

MATERIAL AND SAFETY DATA SHEET



According to 91/155/EC

Issued on : 01 September 1996
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Product : **ORIBIOTIC**

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

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

Identification of the preparation

Trade name : ORIBIOTIC, Ear ointment
Type of use : Veterinary Medicinal product. Ear infections due to bacterial or fungal affections in dogs and cats.
Other data : Ear ointment – List I

Identification of the company

VETOQUINOL S.A.
Veterinary pharmaceutical industry
Magny-Vernois BP 189
70204 LURE CEDEX
FRANCE
Emergency contact: Safety department
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2. CHEMICAL CHARACTERISTICS

Nystatin	10 millions IU
Neomycin (as sulphate)	350 000 IU
Triamcinolone acetonide	0.10 g
Excipient containing 1 g lidocaine	to 100 g

3. HAZARD IDENTIFICATION

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Nystatin : no toxicity by oral or dermal route.

Neomycin sulphate : Harmful by ingestion, inhalation and skin contact. During pregnancy, risks of harmful effects for the child. May cause sensitisation by skin contact.

Triamcinolone acétonide : harmful by inhalation, ingestion or contact with skin. Can cause irritation. Teratogenic, can cause congenital malformation.

4. FIRST-AID MEASURES

Inhalation :
Skin contact : Remove soiled clothing. Wash skin with water and soap.
Eye contact : Wash immediately with plenty of water with the eyelids opened.
In case of irritation, consult an ophtalmologist.
Ingestion : Rinse mouth with water. Contact the nearest 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

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

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 : ointment
Colour : pale yellow
Odour :
pH : 5.5 to 7

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Density :
Solubility :
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 :

Neomycin sulphate :

LD₅₀ (oral/mouse) = 2880 mg/kg
LD₅₀ (oral/rat) = 10000 mg/kg

Triamcinolone acetonide :

LD₅₀ (oral/mouse) = 5 g/kg

Nystatin

LD₅₀ (oral/mouse) = 8g /kg
LD₅₀ (oral/rat) = 10g/kg

Other toxicological information :

12. ECOLOGICAL INFORMATION

Avoid any discharge into aquatic environment and into drains.

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

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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 the reach of children
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 **01 September 1996**. 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.