According to 91/155/EC Vétoquino

Issued on : 27/05/99 Product: MARBOCYL 2 %

Reviewed on: English Version: 30/04/02

Laboratoires VETOQUINOL Veterinary Pharmaceutical specialities 34, Rue du Chêne Sainte-Anne 70200 <u>MAGNY-VERNOIS</u>

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 : MARBOCYL® 2 %

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 for cattle and pigs

Other data : Solution for injection – For animal treatment only.

2. CHEMICAL CHARACTERISTICS

Marbofloxacin	20 mg
Disodium edetate	0.1 mg
Monothioglycerol	0.5 mg
m-cresol	2.0 mg
Excipient	to 1 ml

3. HAZARD IDENTIFICATION

Marbofloxacin:

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

MARBOCYL 2 % Page 1/4

According to 91/155/EC Vétoquino

4. FIRST-AID MEASURES

Inhalation : Move the patient away from the contaminated area and place it in

the open air.

Skin contact : Remove soiled clothing. Wash skin with plenty of water

Eye contact : Flush immediately with plenty of water (for a least 15 minutes) and

maintain the eyelids open. In case of irritation, consult an ophtalmologist.

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

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 : Clear solution

Colour : Yellow-green to yellow-brown

Characteristic temperatures :

pH : 3.0 - 4.5

Density :

MARBOCYL 2 % Page 2/4

According to 91/155/EC Vétoquinol

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:

Marbofloxacin

 LD_{50} (p.o./mouse) = 1781 mg/kg

(s.c./mouse) = 1121 mg/kg

(p.o./rat) = 3772 mg/kg(s.c./rat) = 1837 mg/kg

Product toxicity:

Other toxicological information:

12. ECOLOGICAL INFORMATION

Marbofloxacin

265 mg/l < CE₅₀ (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

13. DISPOSAL CONSIDERATIONS

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

MARBOCYL 2 % Page 3/4

According to 91/155/EC Vétoquino

14. TRANSPORT INFORMATION

Transport by truck or railway

Transport by sea

Transport by air

: Not regulated
: 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 : Keep away from heat

S 24/25: Avoid contact with skin and eyes

S 56 : Dispose of this product and its container at hazardous or special waste collection

point.

S 61 : Avoid release to the environment. Refer to special instructions/Safety data 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 27/05/99. 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.

MARBOCYL 2 % Page 4/4