5 October 2017
EMA/CVMP/617222/2017
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/004321/FULL/0001

Name of the substance: Solvent naphtha, light aromatic

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Zoetis Belgium SA submitted to the European Medicines Agency on 2 October 2015 an application for the establishment of maximum residue limits for solvent naphtha, light aromatic in all food producing species.

On 18 February 2016, 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 13 March 2017.

Recommendation

The Committee, having considered the application, and having evaluated the response to the list of questions, recommends by consensus the inclusion of solvent naphtha, light aromatic in table 1 of the Annex to Regulation (EU) No 37/2010 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Solvent naphtha, light aromatic, with cumene concentration not exceeding 2.5%, and benzene concentration not exceeding 0.0002%	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For cutaneous use only. Only at volume not exceeding 15 µl solvent naphtha/kg bw.	NO ENTRY

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

Annex I

European public MRL assessment report (EPMAR)