EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 November 2014
EMA/CVMP/633015/2014
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: EMEA/V/MRL/004039/FULL/0001

Name of the substance: Propyl 4-hydroxybenzoate and its sodium salt

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, the International Federation for Animal Health (Europe) on behalf of a consortium of 30 marketing authorisation holders, submitted to the European Medicines Agency on 20 May 2014, an application for the establishment of maximum residue limits for propyl 4-hydroxybenzoate and its sodium salt in all food producing species.

Recommendation

The Committee, having considered the application, concluded that the establishment of maximum residue limits for propyl 4-hydroxybenzoate and its sodium salt in all food producing species is not necessary for the protection of human health and therefore recommends by consensus the inclusion of propyl 4-hydroxybenzoate and its sodium salt in table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Propyl 4-hydroxy-benzoate and its sodium salt	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For use as preservative only	NO ENTRY

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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, 6 November 2014

Signature on file

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

Annex I

European Public MRL assessment report (EPMAR)