MONTANIDE™ ISA 201 VG

Ready to use oil adjuvant for veterinary vaccines

MONTANIDE™ ISA 201 VG is a **mineral oil** based adjuvant which has been developed for the formulation of **Water-in-Oil-in-Water** (W/O/W) emulsions. It is based on a **specific enriched light mineral oil** and a highly refined emulsifier obtained from mannitol and purified oleic acid from vegetable origin. MONTANIDE™ ISA 201 VG is free of animal origin ingredients.

Vaccine formulations with MONTANIDE™ ISA 201 VG induce short and long term immunity. Compared to traditional double emulsions, MONTANIDE™ ISA 201 VG emulsions are **stable**, with **low viscosity** and **easy to inject**.

Vaccine preparation:

To prepare 100 g of vaccine with a one-step process:

- MONTANIDE™ ISA 201 VG 50 g
- Aqueous antigenic medium 50 g

For preparation in volume, MONTANIDE™ ISA 201 VG density is about 0.83 at 20°C.

Each phase has to be heated up to **31°C** before mixing. Stable preparations are obtained by mixing the aqueous medium into MONTANIDE™ ISA 201 VG under a **low shear agitation** (to maintain temperature above 30°C). After formulation, emulsions must be cooled down (please refer to full formulation process).

Emulsion characteristics:

PLACEBO EMULSION CHARACTERISTICS			
TYPE	VISCOSITY (mPa.s)	CONDUCTIVITY (µS/cm)	DROPLET SIZE (µm)
W/O/W	30 at 20°C	<10	Max 1

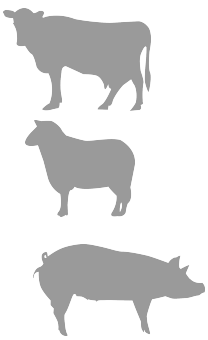
PLACEBO EMULSION STABILITY		
Storage at 4°C	Storage at 20°C	Storage at 37°C
12 months	3 months	Not relevant to predict long term stability for this product

Ready to use oil adjuvant for stable W/O/W emulsion

Induces a short and long lasting immune response

Known to stimulate cell mediated immunity

MONTANIDE™ listed on part I of the Annex of the European Council Regulation n° 37/2010/EU





4111/GB/04/May 2017

Immune response:

MONTANIDE™ ISA 201 VG is capable of improving vaccine efficacy via the induction of a short and long term immune response. It has been shown during laboratory and field trials that it stimulates both humoral and **cell mediated immune responses**. This product is recommended for bacterial, mycoplasma, viral or parasitic antigens.

Animal species:

MONTANIDE™ ISA 201 VG adjuvant is currently used in different vaccines for **cattle**, **swine** and **small ruminants**.

Advantages:

MONTANIDE™ ISA 201 VG has a **low viscosity** and renders fluid W/O/W emulsions through a **one step process** using classical low shear mixing equipment. It offers the properties of W/O/W emulsions, inducing both short and long term protections. Its innovative composition based on a specific enriched mineral oil also allows the induction of a high antigen specific cell mediated immune response.

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 also been considered as safe by the Committee for Veterinary Medical Products (CVMP) for use in immunological products and are included in the part I of the Annex of the European Council Regulation n° 37/2010/EU as substances needing no further Maximum Residue Limit (MRL) studies, or in the Out Of Scope list (EMA-CVMP-519714-2009), 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

Nota:

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Air Liquide Healthcare is a world leader in medical gases, home healthcare, hygiene products and healthcare specialty ingredients. It aims to provide customers in the continuum of care from hospital to home with medical products, specialty ingredients and services that contribute to protecting vulnerable lives.

An affiliate of Air Liquide HEALTHCARE

MONTANIDE™ ISA 206 VG

Ready to use oil adjuvant for veterinary vaccines

MONTANIDE™ ISA 206 VG is a **mineral oil** based adjuvant which has been developed for the formulation of **Water-in-Oil-in-Water** (W/O/W) emulsions. It is based on an injectable mineral oil and a highly refined emulsifier obtained from mannitol and purified oleic acid from vegetable origin. MONTANIDE™ ISA 206 VG is free of animal origin ingredients.

Vaccine formulations with MONTANIDE™ ISA 206 VG induce short and long term immunity. Compared to traditional oil emulsions, MONTANIDE™ ISA 206 VG emulsions are **stable**, with **low viscosity** and **easy to inject**.

Vaccine preparation:

To prepare 100 g of vaccine with a one-step process:

- MONTANIDE™ ISA 206 VG 50 g
- Aqueous antigenic media 50 g

Each phase has to be heated up **at 31°C** before mixing. Stable preparations are obtained by mixing the aqueous medium into the MONTANIDE™ ISA 206 VG a **low shear agitation** (please refer to full formulation process).

Emulsion characteristics:

PLACEBO EMULSION CHARACTERISTICS			
TYPE	VISCOSITY (mPa.s)	CONDUCTIVITY (µS/cm)	DROPLET SIZE (µm)
W/O/W	30 at room temperature	<10	Max 1

PLACEBO EMULSION STABILITY		
Storage at 4°C	Storage at 20°C	Storage at 37°C
>12 months	3 months	Not relevant to predict long term stability for this product

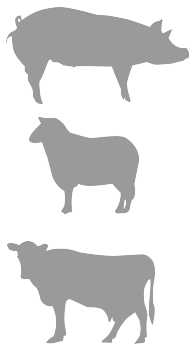
Ready to use oil adjuvant

For stable mineral W/O/W emulsion

Easy to inject vaccines

Induces a short and long lasting immune response

MONTANIDE™ listed on part I of the Annex of the European Council Regulation n° 37/2010/EU





3550/GB/04/May 2017

Immune response:

MONTANIDE™ ISA 206 VG is capable of improving vaccine efficacy via the induction of a **short** and **long immune response**. It has been shown during laboratory and field trials that it stimulates the humoral immune response and improves protection conferred by the antigen. This product is recommended for bacterial, mycoplasma, viral or parasitic antigens.

Animal species:

MONTANIDE™ ISA 206 VG adjuvant is currently used in different vaccines for **cattle, swine** and **small ruminants.**

Advantages:

MONTANIDE™ ISA 206 VG has a low viscosity and renders fluid W/O/W emulsions through a one step process using classical low shear mixing equipment. It offers the properties of W/O/W emulsions, inducing both short and long term protections. MONTANIDE™ ISA 206 VG has been widely used in **FMD vaccines** for swine and cattle.

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 also been considered as safe by the Committee for Veterinary Medical Products (CVMP) for use in immunological products and are included in the part I of the Annex of the European Council Regulation n° 37/2010/EU as substances needing no further Maximum Residue Limit (MRL) studies, or in the Out Of Scope list (EMA-CVMP-519714-2009), 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

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