



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: Canergy 100 mg tablets

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

Use: peripheral vasodilator; purine derivatives

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.

Fax: +31-(0)348-565454

info@levetpharma.com

www.levetpharma.com

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

SECTION 2: HAZARDS IDENTIFICATION

Appearance:**Classification of the Substance or Mixture****EU Classification:**

Acute oral toxicity: harmful (Xn, R 22).

Acute cutaneous toxicity: harmful (Xn, R 21).

Acute inhalation toxicity: harmful (Xn, R 20).

Label Elements**Signal Word:** Danger**Hazard Statements:** H302 – Harmful if swallowed
H312 – Harmful in contact with skin
H332 – Harmful if inhaled**Precautionary Statements:** P101 – If medical advice is needed, have product container or label at hand
P102 – Keep out of reach of children
P103 – Read label before use
P280 – Wear protective gloves/protective clothing/eye protection/face protection
P301 + P312 – IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P330 – Rinse mouth
P363 – Wash contaminated clothing before reuse.
P501 – Dispose of contents/container at a disposal facility in accordance with local regulations

Name: CANERGY 100 MG TABLETS

Other Hazards

None

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
Propentofyllin	55242-55-2	100 mg
Lactose monohydrate	10039-26-6	Classified
Maize starch	9005-25-8	Classified
Crospovidone	94800-10-9	Classified
Talc	14807-96-6	Classified
Silica, colloidal anhydrous	7631-86-9	Classified
Calcium behenate	3578-72-1	Classified
Dried yeast	n.a.	Classified
Chicken flavour	n.a.	Classified

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open. If there is any redness, pain or visual impairment, consult an ophthalmologist.
Skin Contact:	Watch out for any remaining product between skin and clothing, watches, shoes, etc. If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.
Ingestion:	In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor. Seek medical attention, showing the label. If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.
Inhalation:	In the event of massive inhalation of dust, remove the person exposed to fresh air. Keep warm and at rest. If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor. Do not proceed with mouth-to-mouth or mouth-to-nose resuscitation.

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.

Medical Conditions

Aggravated by Exposure: None known

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special hazards arising from the substance or mixture

Hazardous Combustion

Products: Emits toxic fumes of carbon monoxide, carbon dioxide.

Fire/Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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

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:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.**Eyes:** Wear safety glasses or goggles if eye contact is possible.**Skin:** Impervious, disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet
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: eye contact , skin contact.

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

Rat	Oral	LD ₅₀	405 mg/kg
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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

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.