14 July 2016
EMA/CVMP/453264/2016
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/003298/MODF/0004

Name of the substance: Aluminium salicylate, basic (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, COOPHAVET submitted to the European Medicines Agency on 30 January 2013 an application for the modification of maximum residue limits for aluminium salicylate, basic to allow the establishment of a maximum residue limit in bovine milk.

On 13 June 2013 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 10 July 2014.

On 9 October 2014 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the establishment of provisional maximum residue limits for aluminium salicylate, basic for tissues in bovine and caprine species, *Equidae* and rabbits and for milk in bovine and caprine species and *Equidae* and adopted a list of questions to be addressed by the applicant.

Commission Implementing Regulation (EU) 2015/1308 of 29 July 2015 established provisional maximum residue limits for aluminium salicylate, basic in bovine and caprine species, *Equidae* and rabbits. The provisional maximum residue limits expire on 31 December 2016.

COOPHAVET submitted, on 24 March 2016, the responses to the list of questions further to the establishment of provisional maximum residue limits for bovine and caprine species, *Equidae* and rabbits.

Recommendation

The Committee, having considered the response to the list of questions after the establishment of the provisional maximum residue limits, recommends by consensus the removal of the provisional status of the maximum residue limits for aluminium salicylate, basic in bovine, caprine, *Equidae* and rabbit and the modification of the entry for aluminium salicylate, basic in Table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 as follows:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Aluminium salicylate, basic	Salicylic acid	Bovine, caprine, *Equidae*, rabbit	200 µg/kg 500 µg/kg 1500 µg/kg 1500 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antidiarrhoeal and anti-inflammatory agents
		Bovine, caprine, *Equidae*	9 µg/kg	Milk		
	NOT APPLICABLE	All food producing species except bovine, caprine, *Equidae*, rabbit and fin fish	No MRL required	NOT APPLICABLE	For topical use only	

The Norwegian 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 preliminary 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, 14 July 2016

Signature on file

Dr David Murphy
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)