Material Safety Data Sheet
According to 91/155/EC

Issued on : 14/10/02
Reviewed on : English Version : 03/09/09

Product : PRILIMUM DWARF DOGS

SPECIFIC RISKS

None

This product is not classified as a "dangerous preparation" according to the provisions of Appendix IV of Guideline 67/548/CEE

Laboratoires VETOQUINOL
Veterinary Pharmaceutical specialities
34, Rue du Chêne Sainte-Anne
70200 MAGNY-VERNOIS
France
Tel. 33 3 84 62 55 55
Fax 33 3 84 62 55 16

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

Trade name : PRILIMUM DWARF DOGS
Manufacturer/Supplier : VETOQUINOL Laboratories
Service to contact : Pharmacovigilance Office
Emergency telephone : 33 3 84 62 55 55
Type of use : Veterinary Medicinal product
In dogs : treatment of cardiac insufficiency stages II, III, IV according to the NYHA classification, due to a mitral regurgitation or dilated cardiomyopathy. The product may be combined with diuretics, digoxin and antiarrhythmic drugs as necessary.
Other data : Powder for oral solution – List 1

2. CHEMICAL CHARACTERISTICS

Powder :
- Imidapril hydrochloride ....................... 75 mg
- Excipient ......................................to 0.805 g

After reconstitution :
- Imidapril hydrochloride ....................... 2.5 mg
- Excipient ......................................to 1 ml

3. HAZARD IDENTIFICATION

Imidapril :
May be harmful by inhalation, ingestion or skin contact. Direct contact with dust may cause eye irritation or skin contact.

PRILIMUM DWARF DOGS: Powder for oral solution

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4. FIRST-AID MEASURES

Inhalation:
Skin contact: Remove soiled clothing. Wash skin with water and soap.
Eye contact: Wash immediately with plenty of water. In case of irritation, consult an ophthalmologist.
Ingestion: Rinse mouth with water. Contact the closest Anti-Poison Centre.

5. FIRE-FIGHTING MEASURES

Not concerned.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid contact with skin and eyes.
Environmental precautions: Do not allow the product to spread into the environment.
Cleaning method: Impound and absorb with inert absorbents, collect the absorbents in a tight container.

7. HANDLING AND STORAGE

Before reconstitution: Store at ambient temperature.
After reconstitution: Keep in a cool place between 2°C and 8°C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Observe the precautionary measures that usually apply to the use of chemical products.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear solution
Colour: Colourless
Odour: Odorless
pH: 1.9 – 2.9
Reconstitution time: < 30 seconds
Other data: 

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10. STABILITY AND REACTIVITY

Stability : Stable under normal use conditions
Hazardous reactions : None under normal use conditions

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Imidapril :  
LD$_{50}$ (oral/mouse) = 5000 mg/kg  
LD$_{50}$ (IV/mouse) = 500 mg/kg  
LD$_{50}$ (oral/rat) = 3846 mg/kg  
LD$_{50}$ (IV/rat) = 500 mg/kg

Product toxicity :

Other toxicological information :

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of this product and its container at a hazardous or special waste collection centre.

14. TRANSPORT INFORMATION

Transport by truck or railway : Not regulated
Transport by sea : Not regulated
Transport by air : Not regulated
15. REGULATORY INFORMATION

Labelling : According to own criteria
Symbols : None
Risk-phrase : None
Safety-phrase :

S 15 : Store away from heat
S 24/25 : Avoid contact with skin and eyes
S 56 : Dispose of this product and its container at a hazardous or special waste collection centre.
S 61 : Avoid dispersal into the environment. Read the special instructions/Safety sheet.

16. OTHER INFORMATION

This document supplements the technical information notices but does not replace them. The information it contains are based on our knowledge relating to the product concerned on 14/10/02. They are issued in good faith.

The attention of users is also drawn to the potential risks incurred when a product is used for purposes other than those for which it was designed.

Under no circumstances does it exempt the user from familiarisation and implementation of all the texts governing his activity. He alone is responsible for implementing all precautions linked to the use of the product with which he is acquainted.

The purpose of all the regulations mentioned is to assist the end user to fulfil the obligations incumbent upon him during the handling of hazardous products.

This list must not be considered exhaustive. It does not exempt the user from ensuring that other obligations are binding upon him on the basis of texts in addition to those quoted and governing the possession and the use of the product for which he is alone responsible.
1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

Trade name: PRILIMUM SMALL DOGS
Manufacturer/Supplier: VETOQUINOL Laboratories
Service to contact: Pharmacovigilance Office
Emergency telephone: 33 3 84 62 55 55
Type of use: Veterinary Medicinal product

Other data: Powder for oral solution – List I

2. CHEMICAL CHARACTERISTICS

Powder:
- Imidapril hydrochloride ......................... 150 mg
- Excipient .......................................to 0.880 g

After reconstitution:
- Imidapril hydrochloride ......................... 5 mg
- Excipient .......................................to 1 ml

3. HAZARD IDENTIFICATION

Imidapril:
May be harmful by inhalation, ingestion or skin contact. Direct contact with dust may cause eye irritation or skin contact.
4. FIRST-AID MEASURES

Inhalation : Remove soiled clothing. Wash skin with water and soap.
Skin contact : Wash immediately with plenty of water. In case of irritation, consult an ophtalmologist.
Eye contact : Rinse mouth with water. Contact the closest Anti-Poison Centre.

5. FIRE-FIGHTING MEASURES

Not concerned.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Avoid contact with skin and eyes.
Environmental precautions : Do not allow the product to spread into the environment.
Cleaning method : Impound and absorb with inert absorbents, collect the absorbents in a tight container.

7. HANDLING AND STORAGE

Before reconstitution : Store at ambient temperature.
After reconstitution : Keep in a cool place between 2°C and 8°C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Observe the precautionary measures that usually apply to the use of chemical products.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Clear solution
Colour : Colourless
Odour : Odorless
pH : 1.9 – 2.9
Reconstitution time : < 30 seconds
Other data :
10. STABILITY AND REACTIVITY

Stability : Stable under normal use conditions
Hazardous reactions : None under normal use conditions

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Imidapril :

LD_{50} (oral/mouse) = 5000 mg/kg
LD_{50} (IV/mouse) = 500 mg/kg
LD_{50} (oral/rat) = 3846 mg/kg
LD_{50} (IV/rat) = 500 mg/kg

Product toxicity :

Other toxicological information :

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of this product and its container at a hazardous or special waste collection centre.

14. TRANSPORT INFORMATION

Transport by truck or railway : Not regulated
Transport by sea : Not regulated
Transport by air : Not regulated
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Labelling</th>
<th>According to own criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbols</td>
<td>None</td>
</tr>
<tr>
<td>Risk-phrase</td>
<td>None</td>
</tr>
<tr>
<td>Safety-phrase</td>
<td></td>
</tr>
</tbody>
</table>

S 15 : Store away from heat
S 24/25 : Avoid contact with skin and eyes
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Material Safety Data Sheet
According to 91/155/EC

Issued on : 14/10/02
Reviewed on : English Version : 03/09/09

Product : PRILiUM LARGE DOGS

Laboratoires VETOQUINOL
Veterinary Pharmaceutical specialities
34, Rue du Chêne Sainte-Anne
70200 MAGNY-VERNOIS
France
Tel. 33 3 84 62 55 55
Fax 33 3 84 62 55 16

SPECIFIC RISKS

None

This product is not classified as a "dangerous preparation" according to the provisions of Appendix IV of Guideline 67/548/CEE

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

<table>
<thead>
<tr>
<th>Trade name</th>
<th>PRILiUM LARGE DOGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer/Supplier</td>
<td>VETOQUINOL Laboratories</td>
</tr>
<tr>
<td>Service to contact</td>
<td>Pharmacovigilance Office</td>
</tr>
<tr>
<td>Emergency telephone</td>
<td>33 3 84 62 55 55</td>
</tr>
<tr>
<td>Type of use</td>
<td>Veterinary Medicinal product</td>
</tr>
<tr>
<td></td>
<td>In dogs: treatment of cardiac insufficiency stages II, III, IV according to the NYHA classification, due to a mitral regurgitation or dilated cardiomyopathy. The product may be combined with diuretics, digoxin and anti-arrhythmic drugs as necessary.</td>
</tr>
<tr>
<td>Other data</td>
<td>Powder for oral solution – List I</td>
</tr>
</tbody>
</table>

2. CHEMICAL CHARACTERISTICS

Powder :
- Imidapril hydrochloride ......................... 300 mg
- Excipient ........................................... to 1.030 g

After reconstitution :
- Imidapril hydrochloride ......................... 10 mg
- Excipient ........................................... to 1 ml

3. HAZARD IDENTIFICATION

Imidapril :
May be harmful by inhalation, ingestion or skin contact. Direct contact with dust may cause eye irritation or skin contact.
4. FIRST-AID MEASURES

Inhalation : Remove soiled clothing. Wash skin with water and soap.
Skin contact : Wash immediately with plenty of water. In case of irritation, consult an ophtalmologist.
Eye contact : Rinse mouth with water. Contact the closest Anti-Poison Centre.

5. FIRE-FIGHTING MEASURES

Not concerned.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Avoid contact with skin and eyes.
Environmental precautions : Do not allow the product to spread into the environment.
Cleaning method : Impound and absorb with inert absorbents, collect the absorbents in a tight container.

7. HANDLING AND STORAGE

Before reconstitution : Store at ambient temperature.
After reconstitution : Keep in a cool place between 2°C and 8°C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Observe the precautionary measures that usually apply to the use of chemical products.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Clear solution
Colour : Colourless
Odour : Odorless
pH : 1.9 – 2.9
Reconstitution time : < 30 seconds
Other data :
10. STABILITY AND REACTIVITY

Stability : Stable under normal use conditions
Hazardous reactions : None under normal use conditions

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Imidapril :
LD$_{50}$ (oral/mouse) = 5000 mg/kg
LD$_{50}$ (IV/mouse) = 500 mg/kg
LD$_{50}$ (oral/rat) = 3846 mg/kg
LD$_{50}$ (IV/rat) = 500 mg/kg

Product toxicity :

Other toxicological information :

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of this product and its container at a hazardous or special waste collection centre.

14. TRANSPORT INFORMATION

Transport by truck or railway : Not regulated
Transport by sea : Not regulated
Transport by air : Not regulated
15. REGULATORY INFORMATION

Labelling : According to own criteria
Symbols : None
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Safety-phrase :

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