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COMMISSION REGULATION (EC) No 1852/2003

of 21 October 2003

authorising the use for 10 years of a coccidiostat in feedingstuffs

(Text with EEA relevance)

(OJ L 271 , 22.10.2003, p. 13)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 249/2006 of 13 February 2006	L 42	22	14.2.2006

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COMMISSION REGULATION (EC) No 1852/2003

of 21 October 2003

authorising the use for 10 years of a coccidiostat in feedingstuffs

(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 1847/2003 ([2]), and in particular Articles 3 and 9 thereof,

Whereas:

(1) Directive 70/524/EEC provides that Member States are to require that no additive may be put into circulation unless a Community authorisation has been granted.

(2) In the case of additives listed in Part I of Annex C to Directive 70/524/EEC, which includes coccidiostats and other medicinal substances, an authorisation linked to the person responsible for putting them into circulation may be given. Such authorisation may be given for a period of 10 years if all the relevant conditions laid down in that Directive are satisfied.

(3) The assessment of the application for an authorisation for a period of 10 years submitted in respect of the coccidiostat preparation, 'Sacox 120 microGranulate', shows that the relevant conditions laid down in Directive 70/524/EEC are satisfied.

The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the safety and the favourable effects of the coccidiostat preparation which belongs to the group 'Coccidiostats and other medicinal substances', for chickens reared for laying.

(4) Accordingly, the coccidiostat preparation 'Sacox 120 microGranulate' should be authorised for a period of 10 years and included in the list of authorised additives linked to the person responsible for putting them into circulation and authorised for a period of 10 years as provided for in Directive 70/524/EEC.

(5) The assessment of the application shows that certain procedures are required to protect workers from exposure to the additive 'Sacox 120 microGranulate'. However, such protection is assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([3]).

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The additive 'Sacox 120 microGranulate' belonging to the group 'Coccidiostats and other medicinal substances' as set out in the Annex is authorised for use as an additive in animal nutrition under the conditions laid down in the Annex.

Article 2

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 269, 21.10.2003, p. 3.
([3]) OJ L 183, 29.6.1989, p. 1.

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

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ANNEX

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 (mg of active substance/kg of complete feedingstuff)	Maximum content (mg of active substance/kg of complete feedingstuff)	Other provisions	Period of authorisation
'Coccidiostats and other medicinal substances									
E766	►**M1** Huvepharma nv ◄	Salinomycin sodium 120 g/kg (Sacox 120 microGranulate)	**Additive composition:** Salinomycin sodium: ≥ 120 g/kg Silicon dioxide: 10-100 g/kg Calcium carbonate: 350-700 g/kg **Active substance:** Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, CAS number: 53003-10-4, sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (DSM 12217) Related impurities: < 42 mg elaiophylin/kg salinomycin sodium. < 40 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium	Chickens reared for laying	12 weeks	50	50	Indicate in the instructions for use: "Dangerous for equines and turkeys" "This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra-indicated".	11.11.2013'