FORMULATED SOLUTIONS

Balancing your decision when choosing between bag-on-valve and aerosol formulations: A comprehensive guide

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Executive summary

Choosing the right pressurized container closure system is a critical decision that can significantly impact product success.

Aerosols are a popular, well-established solution that offer versatility and cost-effectiveness, while also delivering a consistent spray pattern throughout the product's life cycle.

Alternatively, bag-on-valve (BoV) systems are renowned for maintaining product purity and enabling complete evacuation. Their design facilitates 360-degree spraying, which is particularly beneficial for products used on hard-to-reach areas like the back or scalp or for individuals with limited mobility.

In this whitepaper, Scott Martz, I&D Principal Packaging Scientist, and Scott Carpenter, Vice President, Marketing and Partner Innovation at Formulated Solutions delve into the unique characteristics of aerosol and BoV systems. They explore the key considerations when choosing between the two systems to help you confidently select the optimal solution and deliver impact with every action.

Section 1:

Container closure systems for pressurized dispensing

In the competitive consumer health, cosmetics, personal care and medical device landscapes, product packaging is more than just a container; it's an opportunity to optimize product performance, enhance brand perception and leave a lasting impression on users.

For pressurized product dispensing, the fundamental choice typically lies between two container closure systems: BoV and traditional aerosol. As each system has unique characteristics and capabilities, a comprehensive assessment can identify the optimal solution for each product.

Aerosol systems

Aerosol systems are a well-established and versatile approach to product delivery, widely utilized across consumer and industrial sectors for products such as:

- **Pharmaceutical inhalers**
- **Anti-fungal sprays**
- **Hemorrhoid sprays**
- **Hair growth foams**
- **Topical medications**
- **Sunscreens**
- **Shaving creams.**

Their effectiveness stems from a precisely engineered pressurized mechanism capable of transforming liquids into fine mists, foams or targeted streams.

At the core of an aerosol system lies a metal or plastic container, designed to withstand internal pressures ranging from 15-150 psig. Housed within this container is a carefully formulated blend of two key elements:

- **Product:** The substance intended for dispensing, ranging from deodorants to topicals and pharmaceuticals.
- **Propellant:** A liquefied gas, typically butane, propane or isobutane, maintained under high pressure. The propellant serves the dual purpose of contributing to the final product attributes (e.g., its anatomization) and driving the product's release from the can.

Consisting of a container, a valve and an actuator, aerosol closure systems are designed to deliver the product in specific formats, including sprays, foams, streams or fan sprays while providing controlled and uniform product delivery.

Aerosol functionality is driven by the science of pressure. Introducing the propellant after sealing the container creates a high-pressure environment. Actuating the aerosol releases a carefully calibrated flow of energy through the valve before being dispensed through the actuator and delivered to the intended application area. Each spray lowers the pressure inside the container but some of the liquid propellant turns into gas, which brings the pressure back up for the next spray. The propellant rapidly expands when exiting the nozzle, which determines the final form of the spray in combination with the specific valve design and properties of the formula being dispensed.

1 **Can**

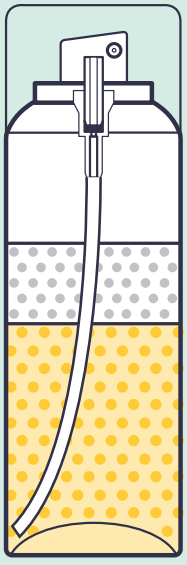
The robust vessel, purpose-built to withstand high pressure and protect the integrity of products.

2 **Valve**

The gatekeeper, ensuring hermetic sealing and controlled product release for a flawless user experience.

3 **Dip Tube**

The lifeline, facilitating a smooth and uninterrupted flow of product from the depths of the can to the valve assembly.



4 **Actuator**

The command center, empowering users with precise control over product delivery – a fine mist, a jet or foam.

5 **Formula Concentrate**

An expertly crafted formula, optimized for maximum performance and stability within advanced aerosol systems.

6 **Propellant**

The driving force behind it all, propelling products and enabling pinpoint accuracy.

Bag-on-valve systems

BoV is an innovative packaging system used across consumer and industrial sectors for a variety of products, including sterile saline nasal sprays, topical analgesics, sunscreen formulas, hydrogels and whipped lotions. Their unique design makes them an ideal choice for both liquid and viscous products.

At the heart of a BoV system lies a metal or plastic container, typically crafted from aluminum or polyethylene terephthalate (PET), engineered to withstand internal pressure. Within this container is a flexible, multi-layer laminate bag or plastic pouch that serves as the product reservoir. This bag is welded to a specialized valve, isolating the product from the propellant, forming a hermetic seal that maintains product integrity and enables controlled dispensing.

The propellant, typically compressed air or nitrogen, is introduced into the space between the bag and the container wall. This pressurized environment acts as the driving force for product expulsion. An actuator or cap, located on the container's exterior, provides the user interface for dispensing.

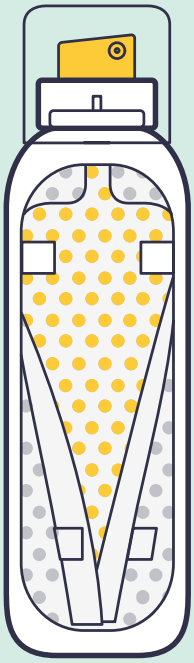
The BoV dispensing mechanism is elegant in its simplicity, ensuring that every aspect of the system works in harmony. Pressing the actuator activates the valve, opening a pathway for the product to escape. The pressurized propellant exerts force on the flexible bag, squeezing it and propelling the product upward through the valve and out of the nozzle. As the product is dispensed from the BoV system, the bag gradually collapses. The product flow is controlled through the size of the orifice of the actuator, enabling controlled delivery and maintaining spray characteristics over the life of the product.

1. **Bag-on-Valve**

   A robust, multi-layer laminate bag hermetically seals the product, preserving its purity and potency. A precision-engineered valve, seamlessly welded to the bag, ensures optimal dispensing and reduces contamination risk.

2. **Product**

   Liquids and viscous products, such as gels, creams and ointments. Optimized for oxygen-sensitive and sterile products across diverse applications.



3. **Propellant**

   Inert gases, such as nitrogen or compressed air, create a powerful yet controlled flow, driving product expulsion with precision and accuracy.

4. **Actuator**

   A user-friendly actuator design effortlessly activates the valve, delivering a precise and uniform product stream or spray.

5. **Can**

   An outer metal container encases the system, providing an impenetrable barrier against light, oxygen and external contaminants.

Section 2:

Key considerations when choosing between BoV and aerosol formulations

Selecting the ideal container closure system for a given product is a critical decision with far-reaching implications. Both BoV and aerosol systems offer unique benefits when tailored to specific applications, and can help turn your next product into the next triumph.

The choice between these two technologies is rarely straightforward, demanding a comprehensive evaluation of several key factors: product purity and compatibility, dispensing performance, cost and regulatory considerations.

1 Product purity and compatibility

Maintaining the purity and stability of a product is non-negotiable, particularly in the healthcare sector where patient safety is paramount. The container closure system is key to preserving product integrity throughout its life cycle, which means it needs careful testing and selection. Some key considerations include:

- **Sealing and sterility**
  Hermetic seals, a standard feature in pressurized dispensing systems, create an impermeable barrier against external contamination. This sealed environment protects against microbes, oxygen and other environmental contaminants, preserving product purity and extending shelf life. Where sterility is paramount, the ability to sterilize the product in the can presents a distinct advantage. This approach allows for the use of non-preserved formulations that can be sterilized post-filling, ensuring product integrity while adhering to strict regulatory requirements.
- **Material compatibility**
  The materials used in container closure systems, such as the container itself, valves, gaskets and seals, must be carefully evaluated for their potential to interact with the product formulation. For example, reactive ingredients such as peroxides can interact with both aerosol and BoV components, leading to degradation or pressure build-up.

  For pharma products as well as some consumer products, rigorous testing and careful selection of compatible materials are essential for compliance with strict regulatory requirements.
- **Oxygen sensitivity**
  For oxidation-sensitive formulations, propellant choice is also a key factor. Inert gasses, such as nitrogen, are inherently better suited for these products as they minimize the introduction of oxygen into the headspace.

The unique characteristics of BoV and aerosol technologies can affect the critical aspects of product purity and compatibility. Understanding these nuances is essential in making an informed decision between the two systems, ensuring the selected technology aligns with the formulation's specific requirements and regulatory needs.

Aerosol considerations

In aerosol products, the formulation directly touches the inside of the container. It's crucial to ensure the product and container are compatible, especially for products with high salt levels (like antiperspirants), high acidity or pH levels. These types of formulations can corrode metal parts or react with the aluminum can, causing leaks and affecting how well the product works. To prevent this, aerosol formulas usually need a pH that's fairly neutral (between 4 and 10) to work well with the container's lining.

The pressurized nature of aerosol systems also necessitates careful selection of both propellants and can strength. The type and amount of propellant, as well as the formulation's reactivity, influence the required strength to ensure product safety in all situations.

When producing products using traditional aerosol systems, most of the atmospheric air is vacuumed out of the headspace during crimping, helping to support the stability of oxygen-sensitive products.

BoV considerations

A key feature of BoV systems is the complete separation of product and propellant, which ensures exceptional product purity and makes the format suitable for even the most sensitive formulas. This separation allows for the dispensing of pure product, without any liquefied propellant, an advantage for pharmaceuticals, cosmetics and personal care products. Separating the product from the propellant, which can be compressed air or nitrogen in BoV systems, also helps to protect products that are sensitive to oxygen.

However, the way BoV systems are designed necessitates a homogenous product formulation. Aerosols can be shaken to re-disperse separated components but BoV products lack headspace for agitation. This makes any formulation prone to separation, such as oil and water mixtures or suspensions containing powders, unsuitable for BoV packaging. Additionally, powders and dry shampoos, which require suspension in a propellant, are generally not compatible with BoV technology due to the lack of agitation within the sealed bag.

While BoV systems are an excellent choice for viscous formulations like gels, creams and ointments, there are also limitations when working with extremely high viscosities. Formulations with low shear thinning properties or that exceed the flow capacity of the valve may create dispensing challenges.

2 Dispensing performance and user experience

A product's dispensing performance and user experience can be the difference between market success and stagnation. Consumers demand innovative delivery methods that meet their unique needs and preferences. Many factors are critical to consider as they could impact user experience, including:

- **Quick-drying formulations**
- **Extended reach for hard-to-reach areas**
- **Ease of use for individuals with limited mobility**
- **Optimal particle size for effective delivery**
- **The sensory experience of dispensing — including the sound and feel.**

By adopting an informed and deliberate approach, developers can evaluate every aspect of dispensing performance to create an optimized user experience.

Aerosol considerations

Aerosol systems are known for their reliable performance and consistent spray patterns. Evaluating certain nuances can help with optimizing aerosol performance and user experience.

One thing to consider is the potential for residual product. The design of traditional aerosol systems often results in a small amount of product in the can that is difficult to expel. Users may need to tilt or invert the can to access the remaining product. As a result, overfilling the aerosol may be needed to help ensure the label claim for product delivery is met.

Additionally, the orientation of the aerosol can during dispensing may influence the spray pattern and product delivery. Holding the can upright typically results in optimal performance, as the dip tube draws product from the bottom. However, tilting or inverting the can may lead to inconsistent dispensing, potentially biasing the ratio of propellant to product.

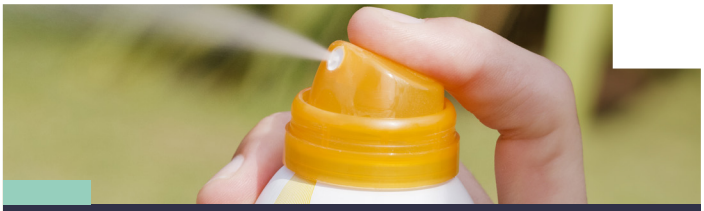
Aerosol systems also generally deliver a drier product experience compared to BoV. This is due to the co-dispensing of propellant with the product. As the propellant rapidly evaporates upon exiting the nozzle, it cools the product, resulting in a perceived "colder" application. This characteristic can be advantageous for certain products, such as topical analgesics designed to cool the skin before delivering a warming sensation.

BoV considerations

BoV systems offer distinct benefits that cater to a wide range of product applications. For many products, particularly thin liquids, BoVs can achieve near-complete evacuation, helping users maximize the value of their purchase. This efficiency is coupled with consistent spray patterns and 360-degree spraying capability, enabling effortless application from any angle, even upside down. The smooth, controlled dispensing, coupled with a quieter actuation compared to traditional aerosols, contributes to a more refined application process, with high user satisfaction.

The versatility of BoV systems extends beyond liquids. They excel in dispensing viscous formulations like creams, gels and ointments, delivering a consistent product experience throughout the container lifespan. Although droplet size may vary slightly as internal pressure decreases, this is often inconsequential for products like sunscreens, where the application method minimizes the impact of minor droplet size fluctuations.

Additionally, the BoV dispensing experience is characterized by a "warmer" application, as the propellant used (typically compressed air or nitrogen) does not significantly cool the product during expulsion. This can be particularly advantageous for products applied to sensitive skin or areas where a cold sensation is undesirable.



Real-world example: Sunscreen dispensing for different user experiences

Consider sunscreen, where user experience and how the product feels directly impact consumer behavior and health outcomes.

Aerosol sunscreens are often combined with lower-cost industry-standard propellants, offering a cost-effective solution for delivering a larger volume of finished product. Their fine mist provides quick and confident coverage, attracting users who prioritize speed and ease of application. However, the lighter spray can be prone to drift in windy conditions, potentially reducing application accuracy.

On the other hand, BoV sunscreens typically contain an undiluted formula but deliver a heavier, more targeted spray with larger droplets. This reduces drift and enhances precision, potentially providing additional application control for the consumer.

Ultimately, the choice between these two systems is informed by the target user's preferences. Those seeking quick, easy and cost-effective applications may gravitate toward aerosols, whereas those prioritizing precision and a more substantial feel may prefer BoV. Understanding these nuances allows product developers to tailor dispensing performance to specific consumer needs, enhancing user experience and driving product adoption.

3 Cost considerations

In product development, cost considerations are a universal concern. This is particularly relevant in the consumer health, cosmetics, personal care and medical device sectors, where packaging can represent a significant portion of the overall product cost. The choice between BoV and aerosol systems often comes with notable cost implications, especially when scaling to large production volumes.

For both aerosol and BoV systems, the potential for a cost advantage depends on the product and product needs.

Aerosol considerations

While the initial investment in aerosol manufacturing involves specialized infrastructure, such as a gas house for handling flammable propellants, subsequent production costs are comparably low. One factor driving this is that aerosols typically require less expensive packaging components.

However, it's important to note that certain factors can increase the cost of aerosol production. For instance, specialized valve designs for specific applications, such as those used for dispensing foams or targeted sprays can add to the overall cost. Similarly, custom consumer-specific actuators or custom packaging options can also drive up expenses.

BoV considerations

BoV systems typically rely on packaging components that contribute to a higher cost. The multi-layered bag and specialized valve system can increase the overall cost per unit.

However, in comparison with aerosol systems, BoV filling equipment is generally less expensive as several pieces of equipment are not needed. Specifically, BoV filling lines do not require complex components like gas houses or water bath testing for pressure integrity.

A comprehensive cost analysis can be used to determine the true cost-effectiveness of both aerosol and BoV systems for each specific product application.

4 Regulatory considerations

Both aerosol and BoV systems must comply with strict regulatory requirements developed with various factors in mind, including:

- **Worker and consumer safety**
- **Product quality and efficacy**
- **Environmental protection.**

This regulatory landscape has seen a number of significant shifts over the last 50 years and continues to evolve. For example, with growing awareness of the environmental impact of products using propellants, regulations continue to focus on driving the development and adoption of lower-global warming potential (GWP) propellant alternatives. Many innovative manufacturers across the industry have been well ahead of the curve for decades when it comes to environmental considerations.

Global regulatory guidance surrounding propellant use includes the Kigali Amendment to the Montreal Protocol (2019) and the U.S. Environmental Protection Agency's Significant New Alternatives Policy (SNAP) program [1, 2]. Regional initiatives are further fueling the search for propellant alternatives and driving innovation through R&D. This includes initiatives from the California Air Resources Board (CARB), which has imposed upper limits on volatile organic compound (VOC) content in consumer products, including various aerosol product categories [3].

As well as environmental regulatory considerations, the production of products using propellants, including aerosol or BoV systems, must comply with regulations surrounding operator and handler safety.

Some aerosol systems rely on flammable propellants like DME, liquefied petroleum gases (LPG) or difluoroethane (152a). These necessitate stringent safety protocols during manufacturing, filling and storage. Specialized facilities like gas houses are required for safe propellant handling, and filling lines often incorporate explosion-proof features [4]. Even in the laboratory setting, adherence to safety protocols is essential when developing aerosol formulations.

Beyond manufacturing, ensuring product safety for consumers is equally crucial. This involves careful and considered formulation design, rigorous testing and robust container construction to prevent leaks, ruptures or unintended discharges. Additional safety measures, such as tamper-evident seals and child-resistant packaging, may be required depending on the product's intended use.

Table 1. Key considerations when selecting between BoV and aerosol container closure systems.

Feature	Bag-on-Valve (BoV)	Aerosol
Product and Propellant	Propellant free. Product stored separately in a flexible inner bag and the outer container.	Mixed within the canister.
Propellant	Typically uses compressed air or nitrogen (inert gasses). Not part of the formula, but instead is captured between the bag and canister and never dispensed.	Uses liquefied gasses like hydrocarbons or compressed gasses like nitrous oxide or nitrogen.
Dispensing Rate	Can dispense nearly 100% of the product.	Typically leaves a residual amount of product in the can.
Spray Pattern	Can change as the pressure decreases with product use.	Consistent throughout the product's life cycle.
Cost	Can be more expensive to produce due to high component costs.	Generally less expensive to manufacture.

Section 3:

Weighing up your decision

The choice between aerosol and BoV systems involves a multifaceted assessment of various factors, including product characteristics, user experience, environmental impact, regulatory compliance and cost considerations. Given the complexities involved, partnering with an experienced formulation and packaging expert can streamline this decision and ensure optimal results for your product.

The ideal partner will possess expertise in both aerosol and BoV technologies, understanding the nuances of each system and providing comprehensive support throughout the product development process. They should actively seek to understand your unique needs and goals, offering tailored solutions that prioritize product purity, stability and user experience.

Additionally, a reliable partner should have ample manufacturing capabilities and a proven track record of delivering high-quality products on time and within budget. A strong understanding of the latest regulatory developments and industry trends ensures your product remains compliant and competitive in the ever-evolving market landscape.

Ever tried the Formulated Solutions approach?

Delivering excellence since 1999, we specialize in innovative solutions for pharmaceutical, consumer health, personal care and medical device applications.

Underpinned by a bedrock of reliable quality, our expertise in both aerosol and BoV technologies, and our focus on customer collaboration, can guide you through the complexities of pressurized dispensing and help you achieve your product goals.

We leverage leading technology to offer increased capacity and faster production times to deliver products to consumers sooner. With four BoV production lines and three aerosol production lines, including a newly validated, fully automated line at the Cleveland, Tennessee facility, we are ready to support your BoV and aerosol manufacturing.

Discover how we can help you choose the ideal formulation and packaging option for your next project.

Contact us

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