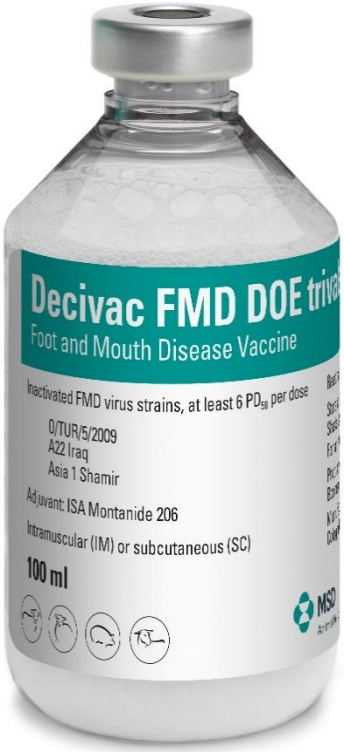
PREQUALIFICATION OF FOOT-AND-MOUTH DISEASE VACCINE

Product overview

Tradename	DECIVAC FMD DOE
Manufacturer	MSD Animal Health
WWW	https://www.msd-animal-health.com

Product image



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

GERMANY *	**BFA V/MKS/2/ 2000, 31 Jul 2000**
The NETHERLANDS*	**REG NL 116656, 22 May 2018**
ALGERIA	
KUWAIT	
LEBANON	
PAKISTAN	
SOUTH KOREA	
THAILAND	
TURKEY	

* The vaccine covered by this PQv listing is the same as that for which national multistrain marketing authorizations have been issued in these two countries. Due to the different epidemiological situation between countries, the strains of FMD virus that are included within the scope of national authorizations, including multistrain authorizations, differs between countries. Likewise, authorizations may differ in terms of the approved minimum potency per strain (usually 3 vs. 6 PD_{50}). This PQv listing includes all strains for which the manufacturer has demonstrated compliance with the technical requirements described in this report (particularly with respect to a minimum potency of 6 PD_{50}), irrespective of the national authorization on which the strains are included.

Prequalification

Prequalification number:	PQv22-003
Prequalification date:	12 April 2024
Prequalification status:	Current

Product description

Target species	Cattle, sheep, pigs, goats

Active ingredients:

Active ingredient	**Potency per dose**
Between one and three inactivated and purified Foot-and-Mouth Disease strains (serotypes O, A, Asia1, SAT 1) Between 1 and 3 strains: O1 Manisa O Turkey 5/2009** O South Korea 7/2010 A22 Iraq A Turkey 20/06 A Malaysia 11/97 A Saudi 23/86 Asia 1 Shamir SAT 1 Zimbabwe	≥6 PD_{50}* per strain

*PD_{50} – 50% protective dose in cattle as described in the WOAH Terrestrial Manual.
** The O/TUR/5/2009 strain (WRL code) belongs to the lineage O PanAsia-2.

Adjuvant	Montanide ISA 206
Formulation	Double Oil Emulsion (DOE)
Shelf life	12 months
Shelf life after first opening	Only after aseptic puncture and subsequent storage at 2 - 8 °C can the contents be used for a working day (8 hours). In other cases, use immediately, do not store.

Storage and transport	2°C – 8°C Protect from light. Do not freeze.
Presentations	Polyethylene terephthalate (PET) bottle 20 ml, 50 ml, 100 ml, 250 ml
Indications	Active immunization to reduce clinical signs and mortality following exposure to foot-and-mouth disease virus.
Onset of immunity	10 days after the first injection of primary vaccination schedule
Duration of immunity	6 months after the completion of the primary vaccination schedule

DIVA (Differentiate Infected from Vaccinated Animals):
DECIVAC FMD DOE has potential marker properties for use in DIVA (Differentiating Infected from Vaccinated Animals). Since the vaccine contains only purified viral structural proteins, repeated vaccination with highest vaccine combination, according to the test requirement in the WOAH Terrestrial Manual on FMD, does not generate antibodies to non-structural proteins.

Primary vaccination schedule:

Two injections of 1 dose each, 3-5 weeks apart.
Administration in cattle, sheep and goats may be by subcutaneous or intramuscular routes (e.g. in the dewlap or neck). In pigs administration should be by the intramuscular route (in the neck).
In areas where FMD is endemic, or in animals with MDA, administration of the second injection of the primary vaccination schedule is strongly recommended.

Revaccination:

- One dose every 6 months.