







Technical Bulletin

MONTANIDE™ ISA 71 VG

Ready to use oil adjuvant for veterinary vaccines

 Ready to use oil adjuvant for stable W/O emulsion

Known to stimulate

cellular immune response

Key Points:

• For an easy to inject vaccines

Contains an original

refined mineral oil

- Induces a strong and long lasting immune response
- MONTANIDE™ listed on Annex II of the European **Council Regulation** 2377/90/EC

 $\mathsf{MONTANIDE}^{^\mathsf{TM}}$ ISA 71 VG is a mineral oil based adjuvant that has been developed for the manufacture of water-in-oil (W/O) emulsions. It comprises a specific enriched light mineral oil and an extremely refined emulsifier obtained from mannitol and purified oleic acid of vegetable origin. MONTANIDE[™] ISA 71 VG is free of animal origin ingredients.

Vaccine formulations with Montanide ISA 71 VG induce a strong and long term immunity. Compared to traditional oil emulsions, MONTANIDE™ ISA 71 VG emulsions are robust, stable and easy to inject.

1. VACCINE PREPARATION:

To prepare 100 g of vaccine, a typical preparation is made of:

MONTANIDE™ ISA 71 VG: 70 g

• Aqueous antigenic medium: 30 a

Stable preparations are obtained by mixing the aqueous medium into the MONTANIDE™ ISA 71 VG. at room temperature or less, under vigorous stirring. The use of a high shear mixer is necessary to prepare a stable and efficient vaccine.

2. EMULSION CHARACTERISTICS: (on placebo antigenic medium)

TYPE	VISCOSITY (mPa.s)	CONDUCTIVITY (µS/cm)	DROPLET SIZE (micron)	STABILITY		
				After storage at 4°C	After storage at 25°C	After storage at 37°C
W/O (water-in- oil)	About 35 at 25°C	< 10 (placebo antigenic medium)	1 or less	More than 12 months	About 6 month	About 15 days

- 3. IMMUNE RESPONSE: MONTANIDE™ ISA 71 VG is capable of improving vaccine efficacy via the induction of a strong and long lasting immunity. It has been demonstrated during lab and field trial that is an excellent adjuvant to stimulate humoral and **cellular responses**. This product is recommended for bacterial, mycoplasma, viral or parasite antigens.
- 4. ANIMAL SPECIES: MONTANIDE™ ISA 71 VG adjuvant is currently employed in different vaccines notably those for cattle, poultry and small ruminants.
- 5. STRENGTH: As this adjuvant induce a strong and long lasting protection, it is suitable when antigen immunogenicity is intrinsically low. Due to its innovative composition based on a specific enriched light mineral oil, this adjuvant designed to raise the **TH1 response** improve significantly the IgG2 production compare to traditional oil adjuvant. Its offers the possibility to reduce the injected dose without loss of efficacy. Indeed diluted antigenic media can be formulated while keeping the same level of protection with a constant injected volume.
- 6. SAFETY AND REGULATORY: The toxicological tests made on MONTANIDE™ ISA range (Berlin test, Oral LD 50, IP LD 50, ocular irritation test, dermal irritation test, pyrogenicity) conclude to the non-toxicity and favourable tolerance of these adjuvants.

Montanide™ adjuvants and their components have been considered as safe by the Committee for Veterinary Medical Products (CVMP) for use in immunological products and are included as authorized substances in the annex of the European Council Regulation n° 470/2009 (previously 2377/90/EC) needing no further MRL studies or included in already registered veterinary commercial products.

The properties of the antigenic media are crucial for the vaccine efficacy but also for its safety. Each team developing a vaccine will have to study the safety and efficacy profile of the underdevelopment formula according to local market acceptance criteria.

For more information on this product or for any advice regarding the optimization of your vaccine, please contact our teams on www.seppic.com