Food and Agriculture Organization of the United Nations

European Commission for the Control of Foot-and-Mouth disease

PREQUALIFICATION OF FOOT-AND-MOUTH DISEASE VACCINE

Product overview

Tradename	BIOAFTOGEN
Manufacturer	Biogénesis Bagó S.A.
WWW	https://www.biogenesisbago.com/en/

Product image for the 120 ml Bioaftogen bottle

Country/region, National Regulatory Authority (NRA) or regional authority where product is registered/authorized and authorization reference:

Argentina, SENASA (Servicio Nacional de Sanidad y Calidad Agroalimentaria)	0095/E
South Korea, APQA (Animal and Plant Quarantine Agency)	403-002
Vietnam, Cục Thú y (Department of Animal Health)	BIB-04
Kuwait, PAAF (Public authority of Agriculture Affairs & Fish, Resources)	412/2020
Jordan (The Hashemite Kingdom of Jordan Ministry of Agriculture Veterinary and Animal Health)	N/A
Cambodia, GDAHP (General Directorate of Animal Health and Production)	FR02 016-1985/1121 BGC-GDAHP
Morocco, (Minister of Agriculture, Maritime Fishing, Rural Development and Water and Forests and the Minister of Health and Social Protection)	AMM No 2272
Israel, (Veterinary Services and Animal Health – Ministry of Agriculture and Rural Development)	9-308-29-20
Thailand, TFDA (Thailand Food and Drug Administration)	2F 3/66 (B)

Prequalification

Prequalification number:	PQv22-001
Prequalification date:	13 Sep 2023
Prequalification status:	Current

Product description

Target species	Bovine, buffaloes, swine, sheep, goats.

Active ingredients:

Active ingredient	Potency per dose
O1 Campos	≥6 PD_{50}*
A24 Cruzeiro	≥6 PD_{50}
A2001 Argentina	≥6 PD_{50}

*PD_{50} – 50% protective dose in cattle as described in the WOAH Terrestrial Manual.

Adjuvant	Mineral oil and saponin
Formulation	Oil emulsion
Shelf life	24 months
Shelf life after first opening	Use immediately after first opening.
Storage and transport	2°C – 8°C Protect from direct sunlight. Do not freeze.
Presentations	Polypropylene bottle 50 ml (25 doses bovine, buffaloes and swine, 50 doses sheep and goats)

	120 ml (60 doses bovine, buffaloes and swine, 120 doses sheep and goats)
Indications	Active immunization against foot and mouth disease.
Onset of immunity	1 week
Duration of immunity	6 months after primo-vaccination, 12 months after subsequent booster doses.

DIVA (Differentiate Infected from Vaccinated Animals):

The inactivated foot-and-mouth disease virus antigens in BIOAFTOGEN are purified and do not contain sufficient amounts of non-structural proteins to induce an antibody response following administration of BIOAFTOGEN vaccine containing an amount of antigen corresponding to ≥6 PD_{50}. Consequently, BIOAFTOGEN does not interfere with serological tests used for sero-surveillance of FMD virus circulation in vaccinated populations.

Primary vaccination schedule:

- Bovine and buffaloes: first vaccination at 8 – 12 weeks old.
  2 mL per dose by intramuscular (IM) injection on the upper neck behind and below the ear; or subcutaneous (SC) injection halfway up the neck behind the shoulder.

- Swine: first vaccination at 4 – 8 weeks old.
  2 mL per dose by intramuscular (IM) injection, on the neck muscle immediately behind the ear.

- Sheep and goat: first vaccination at 4 –12 weeks old.
  1 mL per dose preferably by intramuscular (IM) injection on the neck muscle immediately behind the ear or in the rump; or subcutaneous (SC) injection on the neck muscle or in the armpit.

Revaccination:

6 months after primo-vaccination, 12 months after subsequent booster doses