

Material Safety Data Sheet

According to 91/155/EC



Issued on :
Reviewed on :
English Version : 04/04/05

Product: **CLAVASEPTIN 50 MG**

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

Trade name : CLAVASEPTIN® 50 MG
Manufacturer/Supplier : VETOQUINOL Laboratories
Service to contact : Pharmacovigilance Office
Emergency telephone : 33 3 84 62 55 55
ATC Vet code : QJ01CR02
Type of use : Veterinary Medicinal Product
In dogs: treatment of periodontal infections
In cats: treatment of skin and soft tissue infections.

2. CHEMICAL CHARACTERISTICS

Amoxicillin (as trihydrate)	40 mg
Clavulanic acid (as potassium salt)	10 mg
Excipient to	1 tablet of 95.2 mg

3. HAZARD IDENTIFICATION

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and *vice versa*.

Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

4. FIRST-AID MEASURES

Person developing serious hypersensitivity reactions must receive immediate medical attention.

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 ophtalmologist.
Ingestion	:	Rinse mouth with water. Immediately 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	:	Collect the product with mechanical means. Place in a sealed, labelled container.

7. HANDLING AND STORAGE

Wash hands after handling the tablets.

Do not store above 25° C. Store in the original package.

Handle this product with great care to avoid exposure, taking all recommended precautions.

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	: Oblong, palatable tablets about 9 mm in length
Colour	: Off-white brownish sprinkled
Average mass	: 90.4 – 100.0 mg/tablet
Disintegration	: ≤15 minutes
Resistance to crushing	: ≥30 N
Equilibrium relative humidity at 25°C	: ≤15 %

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Potassium clavulanate

LD₅₀ (oral/male mouse) = 4526 mg/kg

LD₅₀ (oral/male rat) = 9695 mg/kg

LD₅₀ (SC/male mouse) = 2185 mg/kg

LD₅₀ (SC/male rat) = 1781 mg/kg

Amoxicillin trihydrate

LD₅₀ (oral/rat) = > 5000 mg/kg

Product toxicity : Non toxic

12. ECOLOGICAL INFORMATION

The potential risks for human and for the environment resulting from use of CLAVASEPTIN 50 MG are very limited.

Other data: In case of spillage, avoid contact with the environment, with drain water and with surface and ground-water

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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 2 : Keep out of reach of children
 - S 8 : Store in a dry place
 - S 24/25 : Avoid contact with skin and eyes
 - S 47/49 : Keep only in the original container at temperature not exceeding 25°C
 - 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.
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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 **04/04/05**. 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.

Material Safety Data Sheet

According to 91/155/EC



Issued on :
Reviewed on :
English Version : 04/04/05

Product : **CLAVASEPTIN® 250 MG**

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

Trade name : CLAVASEPTIN® 250 MG
Manufacturer/Supplier : VETOQUINOL Laboratories
Service to contact : Pharmacovigilance Office
Emergency telephone : 33 3 84 62 55 55
ATC Vet code : QJ01CR02
Type of use : Veterinary Medicinal Product
In dogs: treatment of periodontal infections

2. CHEMICAL CHARACTERISTICS

Amoxicillin (as trihydrate)	200 mg
Clavulanic acid (as potassium salt)	50 mg
Excipient to	1 tablet of 476 mg

3. HAZARD IDENTIFICATION

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and *vice versa*.

Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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4. FIRST-AID MEASURES

Person developing serious hypersensitivity reactions must receive immediate medical attention.

- 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 ophtalmologist.
Ingestion : Rinse mouth with water. Immediately contact the closest Anti-Poison Centre.
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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 : Collect the product with mechanical means. Place in a sealed, labelled container.
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7. HANDLING AND STORAGE

Wash hands after handling the tablets.

Do not store above 25° C. Store in the original package.

Handle this product with great care to avoid exposure, taking all recommended precautions.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

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

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Oblong, palatable tablets about 14 mm in length
Colour	: Off-white brownish sprinkled
Average mass	: 452.2 – 499.8 mg/tablet
Disintegration	: ≤15 minutes
Resistance to crushing	: ≥60 N
Equilibrium relative humidity at 25°C	: ≤15 %

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Potassium clavulanate

LD₅₀ (oral/male mouse) = 4526 mg/kg

LD₅₀ (oral/male rat) = 9695 mg/kg

LD₅₀ (SC/male mouse) = 2185 mg/kg

LD₅₀ (SC/male rat) = 1781 mg/kg

Amoxicillin trihydrate

LD₅₀ (oral/rat) = > 5000 mg/kg

Product toxicity: Non toxic

12. ECOLOGICAL INFORMATION

The potential risks for human and for the environment resulting from use of CLAVASEPTIN® 250 MG are very limited.

Other data: In case of spillage, avoid contact with the environment, with drain water and with surface and ground-water

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 2 : Keep out of reach of children

S 8 : Store in a dry place

S 24/25 : Avoid contact with skin and eyes

S 47/49 : Keep only in the original container at temperature not exceeding 25°C

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 **04/04/05**. 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.

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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.

Material Safety Data Sheet

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Issued on :
Reviewed on :
English Version : 04/04/05

Product : **CLAVASEPTIN[®] 500 MG**

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

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1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

Trade name : CLAVASEPTIN[®] 500 MG
Manufacturer/Supplier : VETOQUINOL Laboratories
Service to contact : Pharmacovigilance Office
Emergency telephone : 33 3 84 62 55 55
ATC Vet code : QJ01CR02
Type of use : Veterinary Medicinal Product
In dogs: treatment of periodontal infections

2. CHEMICAL CHARACTERISTICS

Amoxicillin (as trihydrate)	400 mg
Clavulanic acid (as potassium salt)	100 mg
Excipient to	1 tablet of 952 mg

3. HAZARD IDENTIFICATION

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and *vice versa*.

Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

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4. FIRST-AID MEASURES

Person developing serious hypersensitivity reactions must receive immediate medical attention.

- 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. Immediately contact the closest Anti-Poison Centre.
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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 : Collect the product with mechanical means. Place in a sealed, labelled container.
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7. HANDLING AND STORAGE

Wash hands after handling the tablets.

Do not store above 25° C. Store in the original package.

Handle this product with great care to avoid exposure, taking all recommended precautions.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

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

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Oblong, palatable tablets about 19 mm in length
Colour	: Off-white brownish sprinkled
Average mass	: 904.4 – 999.6 mg/tablet
Disintegration	: ≤15 minutes
Resistance to crushing	: ≥80 N
Equilibrium relative humidity at 25°C	: ≤15 %

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Raw material toxicity :

Potassium clavulanate

LD₅₀ (oral/male mouse) = 4526 mg/kg

LD₅₀ (oral/male rat) = 9695 mg/kg

LD₅₀ (SC/male mouse) = 2185 mg/kg

LD₅₀ (SC/male rat) = 1781 mg/kg

Amoxicillin trihydrate

LD₅₀ (oral/rat) = > 5000 mg/kg

Product toxicity: Non toxic

12. ECOLOGICAL INFORMATION

The potential risks for human and for the environment resulting from use of CLAVASEPTIN® 500 MG are very limited.

Other data: In case of spillage, avoid contact with the environment, with drain water and with surface and ground-water

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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 2 : Keep out of reach of children
 - S 8 : Store in a dry place
 - S 24/25 : Avoid contact with skin and eyes
 - S 47/49 : Keep only in the original container at temperature not exceeding 25°C
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