



POLYGEN™

(Co-polymer Based Adjuvant)

Technical Bulletin

Summary of Key Points:

- Low molecular weight co-polymer
- Free of animal origin ingredients
- Terminally sterilized
- Ready for addition to antigen -- no further processing required
- Clear & colorless; no effect on final product appearance or viscosity
- Known to stimulate humoral and T-cell responses

POLYGEN™ is a unique, terminally-sterilized, low molecular weight, copolymer adjuvant which can form cross-linkages in solution to become a high molecular weight gel. It is clear and colorless and is free of animal origin ingredients. POLYGEN™ can be mixed directly with vaccine antigens, without any further processing, to enhance the immunogenicity of a finished vaccine.

POLYGEN™ can be used alone or in conjunction with other adjuvants, depending on your needs and applications. It is designed for parenteral application in all animals.

POLYGEN™ has been demonstrated to stimulate a significant interferon gamma response when used in a parasite vaccine for cattle. It has also been used successfully as a carrier for cytosine-phosphodiester-guanine oligodeoxynucleotides (CpG ODN).

POLYGEN™ may be combined with aluminum hydroxide or other MVP adjuvants. Contact MVP Laboratories for procedures.

INFORMATION ABOUT POLYGEN™

Immune Response: POLYGEN™ has the potential for inducing higher levels of humoral antibody, more rapid onset and longer duration of immunity, and better protection with a single vaccine dose as compared to conventional aluminum based adjuvants. POLYGEN™ has also been demonstrated to stimulate excellent interferon gamma responses. It can be used with bacterial, mycoplasma, viral and parasite antigens (either inactivated or modified live) or with subunit vaccines.

Animal Safety: POLYGEN™ has been approved for use in veterinary vaccines by USDA and provides a high degree of safety in companion animals and farm animals, especially with viral, parasite and subunit vaccines. It is normal for POLYGEN™ to exhibit some toxicity in laboratory mice when injected at vaccine concentrations.

Stability: Because of its unique chemical formulation, POLYGEN™ is exceptionally stable.

Syringeability: POLYGEN™ does not alter viscosity of the final vaccine.

Uniformity: The use of highly skilled operators and standardized manufacturing procedures ensures that each batch of POLYGEN™ will be consistent, uniform, and in compliance with established specifications.

Preservatives: Since POLYGEN™ is terminally sterilized, no preservatives are added. Preservatives may be added at the customer's request.

Ingredients: Each lot of POLYGEN™ is manufactured to the highest standards using the finest components available. All ingredients meet USP, NF, or equivalent specifications and/or have been approved for vaccine use by USDA. **POLYGEN™ is free of animal origin ingredients.**

Testing: Each ingredient in POLYGEN™ is thoroughly tested and must meet stringent in-house parameters for identity and consistency. Each lot of final product is thoroughly tested to ensure that it is free of viable bacteria and fungi. To assure batch-to-batch quality and consistency each lot is tested for conductivity, stability, specific gravity and pH. Processes are carefully monitored during manufacturing.

Storage: POLYGEN™ may be stored at 4°C-30°C (39°F-86°F). Temperature extremes should be avoided.

Packaging: POLYGEN™ is available in 10 and 20 liter containers. Other sizes can be supplied to meet customer needs.

INSTRUCTIONS FOR USE

- 1) It is recommended that POLYGEN™ be used at concentrations between 5% (v/v) to 15% (v/v).
- 2) POLYGEN™ should be mixed thoroughly before addition to the antigen. It can be added directly to inactivated or modified live antigens.
- 3) After thorough mixing, the vaccine is ready to fill.
- 4) POLYGEN™ can be lyophilized separately or in the presence of antigen.

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