13 January 2010
EMA/CVMP/13789/2010

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

Procedure no EU/07/159/PFZ

Name of the substance: Sodium salicylate

Basis for the opinion

Pursuant to Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Chevita GmbH submitted to the EMEA on 4 January 2007 an application for the extension of the entry in Annex II of Regulation 2377/90 for sodium salicylate which is restricted to oral use to include turkeys.

On 18 April 2007 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 to the EMEA on 13 November 2007.

On 12 December 2007 the Committee for Medicinal Products for Veterinary Use adopted an opinion recommending the amendment of the current entry in Annex II of Regulation (EEC) No 2377/90 to include sodium salicylate for oral use to turkeys.

After having received the above mentioned opinion the services of the European Commission were consulted on a draft Commission Regulation amending Regulation (EEC) No 2377/90. During the consultation, objections were raised and the opinion was returned to the Committee to consider whether its opinion should be reviewed. On 13 May 2008 the Committee for Medicinal Products for Veterinary Use confirmed its previous opinion recommending the amendment of the current entry in Annex II of Regulation (EEC) No 2377/90 to include sodium salicylate for oral use to turkeys.

On 3 November 2009 the European Commission repeated its request to the Committee to review its previous opinion and to propose the establishment of maximum residue limits for sodium salicylate in turkeys.

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Opinion

The Committee, having considered the application as well as the comments from the European Commission, recommends by consensus the establishment of provisional maximum residue limits for sodium salicylate in turkeys in accordance with the table shown below:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Sodium salicylate	Salicylic acid	Turkey	400 µg/kg 2500 µg/kg 200 µg/kg 150 µg/kg	Muscle Skin+fat Liver Kidney	Not for use in animals producing eggs for human consumption Provisional maximum residue limits expire on 1 January 2015	Anti-inflammatory agents/ Non-steroidal anti-inflammatory agents

The Norwegian and Icelandic CVMP members agree with the above-mentioned recommendation of the Committee.

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

London, 13 January 2010

Signature on file

Dr. G. Moulin
Chairman, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)