EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2011
EMA/CVMP/61867/2011-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/09/170/SCM

Name of the substance: Octenidine dihydrochloride (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Schülke & Mayr GmbH submitted to the European Medicines Agency on 30 July 2009 an application for the establishment of maximum residue limits for octenidine dihydrochloride in all mammalian food producing species.

On 9 December 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 12 August 2010.

On 8 February 2011 the Committee adopted an opinion recommending the establishment of maximum residue limits for octenidine dihydrochloride in all mammalian food producing species.

On 12 July the European Commission requested a reconsideration of the opinion of 8 February 2011 to review the possibility of extrapolation to poultry, eggs and honey.

Recommendation

The Committee, having considered the application, evaluated the response to the list of questions and reviewed the request from the Commission, recommends by consensus the inclusion of octenidine dihydrochloride in table 1 of Commission Regulation (EC) No. 37/2010 of 22 December 2009 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Octenidine dihydrochloride	Not applicable	All mammalian food producing species	No MRL required	Not applicable	For cutaneous use only	Anti-infectious agents/Anti-septics

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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)