

ITEM: Preparation for the prevention of the clinical signs of coccidiosis in lambs and calves, in the form of an oral suspension, composed of a coccidiostat (diclazuril, 2.5 mg/ml), water and other excipients. The preparation must be administered orally in a single dose (1 mg of diclazuril per kg of live weight). The preparation is put up in 200 ml or 1 l, 2.5 l or 5 l containers. It is intended to be sold directly to users without any other packaging. The indications on the product's use (for example, the type of disorders to be treated by the product, method of use and dosage) are set out on the product's container, packaging or enclosed leaflet.

Suggested Tariff Classification

Phase 1

Top 3 candidate chapters

Chapter Justification

- 30** By GRI 1, classify by heading text and legal notes; heading 3004 covers medicaments for therapeutic or prophylactic uses, dosed or packed for retail sale, which matches an oral coccidiostat with dosage and retail containers (3004). Veterinary products fall within Chapter 30 (e.g., 3005 mentions veterinary uses; 30.06 notes include veterinary gels). As a mixture, essential character is given by diclazuril per GRI 3(b).
- 23** Chapter 23 includes preparations of a kind used for animal feeding (23.09) and defines its scope for such products in its Note 1. However, applying GRI 3(a), a medicament of 3004 is more specific than feed preparations, and by GRI 1 the item is packed for retail sale as a prophylactic medicament.
- 29** Chapter 29 covers only separate chemically defined organic compounds (Note 1), not preparations with excipients. Given the item is a preparation, classification as a medicament prevails by GRI 1/3(a) over Chapter 29's scope.

Phase 2

TARIFF CLASSIFICATION OPINION

I. Applicable legal framework

- General Rules of Interpretation (GRI), Rule 1: “Classification is legally determined by the terms of the headings and of any relative Section or Chapter Notes” (translated from Spanish; see GRI 1).
- GRI 3(a): “The heading which provides the most specific description shall be preferred to headings providing a more general description” (translated; see GRI 3(a)).
- GRI 3(b): For mixtures and composite goods, classification shall be according to the material or component which gives them their essential character, when this can be determined (translated; see GRI 3(b)).
- GRI 6: Subheading-level classification is determined by the terms of those subheadings and related Notes, applying the GRIs mutatis mutandis and comparing only subheadings of the same level (translated; see GRI 6 and its Explanatory Note).
- Chapter 30, heading 30.04 (legal text): “Medicaments (excluding products of headings 30.02, 30.05 or 30.06) consisting of mixed or unmixed products, for therapeutic or prophylactic uses, put up in measured doses (including transdermal administration) or in packings for retail sale” (translated).
- Chapter 30, heading 30.03 (legal text): Medicaments for therapeutic or prophylactic uses, but “not in measured doses nor put up for retail sale” (translated).
- Chapter 30, heading 30.02 (legal text excerpts): includes “Vaccines for veterinary medicine” (translated).
- Chapter 30, heading 30.06 (scope per National Explanatory Notes—NESA condensed): this heading covers only the products listed in items a) to k) (e.g., sterile sutures, opacifying preparations for radiological examination, clinical trial placebos/kits, certain gels used as lubricants, etc.) (translated).
- Chapter 23, heading 23.09 (legal text and Note): “Preparations of a kind used in animal feeding” (translated); and Note 1 to Chapter 23 clarifies that heading 23.09 covers products of the types used for feeding animals obtained by processing vegetable or animal materials (translated).

II. Legal-technical analysis

- Product description assessed: an oral suspension for the prevention of the clinical signs of coccidiosis in lambs and calves, containing diclazuril (2.5 mg/ml) as the coccidiostat, with water and excipients; to be administered orally in a single dose;

put up in 200 ml to 5 l containers; sold directly to users; label/package/leaflet shows indications, usage and dosage.

A. Chapter and heading selection

- By GRI 1, the legal text of heading 30.04 governs: it covers medicaments for therapeutic or prophylactic use, put up in measured doses or in packings for retail sale. The described preparation is a prophylactic veterinary medicament against coccidiosis, presented for direct sale to users with instructions and dosage. Therefore, it meets the terms “for therapeutic or prophylactic uses” and “put up ... for retail sale” of heading 30.04.
- Heading 30.03 is inapplicable because it covers medicaments not put up in measured doses nor for retail sale, whereas the product is expressly presented for direct sale with dosage instructions.
- Heading 30.02 is inapplicable; the article is not a vaccine or an immunological product for veterinary medicine, but a chemical coccidiostat oral suspension.
- Heading 30.06 is inapplicable; the product does not fall among the exhaustively listed items a)–k) covered by that heading (e.g., sterile sutures, opacifying preparations, clinical trial kits, gels as medical lubricants, etc.).

Conclusion at heading level: heading 30.04 applies by GRI 1, as the most specific description compared with generic feed preparations of Chapter 23 (see section III) per GRI 3(a).

B. Subheading selection (GRI 6)

- Within 3004, subheadings are distinguished by the presence of particular active classes:
 - 3004.10: containing penicillins/streptomycins (antibiotics) — not applicable.
 - 3004.20: other antibiotics — not applicable.
 - 3004.31–3004.39: containing hormones/derivatives or certain alkaloids and the like — not applicable given the stated active agent is a coccidiostat outside those groups.
 - 3004.50: containing vitamins or products of heading 29.36 — not applicable.
 - 3004.60: antimalarial actives listed in the subheading Note — not applicable (the Note lists artemisinin-related actives; a coccidiostat for veterinary use is not among them).

- Therefore, by GRI 6, the product falls under “Other” subheading 3004.90.

Applying GRI 3(b) to the preparation (active ingredient plus excipients), the essential character is given by the active coccidiostat diclazuril; the excipients do not alter the nature of the product as a prophylactic medicament, supporting classification in 3004, and, within it, in 3004.90 as “Other”.

III. Exclusion of alternative headings or chapters (Chapters 30 and 23 only)

- 30.02 (vaccines, toxins, cultures; including “Vaccines for veterinary medicine”): not applicable because the product is not a vaccine nor an immunological product; it is a coccidiostat oral suspension.
- 30.03 (medicaments, not in measured doses nor for retail sale): excluded because the product is presented for retail sale with dosage/use indications, which places it in heading 30.04, not 30.03.
- 30.06 (limited list of pharmaceutical preparations/articles per Note 4): excluded because the product is not one of the items a)–k) enumerated for that heading (e.g., sterile sutures, opacifying agents, clinical trial placebos/kits, gels as lubricants).
- 23.09 (preparations of a kind used in animal feeding) and Chapter 23 Note 1: excluded. Heading 23.09 covers products used for feeding animals obtained by processing of vegetable/animal materials and of a feeding nature, not medicaments for prophylactic/therapeutic treatment. In contrast, heading 30.04 expressly covers medicaments for therapeutic or prophylactic use put up for retail sale. By GRI 3(a), heading 30.04 is the more specific description for a single-dose prophylactic oral suspension against coccidiosis, rather than the generic scope of animal feed preparations in Chapter 23.

IV. Documentary requirements To substantiate the conditions of heading 30.04 (“for therapeutic or prophylactic uses” and “put up ... for retail sale”), the importer should be able to provide, at minimum:

- Product label, immediate container or outer packaging, and leaflet showing:
 - therapeutic/prophylactic indication (prevention of clinical signs of coccidiosis) and species (lambs, calves),
 - dosage and method of administration (single oral dose; 1 mg/kg), and
 - presentation/pack sizes intended for direct sale to users (200 ml–5 l), corroborating “packings for retail sale” as required by heading 30.04.

- 112 • Technical data sheet or composition indicating the active ingredient (diclazuril) and
113 its concentration, supporting the essential character under GRI 3(b). These
114 documents directly evidence the criteria in the legal text of heading 30.04.

115 V. Conclusion

- 116 • Legal determination: By application of GRI 1 and 3(a), the product is a medicament
117 for prophylactic use, put up for retail sale, of heading 30.04; by GRI 6, as it does not
118 contain antibiotics, hormones, alkaloids, vitamins/products of 29.36, nor
119 antimalarial actives, it falls under subheading 3004.90 (“Other”).

120 Classification table:

- 121 • Chapter: 30
122 • Heading: 30.04
123 • Subheading (requested level): 3004.90
124 • National fraction: Not determined here (classification issued at subheading level as
125 requested)
126 • NICO: Not determined here (classification issued at subheading level as requested)

127 Resolution: Preparation for the prevention of the clinical signs of coccidiosis in lambs and
128 calves, oral suspension with diclazuril, put up for retail sale with dosage and indications, is
129 classified in 3004.90.

130 Note on the user’s important remark: The final classification is 3004.90; accordingly, there
131 is no need to discard 3004.90.