

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	Composition, chemical formula, description, analytical method	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 food-stuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
51766	Huvepharma NV.	Salinomycin sodium 120 g/kg (Sacox 120 microGranulate)	<i>Additive composition</i> (Sacox120 microGranulate): Salinomycin sodium: 114-132 g/kg Silicon dioxide: 10-100 g/kg	Chickens for fattening	—	50	70	1. The additives shall be incorporated in compound feed in the form of a pre-mixture. 2. The following shall be indicated 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'. 3. Salinomycin sodium shall not be mixed with other coccidiostats. 4. A post-market monitoring program on the resistance to bacteria and <i>Eimeria</i> spp. shall be planned and executed by the holder of authorisation.	9 November 2027	150 µg salinomycin sodium/kg of liver; 40 µg salinomycin sodium/kg of kidney; 15 µg salinomycin sodium/kg of muscle, and 150 µg salinomycin sodium/kg. skin/fat.
		Salinomycin sodium 200 g/kg (Sacox 200 microGranulate)	Calcium carbonate: 500-700 g/kg Solid form (Sacox 200 microGranulate): Salinomycin sodium: 190-220 g/kg Silicon dioxide: 50-150 g/kg Calcium carbonate: 50-150 g/kg Solid form <i>Characterisation of the active substance</i> Salinomycin sodium, $C_{42}H_{69}NaO_{11}$, CAS number: 55721-31-8,	Chickens reared for laying	12 weeks	50	50			

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			<p>sodium salt of a polyether monocarboxylic acid produced by fermentation of <i>Streptomyces azureus</i> (DSM 32267)</p> <p>Related impurities:</p> <ul style="list-style-type: none"> — ≤ 10 mg elaiophylin/kg salinomycin sodium. — ≤ 2 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium. — ≤ 10 g 20-desoxysalinomycin/kg salinomycin sodium. — ≤ 10 g 18,19-dihydrosalinomycin/kg salinomycin sodium. — ≤ 10 g methylated salinomycin/kg salinomycin sodium. <p><i>Analytical method</i> (1)</p> <p>For the quantification of salinomycin in the feed additive:</p> <p>High Performance Liquid Chromatography using post-column derivatisation coupled to spectrophotometric detection (HPLC-PCD-UV-Vis).</p>					<p>5. Zero days of withdrawal time.</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, eyes and skin protections.</p>		

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			<p>For the quantification of salinomycin in premixtures and feedingstuffs:</p> <p>High Performance Liquid Chromatography using post-column derivatisation coupled to spectrophotometric detection (HPLC-PCD-UV-Vis) — EN ISO 14183.</p>							

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>