Why Vinyl Should Remain the Preferred Material in Healthcare

A Critical Review of How NGOs Approach Polyvinyl Chloride

vinyl plus healthcare

COMMITTED TO SUSTAINABILITY IN MEDICAL APPLICATIONS

Vinyl's Role in Healthcare – Today in the Coming Years

Discussions about the use of polyvinyl chloride (PVC or vinyl) and other plastics in healthcare are often emotionally charged and shaped by strong preconceptions – particularly from NGOs. As a platform committed to advancing sustainability in medical applications, VinylPlus Healthcare wishes to contribute to this important conversation by offering a balanced, evidence-based perspective.

Plastics-based medical devices are vital for safe and efficient patient treatment and care in hospitals around the globe. Many different polymers are used for medical equipment, with vinyl in the leading role.

The reason for vinyl's dominance is the material's unique properties such as safety, versatility, affordability, and recyclability. Nearly 30% of all plastics-based disposable devices are made of vinyl – a share expected to remain stable in the years to come.

Besides being the most used polymer for life-saving medical devices such as blood bags, oxygen masks, and tubing, vinyl is also the standard base material for blister packaging that safeguards medicines. Moreover, vinyl is widely used in hospital infrastructure, rescue gear, field hospitals, ambulance equipment, rehabilitation and home care, and much more.

During the last decades, the production, use, and end-of-life management of vinyl in Europe have undergone a significant transformation.

Through VinylPlus®, the European PVC industry's commitment to sustainable development, emissions from the production of PVC resin (the raw material for vinyl products) have been reduced below the world's most stringent emission limits, problematic additives have been substituted, and major investments have been made in recycling infrastructure and technologies.

In addition, the European chlor-alkali industry, from which PVC resin is produced, has successfully implemented strategic technology choices to reduce its environmental impact.

This document, supported by third-party evidence, aims to challenge outdated perceptions about vinyl and highlight the progress made in ensuring its safe and sustainable use in healthcare.

VinylPlus Healthcare, May 2025.

Key Points

- **European Chemicals Agency Affirms Safe PVC Resin Production**
  In 2023, the European Chemicals Agency confirmed the safety of PVC resin production in Europe, stating that the risks to both workers and environment are adequately controlled under current operational conditions.

- **Stringent Regulations and Safety Measures**
  Strict EU Occupational Exposure Limits and environmental emission limits ensure safe production of PVC resin in Europe. The industry has further developed voluntary policies enforced by independent bodies to minimise worker exposure and environmental emissions beyond the legal limits.

- **Chlor-Alkali Vital to Society**
  Vinyl is an integral part of the chlor-alkali industry, serving various critical applications such as water treatment, pharmaceuticals, and clean energy production.

- **Safe and Energy-Efficient Chlorine Production**
  Europe has phased out asbestos and mercury technologies in chlorine production, adopting safe, energy-efficient membrane and asbestos-free diaphragm technologies.

- **Less Primary Energy, Lower Carbon Footprint**
  Despite electricity requirements in the chlor-alkali process, vinyl's composition, with approximately 60% chlorine, results in significantly lower primary energy consumption compared to other plastics.

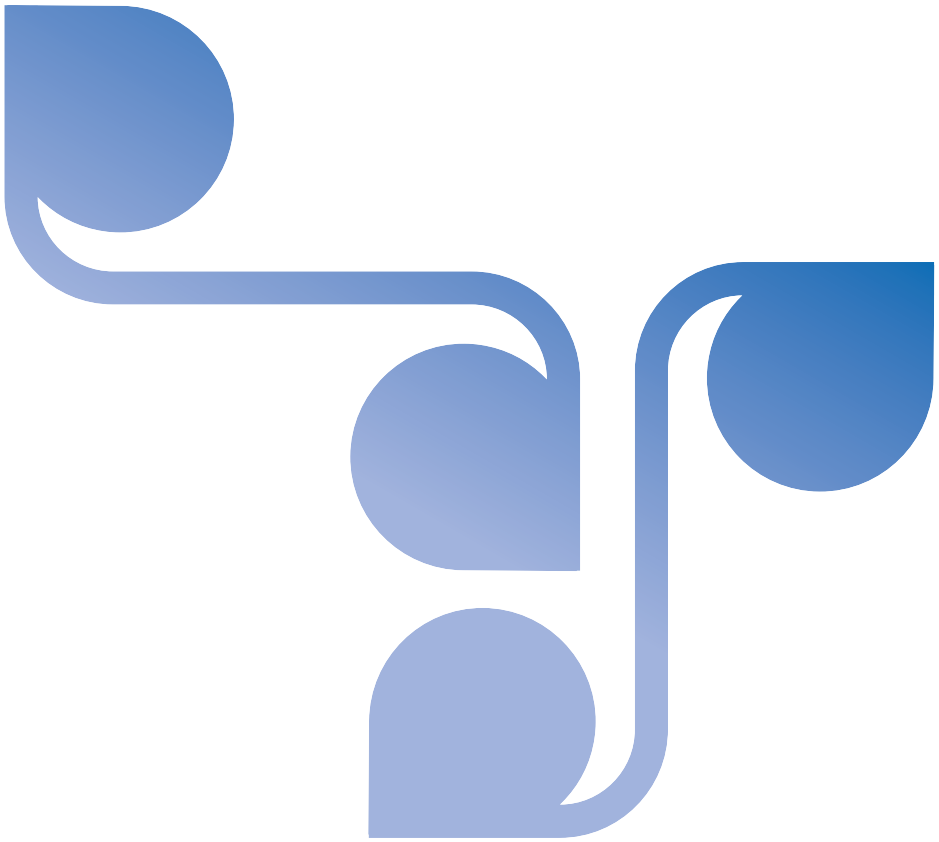
- **Non-Toxic Material With Strict Regulation of Additives**
  Vinyl is non-toxic and inert, with strict regulation and industry responsibility under REACH to ensure the safety of additives, including plasticisers.

- **DEHP Alternatives Available for Medical Devices**
  The European plasticiser industry has invested heavily in developing safe DEHP alternatives, subjected to extensive testing under REACH, and complying with the EU Medical Device Regulation.

- **Environmentally Responsible Vinyl Recycling and Incineration**
  Vinyl waste incineration is carefully managed in Europe to prevent harmful emissions. Additionally, vinyl is increasingly recycled, contributing to a circular economy in healthcare and elsewhere.

- **Complexity of Phasing Out Vinyl**
  Replacing vinyl with alternative materials may introduce other additives (e.g. PFAS), potentially causing unforeseen health effects, and regretful substitutions must be considered. Substitution also poses challenges related to technical performance, life cycle impacts, supply disruptions, and increased costs.

- **DEHP-Free Vinyl Blood Bags in Development**
  Efforts to phase out DEHP from blood bags are in progress, with promising results from non-phthalate vinyl alternatives. In contrast, the development of a PVC-free blood bag remains a challenge.



PVC Resin Production

What NGOs typically claim: "The production of PVC resin generates harmful risks to human and environmental health."

Confirmation of PVC Resin Production Safety in Europe by the European Chemicals Agency
As many other materials, the production of PVC resin, which is the basis for vinyl products, involve toxic substances such as EDC and VCM as intermediates. However, to prevent worker exposure and emissions to the environment, stringent measures are in place, including strict EU Occupational Exposure Limits and environmental emission limits. Additionally, the PVC industry has developed voluntary policies for PVC intermediates that go beyond the legal requirements and are enforced by independent bodies.[1]

The safe nature of PVC resin production in Europe has been confirmed by the European Chemicals Agency in 2023, which states "the risks from PVC resin to workers and the environment are considered adequately controlled with the current operational conditions and companies' safety measures."[2]

The Essential Role of Chlor-Alkali Industry in Modern Society
PVC is part of the chlor-alkali industry, which is foundational for modern society. In the chlor-alkali process, table salt is split into caustic soda and chlorine. Caustic soda or sodium hydroxide is needed to produce alumina, paper, and plays a critical role in water treatment, drinking water purification, cleaning agents, pharmaceuticals, food processes, and much more.

About 30% of all chlorine is used to produce PVC, of which around 1% finds its way into life-saving medical devices such as blood bags and tubing. The remaining 70% of the chlorine is used to disinfect drinking water and treat wastewater, in manufacturing of pharmaceuticals – up to 90% of all medicines depend on chlorine chemistry – batteries for electric cars, solar panels, wind turbine blades, polyurethane (PU) insulation, polycarbonate (PC) protective face shields for firefighters, and many other products.

It is important to note that many chemicals, plastics, and medicines use chlorine, although the end product is chlorine-free.

Environmental Advancements in Chlorine Production
In Europe, asbestos and mercury technology to produce chlorine have been legally phased out since 11 December 2017.[3] Only membrane and asbestos-free diaphragm technologies are considered best available techniques (BAT) under the Industrial Emission Directive. No other techniques can be used under a manufacturing permit.

Further, the Montreal Protocol and industry innovation aim to ensure that ozone-depleting substances are not emitted during chlorine production in Europe.

In PVC resin production, per- and polyfluoroalkyl substances (PFAS) are not directly used as raw materials in the manufacturing processes themselves. However, polymeric PFAS are present in equipment and materials used in production due to their unique properties such as durability in extreme conditions. For example, polymeric PFAS are used in membranes and asbestos-free diaphragms for electrolysis, gaskets and lined pipes or vessels, all of which are critical components in the production process for chlor-alkali and further for PVC.

Perfluorinated membranes and membrane technologies used in chlor-alkali production have no known alternatives at the moment and are therefore essential at present. The production and disposal of production equipment take place under strict environmental protection measures. The industry continues to improve these processes and develop opportunities for reuse and recycling.

The chlor-vinyl industry is actively engaged in following regulatory developments around PFAS and continues to re-evaluate all PFAS-containing materials and equipment and investigate available alternatives. This is to reduce the use of these substances where possible while maintaining the safety and reliability of industry operations.

It should be noted that PFAS are widely used throughout society, in sectors such as aviation, transport, medical devices, energy, electronics, architecture and construction, textiles, food and medicine.[4] For many of these sectors, PFAS' ability to perform under extreme conditions makes them difficult to replace, although it brings environmental and health challenges, which the wider industry is actively working to address.

Vinyl's Energy Efficiency Compared With Other Plastics
Though the chlor-alkali process requires substantial amounts of electricity, the fact that vinyl is made from nearly 60% chlorine means it typically consumes less primary energy and has a lower carbon footprint than other plastics such as polyethylene (PET), high density polyethylene (HDPE), low density polyethylene (LDPE), and polypropylene (PP).[5]

Plasticisers and Other Additives

What NGOs typically claim: "Alternatives to DEHP plasticisers might provide opportunities to reduce toxicity, but data regarding human health effects remain limited and the potential toxicity at high exposure still needs to be fully assessed."

Strict Regulation of Vinyl Additives
The vinyl material as such is inert and non-toxic. Additives in vinyl are regulated by REACH, the strictest chemical regulatory framework in the world. Under REACH, the onus is on the industry to demonstrate the safety of substances – *no data, no market* is the principle.

For medical devices, DEHP is already regulated, with a sunset date set for 2030 in REACH.

The European plasticiser industry has invested over €6 billion in developing safe DEHP alternatives. These alternatives, namely DINCH, DEHT, BTHC, and TOTM, have been subjected to extensive testing under REACH. All toxicological data for these plasticisers are available in the REACH dossiers.

Further, the substitutes are not identified as Substances of Very High Concern (SVHC) and not classified in the Classification, Labelling and Packaging Regulation (CLP).

EU Medical Device Regulation Compliance: Ensuring the Safety of DEHP Substitutes
In addition, these DEHP substitutes also meet the additional requirements under the EU Medical Device Regulation. This regulation mandates a thorough benefit-risk analysis and safe use demonstration for medical devices, ensuring that any material used meets the highest safety standards.[6] The inclusion of these plasticisers in the European Pharmacopoeia, overseen by the European Directorate for the Quality of Medicines & Healthcare (EDQM) under the Council of Europe, further underscores their safety, as the EDQM adheres to rigorous scientific and impartial evaluation processes.[7]

The plasticisers have also been thoroughly evaluated by many independent bodies, such as the European Food Safety Authority (EFSA), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), the Danish Environmental Protection Agency, and the Swedish Chemicals Agency.[8]

Ongoing Obligation for Plasticiser Producers: Updating Safety Data Under REACH
The plasticiser producers are adhering to their obligation as registrants under REACH, which is to update their dossiers with new information that may affect the risk management measures or the classification and labeling of the substance. This includes new data on long-term effects, high dose toxicological effects, or other relevant safety information that becomes available.

Differentiating Plasticisers: Understanding the Safety
It must be stressed that plasticisers in vinyl products are tightly bound within the vinyl matrix through strong non-covalent forces and their migration is extremely low. Further, the observed adverse effects of DEHP and other low molecular weight (LMW) phthalates are caused by their specific molecular structures. As the molecular structure of the DEHP substitutes are very different, they migrate less and do not show the adverse effects like LMW phthalates.

Moreover, comprehensive biomonitoring data for key plasticisers like DINCH and DOTP demonstrate that exposure levels across all sources remain safely within conservative and tolerable limits. These safety thresholds incorporate a substantial safety margin, often 100 times greater than the doses proven to have no effects in extensive animal studies, ensuring a high level of protection for human health.[9]

The Risk of Regretful Substitution: Concerns With Replacing Vinyl

Efforts to phase out vinyl often focus on avoiding plasticisers, based on the misconception that alternative plastic materials are inherently free from problematic additives.

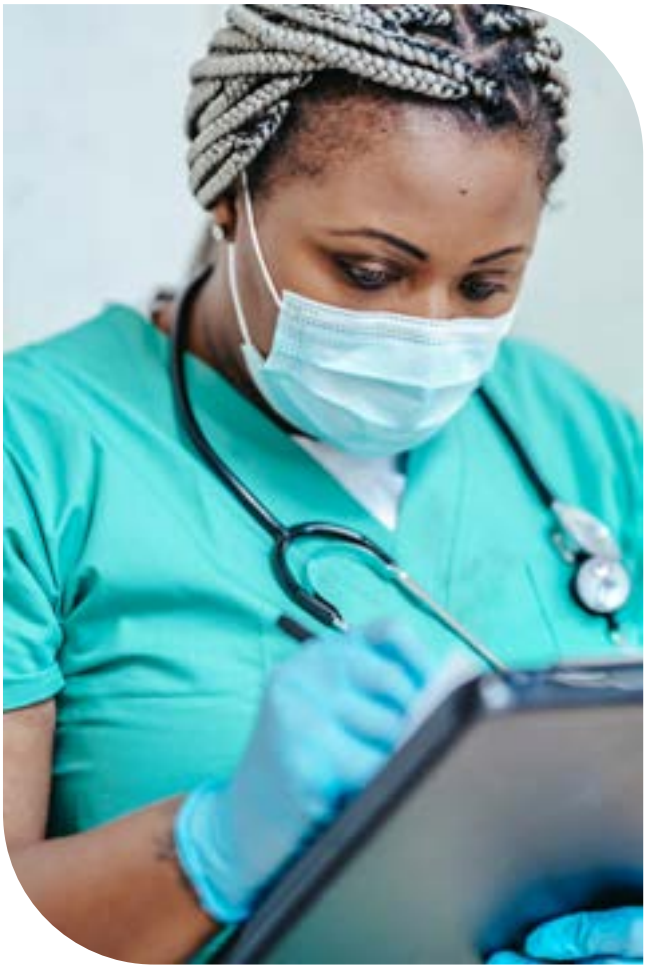
Today, around 16,000 substances are used to provide different properties to different plastics. According to a recent study, at least 4,200 of these chemicals have been identified as substances of potential concern.[10]

A relevant example is the classified phthalate DIBP, which has been found to migrate from polypropylene (PP) and polyethylene (PE) products – likely originating from catalyst mixtures used in their production.[11]

Another study points to the presence and migration of classified phthalates from mattresses and mattress covers made of non-vinyl plastics such as polyethylene vinyl acetate (PEVA), styrene-ethylene-butylene-styrene (SEBS), and polyurethane foam. Notably, the only mattress that fully complied with phthalate emission limits had a certified vinyl cover.[12]

In addition to plasticisers, many alternative plastics rely on flame retardant additives to meet fire safety requirements. These substances — often applied to foams and textiles — can migrate, accumulate in dust, and raise concerns about long-term health effects. In contrast, vinyl is inherently flame-resistant due to its chlorine content and often does not require additional flame retardants, reducing the need for such potentially hazardous additives.

Taken together, these findings and the growing body of evidence suggest that replacing vinyl with other plastics — without thorough safety assessment — risks leading to regretful substitution.



End-of-Life & Circularity

What NGOs typically claim: "The disposal of vinyl generates harmful risks to human and environmental health. Vinyl incineration can release dioxins and generates large amounts of neutralisation residues. Vinyl is the least recyclable plastic and cannot contribute to a non-toxic circular economy."

Vinyl Waste Incineration is Safely Managed
For safety reasons, non-recyclable medical waste is generally incinerated with energy recovery. In Europe, strict regulation ensure technologies are in place to avoid emissions of harmful substances such as dioxins and hydrochloric acid from incineration of chlorine-containing waste.[13]

Vinyl is often cited in discussions about dioxin production during waste incineration. Yet according to the European Chemicals Agency (ECHA), dioxin formation is not directly proportional to the amount of chlorine present in the waste. Instead, it depends significantly on how the incineration process is managed. Further, ECHA states that other sources of chlorine, e.g. salty foods, are always present in the waste.[14]

ECHA acknowledges that waste incineration plants can safely accept waste with vinyl content up to 2%, a threshold that helps manage the release of hydrochloric acid during combustion and mitigate potential boiler corrosion. Europe's incineration facilities possess adequate capacity to handle this level of vinyl waste.[15]

While PP, PE, PET, SEBS, PUR, and other plastics are often advocated by NGOs as safer to incinerate, they can – particularly under suboptimal conditions – release harmful emissions such as volatile organic compounds (VOCs), aldehydes, persistent free radicals, and in some cases highly toxic gases like isocyanates, hydrogen cyanide, and phosgene.[16] Interestingly, the possible formation of dioxins is not unique to vinyl: it requires both chlorine — which is always present in mixed waste streams from sources like food, salt, and paper — and a carbon source, which can readily come from non-vinyl plastics.

Vinyl is Already Part of the Circular Economy
Both rigid and flexible vinyl can be recycled mechanically several times without loss of functional properties.[17] Vinyl has the longest history of plastic recycling. It is estimated 35% of the vinyl waste generated each year is recycled – above the average for plastics.[18] Since 2000, 8,800,000+ tonnes of vinyl have been safely recycled and used in new products through VinylPlus®. Legacy additives in recyclates are being handled safely in accordance with the REACH regulation.[19]

Furthermore, innovation in recycling technologies driven by VinylPlus is expanding the potential for vinyl recovery, even from complex or contaminated waste streams. Technologies include advanced sorting, dissolution processes (physical recycling) for extracting high-purity vinyl, and chemical recycling pathways such as pyrolysis.[20]

Pioneering Medical Plastic Recycling
Vinyl is also leading the way in the healthcare sector: VinylPlus® Med helps hospitals turn their DEHP-free vinyl medical device waste into durable products for the healthcare sector, such as vinyl wall covering and flooring. The partnership brings together hospitals, waste management companies, social entreprises, recyclers, and the vinyl industry. Today, 25 Belgian hospitals are part of the scheme. Plans are underway to roll out VinylPlus Med in other European countries, starting with France.

Recycling Instead of Incineration Yields Significant CO_2 Savings
A recent third-party Life Cycle Assessment (LCA) by Ecovamed evaluated two disposal scenarios for typical vinyl medical tubing in Europe: incineration with energy recovery and acid gas treatment, and recycling into backing for wall covering through VinylPlus® Med. Recycling, with an 80% yield, reduced greenhouse gas emissions by 25% compared to incineration — saving 2.0 $kgCO_2eq$ per kilogram of tubing.[21]

Flexible Medical Vinyl Can Be Mechanically Recycled Again and Again
VinylPlus Healthcare is at the forefront of exploring mechanical recyclability of flexible vinyl. A 2025 study by the Spanish plastics technology centre AIMPLAS shows that vinyl-based medical tubing can be recycled up to six times without compromising quality and without addition of additives. These findings add to a similar study by BASF, which confirmed 11 cycles.[22]

Advancing to Circularity in Pharmaceutical Blister Packaging
PVC is the standard base material for pharmaceutical blister packaging due to excellent barrier properties and processability.VinylPlus® PharmPack is advancing the circularity of rigid PVC pharmaceutical blister packaging through both mechanical and advanced recycling methods. Pre-consumer blister waste is already being mechanically recycled in Europe, with PVC and aluminium separated and reused in new products. To address post-consumer waste, trials in German hospital pharmacies show promising results.

At the same time, the project is piloting advanced physical recycling via the CreaSolv® dissolution technology, which enables the recovery of high-purity PVC and aluminium from complex, multi-layer blister packaging.[23]

Substitution of Vinyl in Healthcare

What NGOs typically claim: "The use of PVC-free materials represents a more precautionary approach."

EU Agencies Identify Challenges With Vinyl Substitution
Healthcare providers are often urged to procure so-called PVC-free medical devices. Yet according to recent reports from the European Union's Chemicals Agency (ECHA) and DG Environment (DG ENV), substitution of vinyl can be very challenging and may have negative consequences for health, environment, and economy:

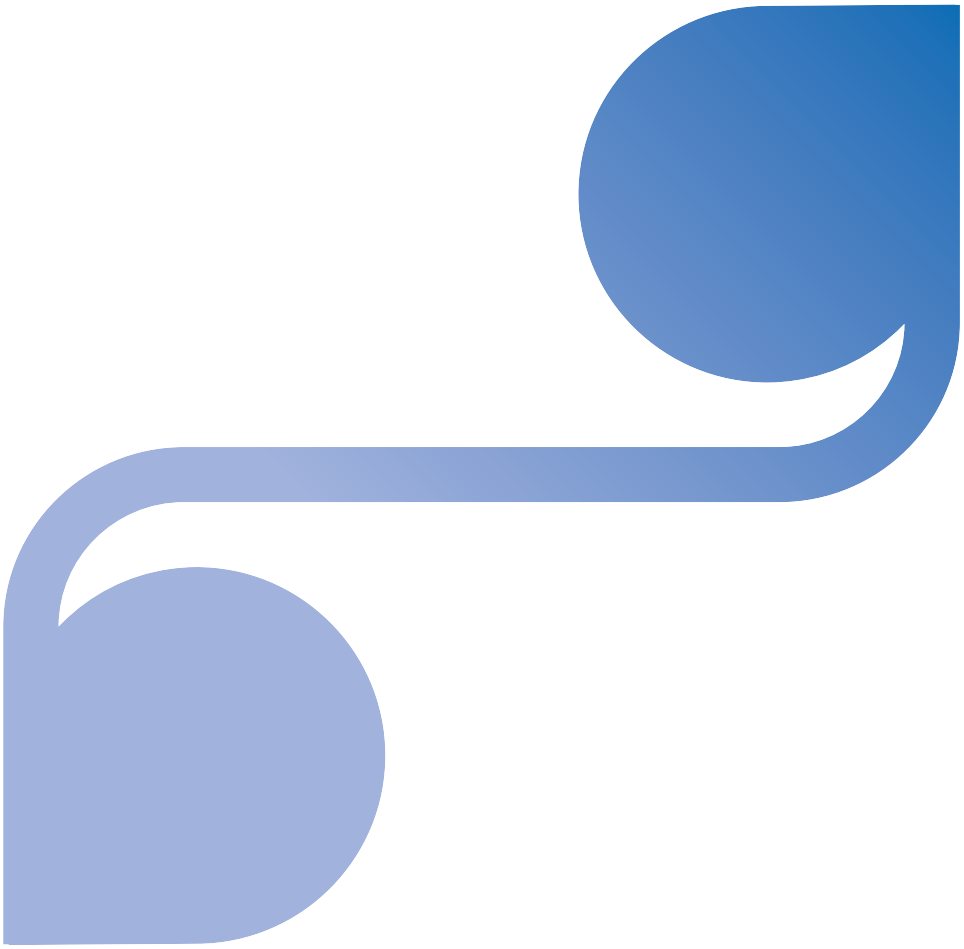
1. *Possible drawbacks in technical performance may compromise patient safety*
   According to DG ENV, "in procuring PVC-free products, hospitals and patients may initially experience some drawbacks in technical performance of new products. These would need careful testing to ensure patient safety is not compromised."[24] Some alternatives, such as polyethylene (PE), polypropylene (PP), polyurethane (PU), ethylene-vinyl acetate (EVA), and thermoplastic elastomers (TPE), are used in certain applications but cannot replace vinyl in all medical uses.[25]

2. *Life Cycle Impacts of Alternatives Are Largely Unknown*
   Due to the lack of comparable studies, it is impossible to draw robust conclusions about vinyl's performance compared to alternative materials from a life cycle perspective. This uncertainty adds another layer of complexity to the decision-making process.[26]

3. *Alternatives May Imply Health Risks*
   According to DG ENV, "use of alternative plastics in direct physical contact with patients poses similar issues to PVC with regard to transfer of toxic additives to the body."[27] For instance, alternative materials like rubber latex is known to cause allergic reactions in some individuals. This presents a significant health risk that must be accounted for when considering alternatives to vinyl.[28]

4. *Possible Disruptions in Supply of Critical Equipment*
   Material changes in medical equipment trigger re-evaluation of safety, efficacy, and reliability. This process demands additional time for testing, revalidation, and re-registration of individual products, thus extending the transition period significantly. Furthermore, alternative materials may face availability constraints.[29]

5. *Possible Strains on Healthcare Budgets*
   PVC alternatives are generally more expensive.[30] Phasing out vinyl may lead to higher material costs, investments, and expenses related to technological redesign of products, new production equipment, testing, validation, and approval of new materials for medical applications. This would result in higher costs for healthcare providers.[31] Data shows the cost of replacing vinyl with alternative materials could lead to a 30% price increase for medical devices.[32]



A PVC-Free Blood Bag Is Not on the Horizon
It is often claimed that a PVC-free blood bag is close to market, yet that is not the case. The PVC-Free Blood Bag Project (2011-2018), a part of the EU's Life+ Environmental Programme, aimed to produce a PVC-free blood bag that met the required specifications, including CE labeling.[33] This aim was not achieved: Gulliksson et al. (2016) found that the novel polyolefin blood storage bag failed to maintain acceptable hemolysis levels within the conventional 42-day storage period.[34]

Since the conclusion of the project in 2018, there has been a notable lack of progression towards a market-ready PVC-free blood bag. This stagnation can be attributed to the absence of continued interest or involvement from commercial partners, blood banks, and other stakeholders in further developing or commercialising the technology.

Towards a DEHP-Free Vinyl Blood Bag
Historically, the use of DEHP as a plasticiser in vinyl blood collection systems, including bags and tubing, has been integral for maintaining the stability and integrity of red blood cells (RBCs), which is crucial for effective blood transfusions. The updated EU Medical Device Regulation and the REACH regulation now mandate the phase-out of DEHP from blood bags before 1 July 2030.[35]

RENOLIT Healthcare, a VinylPlus Healthcare partner and leading film producer for blood bags and other medical applications, is at the forefront of this transition. Early test results of blood bags using a prototype non-phthalate vinyl film, called RENOLIT Bloodprotect 42Plus, show RBC haemolysis level (0.17 ± 0.1%) with no significant difference to DEHP (0.16 ± 0.2%) after 42 days of storage, when using conventional SAG-M storage solution, thereby exceeding the performance of the current DEHP replacements DINCH, DEHT, and BTHC.[36]

By changing to PAGGS-M solution, Dutch national blood organisation Sanquin has found hemolysis rates comparable to DEHP for red blood concentrate (RCC) collected in DINCH-plasticised collection bags and stored for 42 days in blood bags plasticised with DINCH, DEHT, or BTHC.[37] The French Blood Establishment (EFS) has found that RCCs stored in a PVC/Citrate/PAGGS-M storage bag for 49 days were compliant with French quality requirements, as were plasma prepared and stored in a DINCH-plasticised PVC container.[38]

It will be a long-term endeavour to turn the RENOLIT prototype or other solutions to reality. Nonetheless, a game-changing DEHP-free blood bag is on the horizon.

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VinylPlus Healthcare Project Leader Ole Grøndahl Hansen (left) and Consultant Tobias Johnsen (right).

About VinylPlus Healthcare

VinylPlus Healthcare was established in 2025 as a dedicated platform under VinylPlus®, the commitment to sustainable development of the European PVC industry. It brings together the activities of the now-closed PVCMed Alliance with VinylPlus® Med for medical device recycling and VinylPlus® PharmPack for pharmaceutical blister packaging recycling. VinylPlus Healthcare serves as the central hub for sustainability, innovation, and circularity in medical vinyl applications, promoting responsible material use, enhancing recycling initiatives, and fostering collaboration across the healthcare value chain.

vinyl plus healthcare

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COMMITTED TO CIRCULARITY IN PHARMA PACKAGING

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