15 September 2011
EMA/CVMP/149845/2011 – Rev.1
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure no EU/11/185/FVG

Name of the substance: Azamethiphos

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Fish Vet Group Ltd submitted to the European Medicines Agency on 26 January 2011 an application for the establishment of maximum residue limits for azamethiphos in fin fish.

On 7 April 2011 the CVMP recommended the extension of the maximum residue limits for azamethiphos to fin fish.

On 12 September 2011 the European Commission requested the Committee to review its previous opinion and motivate why it considered unnecessary the submission of an analytical method and residue data for fin fish.

Recommendation

The Committee, having considered the application, and reviewed the request from the Commission, recommends by consensus the extension of the maximum residue limits for azamethiphos to fin fish and the modification of the entry in Commission Regulation (EU) 37/2010 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Azamethiphos	Not applicable	Fin fish	No MRL required	Not applicable	No entry	Antiparasitic agents/ Agents against ectoparasites

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The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European Public MRL Assessment Report (EPMAR), provided in Annex I of this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 15 September 2011

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)