This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

►**B**

COMMISSION REGULATION (EC) No 162/2003

of 30 January 2003

concerning the authorisation of an additive in feedingstuffs

(Text with EEA relevance)

(OJ L 26, 31.1.2003, p. 3)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 1519/2007 of 19 December 2007	L 335	15	20.12.2007
►**M2**	Commission Regulation (EC) No 976/2008 of 6 October 2008	L 266	3	7.10.2008

▼B

COMMISSION REGULATION (EC) No 162/2003

of 30 January 2003

concerning the authorisation of an additive 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 Council Regulation No 1756/2002 ([2]), and in particular Article 9 thereof,

Whereas:

(1) Under Article 2(aaa) of Directive 70/524/EEC authorisations for putting coccidiostats into circulation are to be linked to the person responsible for putting them into circulation. Such authorisations may be given for a period of 10 years provided all the conditions laid down in Article 3a of that Directive are met.

(2) The assessment of the request for authorisation submitted in respect of the coccidiostat preparation specified in the Annex to this Regulation, shows that the conditions referred to in Article 3a of Directive 70/524/EEC are satisfied. The coccidiostat preparation may therefore be authorised and included in Chapter I of the list of authorised additives in feedingstuffs referred to in Article 9t(b) of that Directive.

(3) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the safety and the favourable effects on animal productions of the coccidiostat preparation under the conditions set out in the Annex to this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

The additive belonging to the group ‘Coccidiostats and other medicinal substances’ listed in the Annex to this Regulation is authorised for use as additive in animal nutrition under the conditions laid down in the Annex.

Article 2

This Regulation shall enter into force on the day following that 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.

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 265, 3.10.2002, p. 1.

▼M2

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	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff				
Coccidiostats and other medicinal substances										
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 *Active substance:* 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, CAS number: 101831-37-2 *Related impurities:* Degradation compound (R064318): ≤ 0,2 % Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): ≤ 0,5 % individually Total impurities: ≤ 1,5 %	Chickens reared for laying	16 weeks	1	1	—	20.1.2013	1 500 µg diclazuril/kg of wet liver 1 000 µg diclazuril/kg of wet kidney 500 µg diclazuril/kg of wet muscle 500 µg diclazuril/kg of wet skin/fat