



Why Non-PVC multi-layer IV Bags Are Becoming the New Standard in Infusion Therapy

A safer, compliant, and sustainable choice for modern healthcare systems



Healthcare systems worldwide are seeking solutions that increase patient safety, reduce regulatory risk, support sustainability objectives, and provide consistent clinical performance. PVC-Free IV bags, are quickly transitioning from an alternative to an expected standard, driven by strong clinical, environmental, and compliance drivers.

As regulatory pressure on PVC and DEHP intensifies and clinical awareness increases, selecting the right IV bag material is becoming a critical decision for both patient safety and long-term compliance.

Non-PVC solutions offer a strategic advantage by reducing drug interaction risks, limiting harmful exposure, and future-proofing medical devices against evolving regulations

DEHP Exposure from PVC Medical Devices

Polyvinyl chloride (PVC) has long been used in IV bags and infusion sets due to its durability and flexibility. To achieve this flexibility, PVC is typically plasticized with additives such as di(2-ethylhexyl) phthalate (DEHP). Unlike chemically bound polymer components, DEHP is not covalently bound to the PVC matrix and can migrate into solutions that come into contact with the material. This migration is especially pronounced when the infused solution contains lipids, surfactants, or alcohols, or when infusions are administered over extended durations.¹

DEHP exposure is a concern because the compound has been associated with endocrine disruption, reproductive toxicity, and potential

developmental effects in animal and human studies.² Regulatory and clinical bodies have identified several high-risk patient populations, including neonates in intensive care units (NICUs), pediatric patients, pregnant women, and oncology patients receiving repeated infusions.³ In these settings, exposure may occur through multiple medical devices simultaneously (e.g., IV bags, tubing, catheters), potentially leading to cumulative doses significantly higher than typical environmental exposure.⁴

Non-PVC infusion systems eliminate this specific exposure pathway while maintaining the functional requirements of IV drug delivery.

Regulatory Momentum Around DEHP and PVC Medical Materials

Why Regulators Are Increasingly Scrutinizing DEHP

Over the past two decades, regulatory authorities worldwide have increased scrutiny of phthalates such as di (2-ethylhexyl) phthalate (DEHP) due to their classification as substances of very high concern (SVHC). DEHP is also classified in the EU as a reproductive toxicant and endocrine-disrupting chemical.⁵

Because DEHP is not chemically bound to PVC polymers, it can migrate into drug products or infusion fluids during storage or administration. This potential exposure route has driven regulators and pharmacopeial bodies to strengthen requirements related to materials of construction, extractables and leachables (E&L), and the use of safer alternatives in pharmaceutical packaging and delivery systems.⁶

As a result, manufacturers of drug products, combination products, and medical devices are increasingly expected to evaluate alternatives to DEHP-plasticized PVC and demonstrate that their systems meet evolving regulatory expectations.

- **EU REACH:** Authorization Requirements for DEHP

Under the European Union's REACH Regulation, companies wishing to continue using DEHP in medical devices and related applications, the European Commission has established the following regulatory milestones:

Latest application date: 1 January 2029

Sunset date: 1 July 2030

After the sunset date, products containing DEHP cannot be placed on the EU market unless a specific authorization has been granted.⁷

These timelines effectively signal a long-term transition away from DEHP-plasticized PVC within the European healthcare ecosystem and encourage manufacturers to evaluate alternative materials well in advance of the deadline.

- In the **United States**, the U.S. Food and Drug Administration, through its Center for Drug Evaluation and Research, recommends avoiding the use of DEHP and certain other phthalates in drug and biologic products whenever possible, advising manufacturers to justify their use and evaluate safer alternatives during product development and lifecycle management.⁸

At the same time, state-level regulations are reinforcing this direction, particularly in California, where DEHP is listed as a chemical known to cause cancer and reproductive harm under California Proposition 65, and policy initiatives are moving toward further restrictions on DEHP-containing healthcare materials by 2030.⁹

Better for the Planet

PVC's chlorine chemistry complicates end-of-life management and, under uncontrolled thermal conditions (e.g., low-efficiency incineration or open burning), can contribute to the formation of hazardous by-products such as dioxins and furans.

While modern, well-controlled medical waste incineration can significantly reduce these emissions, **PVC** remains more difficult to recycle due to its chlorine content, additive complexity (e.g., plasticizers), and potential to cause corrosion and contamination in recycling streams. Life-cycle assessment (LCA) studies highlight that chlorine production and associated emissions are key contributors to PVC's environmental burden¹⁰.

In contrast, **Non-PVC** materials such as polyolefins contain no chlorine, enabling more straightforward mechanical recycling, lower risk of halogen-related emissions, and improved compatibility with circular material systems. Healthcare-focused LCAs further emphasize that environmental outcomes are highly dependent on waste management scenarios, but materials with simpler compositions tend to offer greater end-of-life flexibility and reduced toxicity risks¹¹.

While some comparative LCAs report similar overall impacts between PVC and alternative polymers depending on application and assumptions¹², polyolefin-based IV bags are increasingly favored in green procurement frameworks due to their reduced hazardous emission potential and better alignment with circular healthcare strategies.

Proven Compatibility & Performance

Drug Sorption in PVC Infusion Systems

In addition to plasticizer migration, PVC materials can adsorb or absorb certain drugs, particularly hydrophobic compounds. Sorption occurs when drug molecules partition into the polymer matrix

of the container or tubing, leading to a reduction in the amount of drug delivered to the patient. This phenomenon has been documented for several IV-administered medications commonly used in hospital settings. For example:

Nitroglycerin, a vasodilator frequently administered via IV infusion for acute cardiac conditions, is well known to sorb into PVC infusion containers and tubing. Studies have reported drug losses exceeding 50% in PVC containers during storage or infusion, while minimal loss was observed in alternative non-PVC containers¹³⁻¹⁶.

Diazepam, used intravenously for seizure control and sedation, is highly lipophilic and can be strongly adsorbed by PVC materials. Losses of up to ~70% over 24 hours have been reported in PVC bags, whereas negligible loss occurs in glass or polyolefin-based systems¹³⁻¹⁶.

Isosorbide dinitrate, another nitrate vasodilator used intravenously for cardiovascular indications, has demonstrated approximately 20–25% loss in PVC infusion bags due to sorption¹³⁻¹⁵.

Warfarin sodium, when prepared as an IV infusion

in saline, has shown up to ~24% loss in PVC containers, while remaining stable in non-PVC alternatives¹³⁻¹⁵.

Insulin, used in continuous IV infusions in critical care settings, can also adsorb to PVC infusion materials, with reported losses ranging from ~30–40% under certain conditions depending on tubing and flow rates¹⁴⁻¹⁷.

The degree of sorption depends on several factors, including drug lipophilicity, infusion duration, temperature, and surface area of contact between the drug solution and the polymer. Non-PVC IV bag systems made from polyolefin-based materials or multi-layer non-PVC structures can significantly reduce this effect, with multiple studies reporting near-complete drug recovery (typically >90–95% of initial concentration retained) for highly sorptive drugs such as nitroglycerin and diazepam when using polyethylene or polypropylene-based containers instead of PVC¹³⁻¹⁷. For insulin and other peptide-based drugs, adsorption losses are similarly reduced to minimal or clinically negligible levels in non-PVC systems, improving dose accuracy and reducing the need for overfilling or dosing adjustments¹⁴⁻¹⁵.

Delivered dose loss due to sorption - comparison between PVC and Non-PVC bags for some commonly used IV drugs in hospital setting

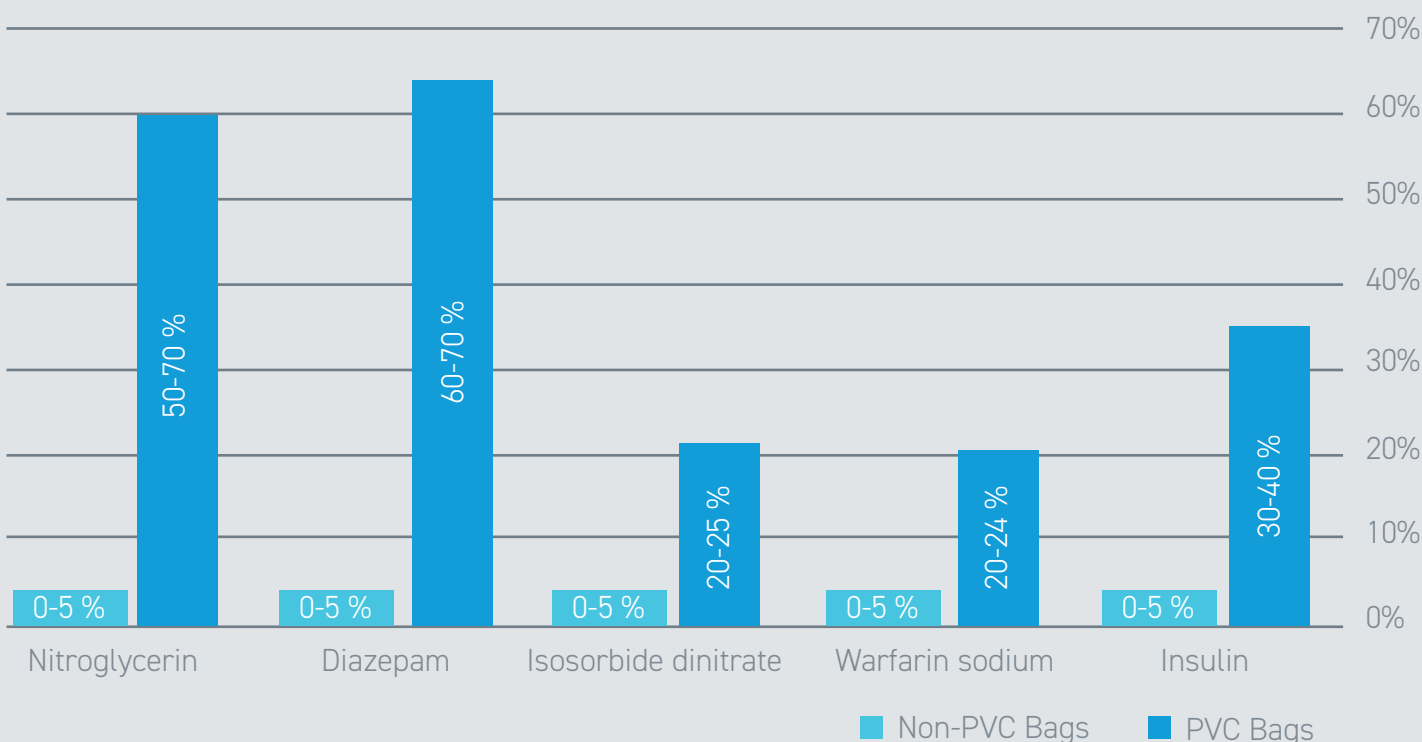


Figure 1: Estimated delivered dose loss associated with container material for selected intravenous drugs. Highly lipophilic drugs such as nitroglycerin and diazepam show substantial loss in PVC containers due to sorption into plasticized materials, whereas **non-PVC multi-layer polyolefin-based** containers demonstrate minimal loss and high dose retention. Peptide drugs such as insulin similarly exhibit reduced adsorption in non-PVC systems. Values shown represent typical ranges reported in the literature under clinically relevant infusion conditions and are intended for comparative illustration.¹³⁻¹⁷

In addition, Non-PVC bag platforms allow for more consistent material behavior during sterilization and storage, reducing variability linked to plasticizer migration or long-term material aging¹⁸⁻²¹. This stability helps ensure that the bag’s mechanical properties, drug contact surface, and transparency remain predictable over time^{19,21}, supporting safer handling in pharmacy preparation areas and improving reliability across different clinical environments²⁰.

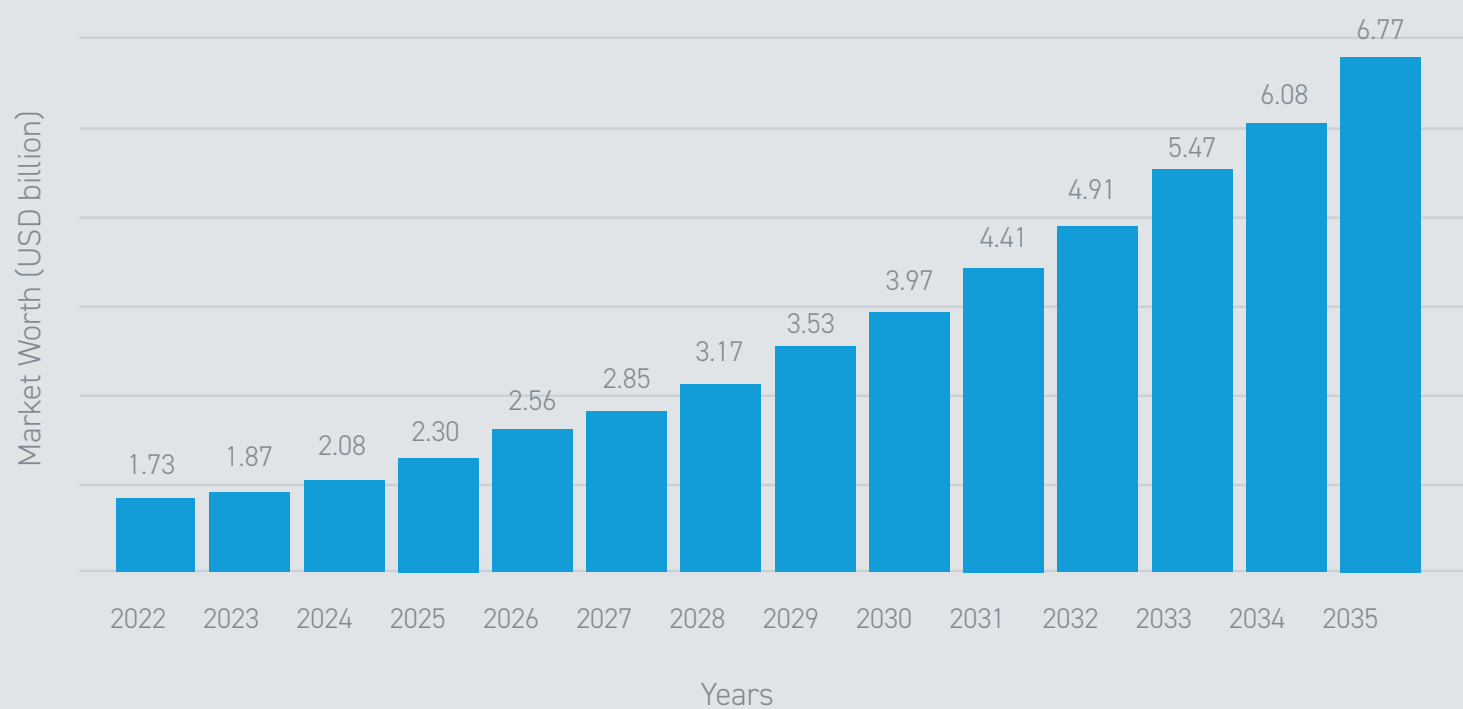
Market Trends: Non-PVC Solutions Becoming the Default

Hospitals, group purchasing organizations, and public tenders increasingly prioritize PVC-free and DEHP-free products within sustainability and patient safety roadmaps. Advocacy groups and healthcare networks maintain databases of Non-PVC medical devices, accelerating adoption and simplifying procurement.²²

Market analyses consistently forecast growth for non-PVC IV solution containers through 2030–2035, driven by regulatory signals, environmental objectives, and advances in polymer technology.²³⁻²⁵ Although unit costs may be higher today, supply chains are expanding, and compliance pressure continues to increase, positioning Non-PVC systems as a future-proof standard.²⁵

Figure 2: The table shows the yearly growth trend of the global market of non-PVC IV bags, between 2022 and 2035

Global Non-PVC IV Bags Market Worth (2022–2035)²³⁻²⁴



Make the Shift, What You Get

These scientific and regulatory considerations translate into tangible advantages for both medical device manufacturers and healthcare providers

Reduced drug loss



Non-PVC materials limit sorption, helping maintain the intended dose—especially for lipophilic or long-infusion drugs—reducing the risk of underdosing and improving therapy effectiveness.

More predictable therapy



Improved material compatibility enables more consistent and reliable drug delivery, particularly in continuous infusion therapies where stability is critical.

Lower DEHP exposure



Eliminates exposure to a substance classified as a reproductive toxicant, helping protect vulnerable patient populations (e.g. neonates, oncology) and supporting safer clinical environments.

Regulatory alignment



Helps anticipate tightening global regulations (EU REACH, FDA guidance), reducing the risk of future reformulation, revalidation, or product changes.

Reduced migration risk



Minimizes extractables and leachables concerns, simplifying validation processes and reducing long-term compliance risks.

Sustainability impact



Supports ESG objectives by reducing reliance on materials with complex disposal profiles and improving the environmental footprint of medical devices.

Why GVS Non-PVC Solutions

- **From PVC to Non-PVC IV Bags—partner with experts who understand the entire system.**
At GVS, we go beyond the bag. Our heritage in advanced filtration for highly regulated healthcare applications brings deep expertise in membranes, flow dynamics, and contamination control—critical elements in delivering safe, high-performance infusion solutions.
- **Proven expertise in filtration & medical materials**
We support critical infusion applications with established IV filtration technologies ([GVS IV filters](#)), including dedicated filter families and sterilizing-grade options—helping safeguard therapies where performance and patient safety are paramount.

- **An integrated approach to materials & design**

Our application-driven approach to bag development combines material science with real-world performance. We offer a broad portfolio of film options tailored for Large Volume Parenterals (LVPs), chemotherapy, TPN, and other demanding therapies—supported by a direct supply chain model and a quality system aligned with ISO 13485.

- **Guiding your transition away from PVC**

The shift from PVC is accelerating, driven by evolving expectations around DEHP, extractables & leachables (E&L), and global regulatory pressures. Our PVC-free bag platforms are designed to help pharma companies and CMOs build a future-ready strategy—aligned with tightening requirements such as EU REACH and evolving USP guidance.

- **Scalable, end-to-end manufacturing capabilities**

From extrusion and co-extrusion to assembly and injection molding ([GVS medical components](#)), GVS delivers fully integrated manufacturing at industrial scale. With in-house development of welding technologies, we offer unmatched flexibility, control, and technical depth.

- **Ready to accelerate your transition to PVC-free solutions?**

Let's work together to define the optimal bag architecture, validation strategy, and supply model for your product and process.

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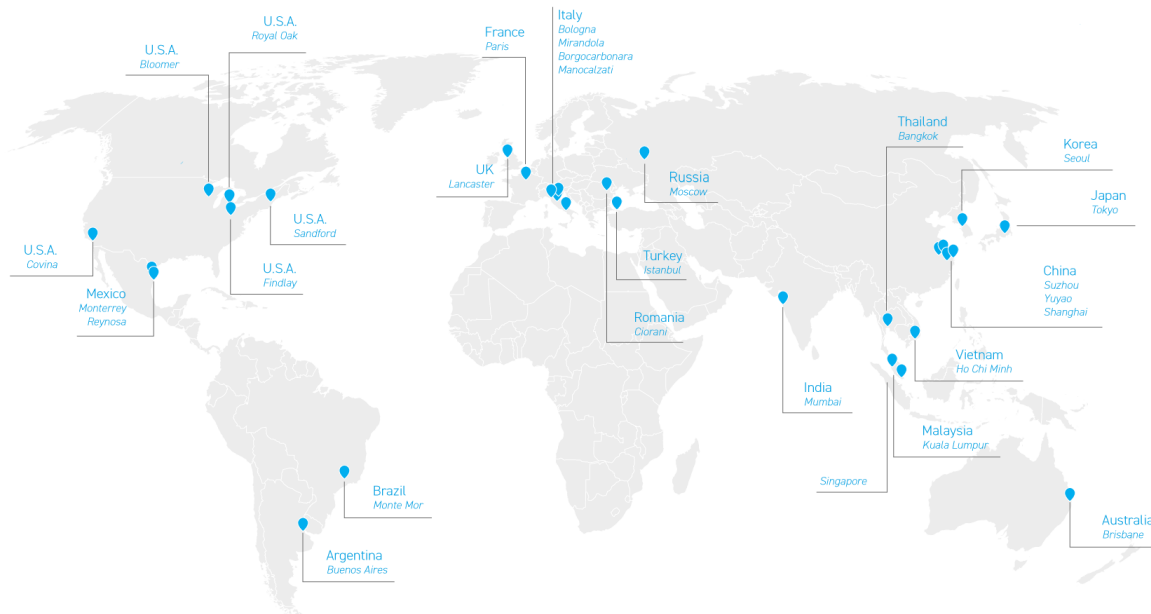
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