CARBIGEN®

(Polymer Based Adjuvant)

KEY POINTS

- Carbomer based
- Free of animal origin ingredients
- Terminally sterilized
- Best with acid stable antigens
- Known to stimulate humoral and T-cell responses
- Effective for intranasal or parenteral products
- Manufactured using components on Annex II, EC Regulations No. 470/2009 and/or various GRAS lists

CARBIGEN® is a terminally-sterilized, carbomer-based adjuvant suspension containing a proprietary emulsified component and is free of animal origin ingredients. Its milky-white appearance creates a smooth, uniform mixture when added to your veterinary vaccine.

CARBIGEN is prepared in a non-buffered base and has a low pH (approximately 2.7). In order to obtain maximum benefit when combined with acid stable antigens add ***CARBIGEN*** to the antigen at the lowest pH possible for maximum antigen binding. Then, adjust the pH to between 6.8 and 7.2 for optimal antigen encapsulation.

If ***CARBIGEN*** is to be used with an acid labile antigen the adjuvant should be either first mixed with a sodium-containing buffer such as phosphate buffered saline or pH adjusted upward to a more antigen-friendly pH.

The polymer used to make ***Carbigen*** is a pharmaceutical grade, cross-linking polymer that encapsulates the antigen, providing a slow release as well as a depot effect. The depot effect with slow release improves the presentation of antigen to effector cells and provides a significant enhancement of the immune response and vaccine efficacy.

CARBIGEN has been used intranasally, by spray and immersion to produce IgA and IgG responses against various disease organisms.

INFORMATION ABOUT CARBIGEN

Immune Response: ***CARBIGEN*** has the potential to elicit higher levels of humoral antibody and cellular immunity, more rapid onset of immunity and enhanced protection with a single vaccine dose as compared with conventional aluminum based adjuvants. It may be combined with bacterial and viral antigens and administered parenterally or intranasally. ***CARBIGEN*** has been evaluated as an adjuvant for PCV2 vaccines and displays an excellent efficacy and safety profile.

Animal Safety: Carbopol-based adjuvant suspensions have been used in veterinary vaccines since the 1970's. They have been demonstrated to be safe and effective when used in all animal species. Each lot is safety tested in mice prior to release.

Stability: ***CARBIGEN*** is an emulsified suspension. As such, it does not separate upon storage.

Syringeability: Vaccines containing up to 20% ***CARBIGEN*** easily pass through a 25 gauge needle.

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

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

Ingredients: Each lot of ***CARBIGEN*** is manufactured to the highest standards using the finest components available. All ingredients meet USP, NF, EC Regulation No. 470/2009, or equivalent specifications and/or have been approved for vaccine use by USDA and regulatory agencies in other countries. ***CARBIGEN*** is free of animal origin ingredients.

Testing: Each ingredient contained in ***CARBIGEN*** 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 viscosity, specific gravity and pH. Macroscopic appearance is also carefully monitored during the manufacturing process. Other testing may be conducted at the customer's request.

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

Packaging: ***CARBIGEN*** is available in 10, 20 and 50 liter volumes. Other size containers can be provided at the customer's request. ***CARBIGEN*** is also available in sterile bags.

INSTRUCTIONS FOR USE

1) With **acid stable** antigens (for example, PCV2), add ***CARBIGEN*** to the antigen at a concentration up to 12% v/v for injectables, or at concentration 20% to 40% v/v for spray and immersion vaccines. Mix well for a minimum of two hours and gradually raise the pH with 10N NaOH to approximately 7.0. After the pH is adjusted, mix for an additional period of time (up to 12 hours). Make sure the pH is stable before filling the vaccine into final containers.

2) With **acid sensitive** antigens (for example, SIV), transfer the required volume of ***CARBIGEN*** **to a mixing vessel** equipped with a mixer (up to 12% v/v for injectables, and 20% to 40% v/v for spray and immersion vaccines). Carefully adjust the pH of the ***CARBIGEN*** upward with 10N NaOH* to as low a pH as the antigen will tolerate (for SIV this may be approximately pH 6.5). The lower the pH that the antigen can tolerate, the better will be the adjuvanting characteristic of ***CARBIGEN***. Note: ***CARBIGEN***'s viscosity will increase as the pH increases. If necessary, a small amount of NaCl solution or PBS may be added to reduce the viscosity. When the ***CARBIGEN*** **pH** reaches the desired pH range, start adding the antigen into the ***CARBIGEN*** vessel. First, add about 10% of the **antigen** and mix thoroughly and notice that the ***CARBIGEN***-antigen mixture thins out. Mix long enough to produce a consistent mixture and check the pH and adjust it to about pH 6.8. Add the remaining **antigen** and mix for 2 to 12 hours. After mixing, check pH again and readjust to 6.8 to 7.2, if necessary.

Caution: Do not to raise the pH above 7.5. Addition of HCl or other acids to bring pH down may decrease the effectiveness of the adjuvant.

The Adjuvant Company That Understands Vaccines

MVP adjuvants®

To speak with an adjuvant expert: 402.331.5106 or 800.856.4648