SAFETY DATA SHEET

According to 1907/2006/EC, Article 31

Version: Date of the first version: Date of the last version:

1 IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING

Identification of the preparation: Phenoleptil 100 mg tablets

Code:

Application of the preparation: Veterinary Medicinal Product. **FOR VETERINARY USE ONLY**

Presentation: White to almost white tablets, possibly with brown spics.

Manufacturer / Supplier:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Further information obtainable from
Le Vet B.V.
Tel: +31 (0)348 565858
Fax : +31 (0)348 565454
Email address of the competent person: freek@levetpharma.com

2. HAZARDS IDENTIFICATION

Note: The directive 2006/8/EC concerning the classification, packaging and labelling of dangerous preparations does not apply to the medicinal products for human or veterinary use in their finished state, intended for the final user.

Most important hazard:

Specific hazards: People with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product. Wash hands after use.
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the doctor

3. COMPOSITION / INFORMATION ON INGREDIENTS

Components contributing to the human and environment hazards

N°CAS : 50-06-6	**Phenobarbital**	Conc.: 100 mg / tablet

4. FIRST AID MEASURES

General advice: MEDICAL ADVICE SHOULD BE GIVEN IN ANY CASE OF CONTAMINATION.

Inhalation: Not applicable

Skin contact: Wash hands after skin contact.

Eye contact: In the event of eye contact flush the eye with copious amount of clean water and seek medical advice.

Ingestion: In case of accidental ingestion or eye irritation, seek medical help and show the doctor the package insert.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:	Carbon dioxide (CO_2), water spray, alcohol resistant-foam or polyvalent powder.
Extinguishing media which must not be used for safety reasons	Not applicable
Specific methods	Keep non-essential personnel and unprotected people away. Do not enter fire area without suitable protective equipment. If possible and without risk, cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or watercourses.
Specific fire hazards:	None
Special protective equipment	Use protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	None
Environmental precautions	Any unused product or waste materials should be disposed off in accordance with national requirements.
Methods for cleaning up:	Place in a suitable container for disposal in accordance with the waste regulations.

7. HANDLING AND STORAGE

Handling

- Precaution(s):	Wash hands after use. In case of accidental ingestion, seek medical help and show the doctor the package insert. See also the label and /or insert leaflet. -See also Section 8.
- Storage conditions:	Store in the retailing package tightly closed to protect from light. Keep out of reach of children.
- Material to avoid	No information

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Measures to be taken in order to minimise worker exposure	This is a veterinary medicinal product: consult the recommended precautions of the insert leaflet. must read carefully the leaflet before use.
Personal protection equipment:	
- Respiratory protection:	Not applicable.
- Hand protection:	Avoid contact with skin
- Skin and body protection:	Avoid contact with skin
- Eye protection:	Avoid contact with eyes
Hygiene measures:	Wash hands and exposed skin thoroughly after use. Do not smoke, eat, or drink when handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Physical state / form: Tablet

10. STABILITY AND REACTIVITY

Stability:	Preparation is stable in normal use (see section 7)
Conditions to avoid:	no information
Materials to avoid :	no information
Dangerous decomposition products:	Not applicable

11. TOXICOLOGICAL INFORMATION

General information: Product is an opiate and susceptible to addiction.

12. ECOLOGICAL INFORMATION

General information: No information available on the product itself

Environmental toxicity: This product does not have risk hazard for environment in normal use.
Do not allow to enter drains or waters courses

13. DISPOSAL CONSIDERATION

Waste / unused products: Any unused product or waste materials should be disposed off in accordance with national requirements.

Contaminated packaging: Any unused product or waste materials should be disposed off in accordance with national requirements.

14.TRANSPORT INFORMATION

General information(s): Transport followed ADR, IMDG, IATA

- ONU N°: No recommended limitations

- Class: Opiate

15. REGULATORY INFORMATION

Labelling: Labelled according to the labelling regulation in force for veterinary medicinal products
Note: The directive 2006/8/EC concerning the classification, packaging and labelling of dangerous preparations does not apply to the medicinal products for human or veterinary use in their finished state, intended for the final user.

Symbol(s)

R-phrase(s) **R 22**: Harmful by ingestion

S-phrase(s): **S 2:** Keep out of reach of children
S 20/21: When using do not eat, drink or smoke
S 46: If swallowed, seek medical advice immediately and show this container or label

16. OTHER INFORMATION

Important remarks: The information and recommendations given on this data sheet are based on our present knowledge. This product is a veterinary medicinal product. The user must refer to the relevant product label and/or insert leaflet and the product must be used strictly in accordance with the instructions and recommendations of the product label and/or insert leaflet. The user is always responsible for ensuring that the requirements of relevant legislation are complied with.

Restrictions: **FOR VETERINARY USE ONLY**
The product should not be used for others purposes than those recommended.

R-phrase(s) used:

Version:	Date of the first version:	Date of the last version:

History

- First date edition: 10 May 2010
- Date of revision 10 May 2010
- Version: 1.0
- Modifications : -