg)		Iyakuin Kenkyu. Study of Medical Supplies. Vol. 25, Pg. 815, 1994.

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12. Ecological Information

N/A

13. Handling Information

Waste treatment methods

Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Hand over to disposers of hazardous waste.

Uncleaned packagings:

Recommendation:

Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning. Packagings that cannot be cleaned are to be disposed of in the same manner as the product. Packaging containing residues of or contaminated by dangerous substances. Disposal must be made according to official regulations. Packaging must be disposed of in compliance with country-specific regulations or must be passed to a packaging return system.

14. Transport Information

Transport over land ADR/RID and GGSV/GGVE (Germany)

ADR/RID class:	Not dangerous	Number and letter:	
Name of material:			

River transport ADN/ADNR N/A

Sea transport IMDG

IMDG class:	Not dangerous	UN-No:		Packaging group:	
EMS:		MFAG:			
Name of material:					

Air transport ICAO-TI and IATA-DGR

ICAO/IATA class:	Not dangerous	UN/ID No:		Packaging group:	
Name of material:					

15. Regulatory information

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

The substance is not mentioned in the list of substances in Directive of European Council No. 793/93 on evaluation and control of risks of existing chemical substances.

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The substance is not mentioned in the list of substances in Directive of European Council No. 172/2008, Appendix VI which determines harmonized classification and labelling.

This substance is not restricted by any prescript.

Chemical safety assessment : Not required

Classification from ECHA.

16. Other Information

All the regulatory instructions mentioned are intended to help the addressee to comply with his obligations when using the product. This list cannot be considered as exhaustive and does not discharge the addressee from his duty to enquire about all other regulatory provisions which may apply to the possession and handling of the product for which he bears sole liability. The information given in this sheet has been introduced in accordance with the guidelines established by Regulation EC n°1907/2006 (REACH). This data sheet complements the user's instructions, but does not replace them. Users are further reminded of the possible risks of using a product for purposes other than those for which it was intended. The required information complies with current EC legislation. Addressees are requested to apply any additional national requirements.

Sources of raw data : ECHA 2018 ; Alven Laboratories s.r.o. SDS from 5.10.2017; MSDS Sigma-Aldrich from 24.6.2015

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