



KEY POINTS

- Low molecular weight copolymer
- Free of animal origin ingredients
- Terminally sterilized
- Ready for addition to antigen—no temperature control or homogenization required
- Known to stimulate strong T-cell response
- EC Reg No. 470/2009, and USP-NF compendia compliant

Polygen® is a unique adjuvant formulated with a low molecular copolymer. It is a clear aqueous adjuvant with low viscosity. It is ready-to-use and can be mixed directly with vaccine antigen(s), without any further processing.

This antigen-friendly adjuvant is easy to use, as it can be mixed with your antigen at any temperature using only mild mixing without high-shear homogenization. Such a process will help to maintain antigen integrity, thus, enhance immunogenicity and improve vaccine safety.

Polygen can be used together with other adjuvants, depending on your needs and applications.

Designed for parenteral application in all animals, Polygen has been successfully used in, bovine, equine, swine, canine and feline vaccines where T-cell response is critical for protection. It has been demonstrated to stimulate significant interferon-gamma and interleukin-12 responses in cattle.

INFORMATION ABOUT POLYGEN

Ingredients: All ingredients meet USP, NF, or equivalent specifications and/ or have been approved for vaccine use by the United States Department of Agriculture (APHIS) and by European Medicinal Agency.

Manufacturing and Testing: Each ingredient in Polygen is thoroughly tested and meets stringent in-house parameters for identity and consistency. Each lot of final product is thoroughly tested for purity to ensure that it is free of viable bacteria and fungi, and for batch-to-batch quality and consistency. Processes are carefully monitored during manufacturing.

Immune Response: Polygen has the potential to induce strong cell-mediated and humoral antibody responses with a rapid onset. High levels of serum interferon gamma responses have been reported after vaccination with vaccines containing Polygen. Polygen can provide better and long-lasting protection with a single vaccine dose as compared to conventional aluminum based adjuvants. It has been used with bacterial, mycoplasma, viral and parasite antigens and with whole organisms or subunit antigens. Polygen can also be used in modified live antigens and can be lyophilized or used as part of an antigen stabilizer.

Safety: All ingredients in Polygen are approved for use in livestock by USDA, EMA (comply with EC37/2010, EC470/2009) and USP-NF. Polygen provides a high degree of safety in companion animals and livestock. Polygen does exhibit some inexplicable toxicity in laboratory mice when injected intraperitoneally.

Stability: Because of its unique formulation, Polygen is an exceptionally stable adjuvant.

Syringeability: Polygen *is a clear aqueous adjuvant that* does not alter viscosity or consistency of the final vaccine.

Preservatives: Because Polygen is terminally sterilized, preservatives are not generally added. Formaldehyde, gentamicin or other preservatives of choice may be added at the customer's request.

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-, 20- and 50-liter containers. Other sizes can be supplied to meet customer needs.

POLYGEN[®] INSTRUCTIONS FOR USE

1. For most vaccines, we recommend that POLYGEN be used at a concentration up to 20% (v/v). Determine the amount of adjuvant required based on the targeted inclusion rate and total volume of the vaccine.
2. Gentle agitation prior to use is recommended.
3. Mix the antigen at moderate speed using standard equipment (e.g. Lightning mixer or magnetic stirrers).
4. While the antigen is mixing, add Polygen slowly and continue mixing for at least 2 hours.
5. Check the pH and adjust if necessary (recommended range is 6.8 - 7.2).
6. It is recommended that the product continue to be gently mixed throughout filling to help assure consistency.
7. Products containing Polygen may be administered intramuscularly or subcutaneously to a wide variety of animals.

The Adjuvant Company That Understands Vaccines