

Material Safety Data Sheet

According to 91/155/EC



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Product : **AURIZON**

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

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 : **AURIZON**
Manufacturer/Supplier : VETOQUINOL Laboratories
Service to contact : Pharmacovigilance Office
Emergency telephone : 33 3 84 62 55 55
Type of use : Veterinary Medicinal product
Anti-infectious and antifungal for dogs
Other data : Ear drop suspension – List I

2. CHEMICAL CHARACTERISTICS

Marbofloxacin	3 mg
Clotrimazole	10 mg
Dexamethasone (in the form of acetate)	1 mg
Excipient	1 ml

3. HAZARD IDENTIFICATION

Marbofloxacin :

Slightly irritating for skin with red spot symptoms and itching. Slightly irritating for eyes.

Clotrimazole :

Poison by intraperitoneal route. Moderately toxic by ingestion.

Dexamethasone :

Harmful by inhalation, skin contact and ingestion. Can lead to sensitization by skin contact. Possible risks of irreversible effects.

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4. FIRST-AID MEASURES

- Inhalation : Place the patient in the open air. If breathing is difficult, call a physician
Skin contact : Remove soiled clothing. Wash skin with water.
Eye contact : Wash immediately with plenty of water (for at least 15 minutes) and maintain the eyelids open. In case of persistent irritation, consult an ophtalmologist.
Ingestion : Rinse mouth with water. 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 : Impound and absorb with inert absorbents, collect the absorbents in a tight container.
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7. HANDLING AND STORAGE

Store at ambient temperature.

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 : Homogeneous suspension
Colour : Beige to yellow
Relative density : $\geq 0.960 \leq 0.980$
Removable volume : 10.0 – 11.0 ml
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 :

Marbofloxacin : LD₅₀ (oral/mouse) = 1781 mg/kg
LD₅₀ (SC/mouse) = 1121 mg/kg

LD₅₀ (oral/rat) = 3772 mg/kg
LD₅₀ (SC/rat) = 2094 mg/kg

Clotrimazole : LD₅₀ (oral/mouse) = 923 mg/kg
LD₅₀ (IP/mouse) = 347 mg/kg

LD₅₀ (oral/rat) = 708 mg/kg
LD₅₀ (IP/rat) = 461 mg/kg

Dexamethasone : LD₅₀ (oral/mouse) = > 2 g/kg

LD₅₀ (oral/rat) = > 3 g/kg

Product toxicity :

Other toxicological information :

12. ECOLOGICAL INFORMATION

Marbofloxacin : 265 mg/l < EC 50 (48 h/Daphnia Magna) < 283 mg/l
62,3 mg/l < NOEC (48 h) < 127 mg/l
Log Kow = - 0.835 at pH 7
Solubility in water = 7.52 mg/l at pH 7

Clotrimazole : Do not allow the product to spread into water, wastewater or soil.

Dexamethasone : 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 2 : Keep away from 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.
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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 09/02/01. 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.