According to 91/155/EC



Issued on

: 01/09/96

Reviewed on: English Version: 03/09/09

TOLFINE Product:

Laboratoires VETOQUINOL

Veterinary Pharmaceutical specialities

34, Rue du Chêne Sainte-Anne 70200 MAGNY-VERNOIS

France

Tel. 33 3 84 62 55 55

33 3 84 62 55 16 Fax

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

: TOLFINE

Manufacturer/Supplier

: VETOQUINOL Laboratories : Pharmacovigilance Office

Service to contact Emergency telephone

: 33 3 84 62 55 55

Type of use

: Veterinary Medicinal product

Other data

: Non steroidal anti-inflammatory - Analgesic - Antipyretic for cattle and

swine.

Solution for injection – List II

CHEMICAL CHARACTERISTICS

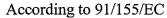
Tolfenamic acid......4,00 g Excipient Q.S...... 100 ml

3. HAZARD IDENTIFICATION

Tolfenamic acid: Harmful when ingested, inhaled and in contact with skin. A slight gastric intolerance may occur during long-term treatment.

Other component: Flammable. Slightly irritating when in contact with skin. Moderately irritating when in contact with eyes. Irritating for the respiratory tract and the mucous membranes.

Absorbing large quantities may cause gastrointestinal disorders, nausea, dizziness, sleepiness, vomiting and possibly kidney lesion.





FIRST-AID MEASURES

Inhalation

Skin contact

: Remove soiled clothing. Wash skin with water.

Eye contact

: Wash immediately with plenty of water. In case of irritation, consult

an ophtalmologist.

Ingestion

: Rinse mouth with water. Contact the closest Anti-Poison Centre.

FIRE-FIGHTING MEASURES

Recommended extinguishing methods: -Extinguishing measures to be avoided: -

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.

HANDLING AND STORAGE

Store at ambient temperature.

EXPOSURE CONTROLS AND PERSONAL PROTECTION

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

According to 91/155/EC



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : slightly viscous solution : colourless to slightly yello

Colour : colourless to slightly yellow

Odour : - Characteristic temperatures : -

pH : 7,5 to 9,5

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:

Tolfenamic acid:

 DL_{50} (oral/rat) = 508,4 mg/kg

 DL_{50} (SC/rat) = 246-334 mg/kg

 DL_{50} (IP/rat) = 238-299 mg/kg

 DL_{50} (IV/rat) = 112 mg/kg

Product toxicity:

 DL_{50} (IV/mouse) = 72,77 mg/kg

 DL_{50} (IM/mouse) = 273,7 mg/kg

Other toxicological information:

According to 91/155/EC



12. ECOLOGICAL INFORMATION

No data available.

Ecotoxicity

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 8

: Store in a dry place

S 15

: Store away from heat

S 24/25: Avoid contact with skin and eyes

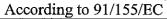
S 56

: 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 01/09/96. 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.