

ANNEX

| Identification number of additive | Name of the holder authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|----------------------------------|---------------------------------|---|-------------------------------|-------------|---|-----------------|---|--|
| | | | | | | mg of active substance/kg of complete feedingstuff with a moisture content of 12% | | | |
| Additive category: coccidiostats and histomonostats | | | | | | | | | |
| 51777 | HuvePharma NV | Amprolium hydrochloride (COXAM) | <p>Additive composition</p> <p>Amprolium HCl: 250 g/kg</p> <p>Liquid paraffin: 30 g/kg</p> <p>Rice hulls <i>q.s.</i> to 1,000 g.</p> <p>Characterisation of the active substance</p> <p>Amprolium hydrochloride (>97.5%purity)</p> <p>C₁₄H₁₉ClN₄.HCl,</p> <p>(1-[(4-amino-2-propyl-5-pyrimidinyl)methyl]-2-methylpyridinium chloride monohydrochloride,</p> <p>CAS Number: 137-88-2</p> <p>Related impurities:</p> <p>2-picoline < 0.52%</p> <p>sulfated ash ≤ 0.1%</p> <p>Analytical method¹</p> <p>For the quantification of amprolium in the feed additive:</p> <p>- Reversed-Phase High Performance Liquid Chromatography using Ultraviolet detection at 268 nm (RP-HPLC-UV).</p> <p>For the quantification of amprolium in premixtures and feedingstuffs:</p> <p>- Cation exchange High Performance Liquid Chromatography using</p> | Chickens for fattening | - | 125 | 125 | <p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. The additive shall be incorporated in compound feed in the form of a premixture.</p> <p>3. The additive shall not be mixed with other coccidiostats.</p> <p>4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp.</p> <p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of their 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 skin and breathing protection.</p> | [10 years from the date of entry into force of this Regulation. To be completed by the OP] |

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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>

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|--|--|--|---|--|--|--|--|--|--|
| | | | Ultraviolet detection at 264 nm (IE-HPLC-UV) - Regulation (EC) No 152/2009. | | | | | | |
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