EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2010
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Veterinary Medicine and Product Data Management

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

Procedure no: EU/09/169/SNA

Name of the substance: Isoeugenol

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Scan Aqua AS submitted to the European Medicines Agency on 7 July 2009 an application for the establishment of maximum residue limits for isoeugenol in Atlantic salmon and rainbow trout.

On 11 November 2009 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 18 June 2010.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for isoeugenol in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Isoeugenol	Isoeugenol	Fin fish	6000 µg/kg	Muscle and skin in natural proportions	Not applicable	Anaesthetic

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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 analytical method for monitoring of residues is appended to this opinion.

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

London, 15 September 2010

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

Annex I

European public MRL assessment report (EPMAR)