

10 December 2015 EMA/CVMP/758984/2015 Committee for Medicinal Products Veterinary Use

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

Procedure no: EMEA/V/MRL/004268/FULL/0001

Name of the substance: Copper carbonate (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Warburton Technology submitted to the European Medicines Agency (EMA) on 23 June 2015 an application for the establishment of maximum residue limits for copper carbonate in all food producing species.

Recommendation

The Committee, having considered the application, concluded that the establishment of maximum residue limits for copper carbonate in all food producing species is not necessary for the protection of human health and therefore recommends by consensus the inclusion of copper carbonate 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 provision s	Therapeutic classification
Copper carbonate	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Alimentary tract and metabolism/ Mineral supplement

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The Icelandic CVMP member agrees 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, 10 December 2015

Signature on file

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

European public MRL assessment report (EPMAR)