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# COMMISSION REGULATION (EC) No 2430/1999

**of 16 November 1999**

**linking the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances in feedingstuffs to persons responsible for putting them into circulation**

**(Text with EEA relevance)**

(OJ L 296, 17.11.1999, p. 3)

Amended by:

| | | Official Journal | | |
|---|---|---|---|---|
| | | No | page | date |
| ►M1 | Council Regulation (EC) No 1756/2002 of 23 September 2002 | L 265 | 1 | 3.10.2002 |
| ►M2 | Commission Regulation (EC) No 2037/2005 of 14 December 2005 | L 328 | 21 | 15.12.2005 |
| ►M3 | Commission Regulation (EC) No 249/2006 of 13 February 2006 | L 42 | 22 | 14.2.2006 |
| ►M4 | Commission Regulation (EC) No 1519/2007 of 19 December 2007 | L 335 | 15 | 20.12.2007 |
| ►M5 | Commission Regulation (EC) No 552/2008 of 17 June 2008 | L 158 | 3 | 18.6.2008 |
| ►M6 | Commission Regulation (EC) No 976/2008 of 6 October 2008 | L 266 | 3 | 7.10.2008 |
| ►M7 | Commission Regulation (EU) No 874/2010 of 5 October 2010 | L 263 | 1 | 6.10.2010 |
| ►M8 | Commission Regulation (EU) No 885/2010 of 7 October 2010 | L 265 | 5 | 8.10.2010 |

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# COMMISSION REGULATION (EC) No 2430/1999

## of 16 November 1999

## linking the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances in feedingstuffs to persons responsible for putting them into circulation

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([1]), as last amended by Commission Regulation (EC) No 1636/1999 ([2]), and in particular Article 9h(3)(b) and Article 9i(3)(b) thereof,

Whereas:

(1) because of the risk for human and animal health posed by the circulation in the Community of poor copies of zootechnical additives, Directive 70/524/EEC, as amended by Council Directive 96/51/EC ([3]), provides for the linking of the authorisation of certain classes of additives to the person responsible for putting them into circulation;

(2) in particular Article 9h of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex I after 31 December 1987 and belonging to the group of coccidiostats and other medicinal substances and transferred to Chapter II of Annex B by authorisations linked to the person responsible for putting them into circulation for a period of 10 years;

(3) in particular Article 9i of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex II before 1 April 1998 and belonging to the group of coccidiostats and other medicinal substances and transferred to Chapter III of Annex B by provisional authorisations linked to the person responsible for putting them into circulation;

(4) the additives listed in the Annexes to this Regulation were the subject of new applications for authorisation by the person responsible for the dossier on the basis of which the former authorisations were given or by their successors. The applications relating to those additives were accompanied by the required monographs and identification notes;

(5) the linking of the authorisation to a person responsible for putting the additive into circulation is based on a purely administrative procedure and did not entail a fresh assessment of the additives. Although the authorisations are given for a specified period they may be withdrawn at any time in accordance with Article 9m and Article 11 of Directive 70/524/EEC. In particular, authorisations of additives may be withdrawn as a result of the re-evaluation carried out under Article 9g of Directive 70/524/EEC;

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 194, 27.7.1999, p. 17.
([3]) OJ L 235, 17.9.1996, p. 39.

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(6) the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

*Article 1*

The provisional authorisations of the additives listed in Annex I to this Regulation are replaced by authorisations granted to the person responsible for putting the additive in circulation, inserted in the second column of Annex I.

*Article 2*

The provisional authorisations of the additives listed in Annex II to this Regulation are replaced by provisional authorisations granted to the person responsible for putting the additive into circulation, inserted in the second column of Annex II.

*Article 3*

This Regulation shall enter into force on the seventh day of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

*ANNEX I*

| Registration number of additive | Name and registration number of person responsible for putting additive into circulation | Additive (trade name) | Composition, chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | Period of authorisation | ►M2 Maximum Residue Limits (MRLs) ◄ |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | | |
| E 758 | ►M5 Alpharma (Belgium) BVBA ◄ | Robenidine hydrochloride 66 g/kg (Cycostat 66 G) | **Additive composition:**<br>Robenidine hydrochloride: 66 g/kg<br>Lignosulfonate: 40 g/kg<br>Calcium sulfate dihydrate: 894 g/kg<br>**Active substance:**<br>Robenidine hydrochloride, $C_{15}H_{13}Cl_2N_5.HCl$,<br>1,3-bis[(p-chlorobenzylidene)amino]-guanidine hydrochloride,<br>CAS number: 25875-50-7<br>Related impurities:<br>N.N′.N″-Tris[(p-Cl-benzylidene)amino]guanidine: ≤ 1 %<br>Bis-[4-Cl-benzylidene]hydrazine: ≤ 1 % | Rabbits for breeding purposes | — | 50 | 66 | Use prohibited at least five days before slaughter | 30.9.2009 | |
| ▼M7 ——— ▼B | | | | | | | | | | |
| E 764 | ►M3 Huvepharma nv ◄ | Halofuginone hydrobromide 6 g/kg (Stenorol) | **Additive composition:**<br>Halofuginone gydrobromide: 6 g/kg<br>Gelatine: 13,2 g/kg<br>Starch: 19,2 g/kg<br>Sugar: 21,6 g/kg<br>Calcium carbonate: 940 g/kg<br>**Active substance:**<br>Halofuginone hydrobromide, $C_{16}H_{17}BrClN_3O_3$, HBr<br>DL-trans-7-bromo-6-chloro-3-(3-(3-hydroxy-2-piperidy)acetonyl)quinazolin-4(3H)-one hydrobromide,<br>CAS number: 64924-67-0<br>Related impurities:<br>Cis-isomer of halofuginone: < 1,5 % | Chickens for laying | 16 weeks | 2 | 3 | — | 30.9.2009 | |

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| Registration number of additive | Name and registration number of person responsible for putting additive into circulation | Additive (trade name) | Composition, chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | Period of authorisation | ►M2 Maximum Residue Limits (MRLs) ◄ |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | | |
| ▼M1 ——— | | | | | | | | | | |
| ▼B | | | | | | | | | | |
| E 770 | ►M5 Alpharma (Belgium) BVBA ◄ | Maduramicin ammonium alpha 1 g/100 g (Cygro 1 %) | **Additive composition:** Maduramicin ammonium alpha: 1 g/100 g Benzyl alcohol: 5 g/100 g Corn cob grits qs 100 g **Active substance:** Maduramicin ammonium alpha, $C_{47}H_{83}O_{17}N$, CAS number: 84878-61-5, ammonium salt of a polyether monocarboxylic acid produced by *Actinomadura yumaensis* (ATCC 31585) (NRRL 12515) Related impurities: Maduramicin ammonium beta: < 10 % | Chickens for fattening | — | 5 | 5 | Use prohibited at least five days before slaughter Indicate in the instructions for use: 'Dangerous for equines' 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicate' | 30.9.2009 | |
| ▼M6 E 771 | Janssen Pharmaceutica nv | Diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix) Diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix) | **Additive composition:** Diclazuril: 0,5 g/100 g Soybean meal: 99,25 g/100 g Polyvidone K 30: 0,2 g/100 g Sodium hydroxide: 0,0538 g/100 g Diclazuril: 0,2 g/100 g Soybean meal: 39,7 g/100 g Polyvidone K 30: 0,08 g/100 g Sodium hydroxide: 0,0215 g/100 g Wheat middling: 60 g/100 g | Chickens for fattening | — | 1 | 1 | — | 30.9.2009 | 1 500 µg diclazuril/kg of wet liver 1 000 µg diclazuril/kg of wet kidney 500 µg diclazuril/kg of wet muscle |

▼M6

| Registration number of additive | Name and registration number of person responsible for putting additive into circulation | Additive (trade name) | Composition, chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | Period of authorisation | ►M2 Maximum Residue Limits (MRLs) ◄ |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | | |
| | | | **Active substance:**<br>Diclazuril<br>$C_{17}H_9Cl_3N_4O_2$,<br>(±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile,<br>CAS number: 101831-37-2<br>Related impurities:<br>Degradation compound (R064318): ≤ 0,2 %<br>Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): ≤ 0,5 % individually<br>Total impurities: ≤ 1,5 % | | | | | | 500 µg diclazuril/kg of wet skin/fat |
| ▼M8 ——— | | | | | | | | | | |

►M1 ——— ◄

*ANNEX II*

| Registration number of additive | Name and registration number of person responsible for putting additive into circulation | Additive (trade name) | Composition, chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | Period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | |
| 26 | Hoechst Roussel Vet GmbH | Salinomycin sodium 120 g/kg (Sacox 120) | **Additive composition:**<br>Salinomycin sodium ≥ 120 g/kg<br>Silicium dioxide 10-100 g/kg<br>Calcium carbonate: 350-700 g/kg<br>**Active substance:**<br>Salinomycin sodium,<br>$C_{42}H_{69}O_{11}Na$,<br>CAS number: 53003-10-4,<br>sodium salt of a polyether mono-carboxylic acid produced by fermentation of *Streptomyces albus* (DSM 12217)<br>Related impurities:<br>< 42 mg elaiophylin/kg sali-nomycin sodium<br>< 40 g 17-epi-20-desoxy-sali-nomycin/kg salinomycin sodium | Rabbits for fattening | — | 20 | 25 | Use prohibited at least five days before slaughter<br>Indicate in the instructions for use:<br>'Dangerous for equines'<br>'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated' | 30.9.2000 (1) |
| | | | | Chickens reared for laying | 12 weeks | 30 | 50 | Indicate in the instructions for use:<br>'Dangerous for equines'<br>'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated' | 30.9.2000 (2) |
| 27 | Janssen Animal Health B.V.B.A. | Diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix)<br>Diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix) | **Additive composition:**<br>Diclazuril: 0,5 g/100 g<br>Soybean meal: 99,25 g/100 g<br>Polyvidone K 30: 0,2 g/100 g<br>Sodium hydroxyde: 0,0538 g/100 g<br>Diclazuril: 0,2 g/100 g<br>Soybean meal: 39,7 g/100 g<br>Polyvidone K 30: 0,08 g/100 g<br>Sodium hydroxide: 0,0215 g/100 g<br>Wheat middlings: 60 g/100 g | Turkeys | 12 weeks | 1 | 1 | Use prohibited at least five days before slaughter | 30.9.2000 (1) |
| | | | | Chickens reared for laying | 16 weeks | 1 | 1 | — | 30.9.2000 (3) |

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| Registration number of additive | Name and registration number of person responsible for putting additive into circulation | Additive (trade name) | Composition, chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | Period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | |
| | | | **Active substance:**<br>Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile,<br>CAS number: 101831-37-2<br>Related impurities:<br>Degradation compound (R064318): ≤ 0,2 %<br>Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): ≤ 0,5 % individually<br>Total impurities: ≤ 1,5 % | | | | | | |
| 28 | Roche Vitamins Europe Ltd | Maduramicin ammonium alpha 1 g/100 g (Cygro 1 %) | **Additive composition:**<br>Maduramicin ammonium alpha: 1 g/100 g<br>Benzyl alcohol: 5 g/100 g<br>Corn cob grits qs 100 g<br>**Active substance:**<br>Maduramicin ammonium alpha, $C_{47}H_{83}O_{17}N$,<br>CAS number: 84878-61-5,<br>ammonium salt of a polyether monocarboxylic acid produced by *Actinomadura yumaensis* (ATCC 31585) (NRRL 12515)<br>Related impurities:<br>Maduramicin ammonium beta: < 10 % | Turkeys | 16 weeks | 5 | 5 | Use prohibited at least five days before slaughter<br>Indicate in the instructions for use:<br>'Dangerous for equines'<br>'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated' | 30.9.2000 (2) |

(1) First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).
(2) First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).
(3) First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).