Landscape Analysis of Drivers, Enablers, and Barriers to Plasticizer Substitution

CASE STUDIES:

- LUXURY VINYL TILE
- SCREEN-PRINTED APPAREL
- INFLATABLE PVC TOYS
- GARDEN HOSES
- IV FLUID DELIVERY PRODUCTS

Below are full case studies, including table summaries for the case studies included in the Landscape Analysis.

CASE STUDY ON LUXURY VINYL TILE

Product description

Luxury vinyl tile flooring (LVT) is made as glue-down or floating tiles and planks and consists of up to four distinct layers fused: a resilient vinyl backing, a vinyl color layer, a vinyl photographic film layer, and a urethane or aluminum oxide top layer for wear resistance.

Consumers favor LVT because of the ease of installation over different kinds of subfloors and attractive visuals. LVT has photo realistic 3-D graphics that simulate natural wood or stone, is highly durable, and provides the promise of no/low maintenance.

LVT experienced rapid market penetration and growth, starting in 2012 in the U.S. when big-box stores began to carry the product. From 2012 to 2015, the market grew from nothing to become the number one flooring material sold.

Types of plasticizers used historically

Early LVT products were developed with DOP (DEHP) and DINP as the primary plasticizers, with DOP being dominant in products manufactured in Asia, since it was significantly cheaper and is a more efficient plasticizer (less DOP is required to provide the same performance. The substitution factor (SF) for DINP vs. DOP is 1.06. DINP is 6% less efficient than the plasticizing efficiency of DOP). Tarkett was the first company to manufacture LVT in the U.S. in 2011 and developed its first product with DEHT/DOTP.

Analysis of drivers and barriers

Table Key:

✓ **=** Driver or enabler was a factor, **I =** Driver or enabler was an indirect factor

Factor column is blank = Driver or enabler was not a factor

Drivers	Factor	Key Developments
Brand culture & action	✓	2010/11 – Tarkett selected DEHT/DOTP and DINCH for their LVT products in 2010 and started production in 2011. Many of their customers requested that they avoid the use of phthalates in their flooring. Tarkett applied the "precautionary principle". They selected plasticizers that were already used for toys, for which toxicological studies existed, and which showed no risk for their applications. Other U.S. LVT manufacturers followed, with most U.S. LVT producers using non-phthalate plasticizers by 2014.
NGO pressure	✓	2014 – Healthy Building Network (HBN) releases its research brief Phthalate-free Plasticizers in PVC. 2015 – NGOs released results of testing of vinyl floor tiles sold at large U.S. home improvement retailers, finding that 58% of vinyl floor tiles tested contained ortho-phthalates. Flooring with

		phthalates was predominantly lower-cost LVT flooring containing DOP, manufactured, and supplied by Asian companies. 2014-2016 – NGOs met with large U.S. retailers challenging them to eliminate ortho-phthalates. 2019 – Kingfisher released their Sustainable Chemicals Roadmap, committing to phase out ortho-phthalates from their own-brand products by 2025.
Retailer action	✓	April 2015 – Home Depot announced that it would discontinue the use of phthalates in vinyl flooring by the end of the year. Lowe's, Lumber Liquidators, Menards, and Ace Hardware followed.
Regulations/Other government action	I	CSPC's 2008 restrictions on phthalates in children's toys was a factor in Tarkett's decision to formulate their new LVT products without phthalates.
Consumer pressure	N/A	
Industry standards	N/A	
Green Stds & Certs	N/A	
Enablers/Barriers		**Key Issues**
Alternatives & Switching: • **Performance/ track record** • **Safety/availability of safety data** • **Cost** • **Scale** • **Multiple suppliers** • **Switching process, costs & time**	✓	**Performance/track record.** There was a track record of acceptable performance of alternatives (DEHT/DOTP and DINCH) in the toy industry, driven by the phthalate restrictions in the 2008 CPSIA. For Tarkett, while the company understood that DEHT/DOTP could perform adequately in LVT, significant resources were required to develop an LVT product with good performance characteristics. **Safety/availability of safety data.** In 2010, Tarkett's view was that the non-ortho-phthalates DEHT/DOTP and DINCH were safer alternatives to ortho-phthalates in vinyl flooring. DEHT/DOTP and DINCH were, at the time and still today, not regulated by the U.S. CPSC for use in toys. **Cost.** In 2011, the cost of using DEHT/DOTP and DINCH was close to the main incumbent DINP being used in the U.S.; DINP was the main incumbent because it was more available than DOP in the U.S., at the time. DOP was more widely available in Asia and the cost of using DOP in products manufactured in Asia was lower. **Quantity/Scale/Multiple Suppliers.** Producers scaled up quantities of DEHT/DOTP and DINCH for use in toys and children's products in 2011. In 2010 when Tarkett decided to switch to DEHT/DOTP for products produced for the U.S. market and DINCH for European products, there was only one supplier for each, creating some risk for Tarkett and other early adopters. The number of suppliers and supply grew in 2014/2015 along with the market for LVT, particularly in Asia. **Switching process, costs, & time.** All the plastisol processing (i.e., compounding) is done in-house at flooring companies (no external compounders/formulators were involved). No new equipment was needed to produce flooring with new plasticizers. Reformulation was required in some cases. For example, some products needed to include fast fusers like dibenzoate, which took time and money to test but ultimately lowered the processing temperatures and press pressures required. LVT is 5-9 layers, and each layer must be compatible with adjacent layers; U.S. LVT manufacturers that switched to DEHT/DOTP worked closely with their supplier to ensure that the layers were compatible.
Transparency		LVT manufacturers knew which plasticizers were being used in their flooring.

Segments of this market where substitution has not yet occurred and why

For the U.S. market, the switch is >95% and essentially complete, which happened largely as a result of NGO actions, starting with the 2015 HBN report. All segments of the vinyl flooring industry and carpet have switched to either non-phthalate plasticizers or to different resins where plasticizers are not needed.

Trends

Non-plasticized flooring. Some LVT manufacturers in the U.S. and Europe are moving to non-plasticized, harder, less flexible vinyl flooring. First-generation LVT was very flexible, with high concentrations of plasticizers designed to hide imperfections in the underlying floor. Over time, these imperfections came through the LVT to create blemishes. Second generation LVT is made of more rigid, non-plasticized (or less plasticized) vinyl that masks the imperfections better over time. Some LVT manufacturers use a wood core layer, a lightly plasticized PVC core, or a fully unplasticized PVC core. An unplasticized PVC core can solve other technical or performance problems such as migration issues in adhesives, hydrolysis issues in uncured concrete, and can lower cost. In current products, "unplasticized" can still mean up to 3% plasticizer content overall, while some third-generation products are totally free of plasticizers.

Prices coming down, use going up. Historically, the cost of plasticizers was significantly more than the vinyl polymer. Now, plasticizer prices are closer in price to vinyl (but still higher). As plasticizers become cheaper, they can be used as a filler, in place of fillers such as calcium carbonate and clay. Manufacturers of vinyl flooring are constantly looking for ways to reduce the manufacturing cost of their products and as the relative cost of raw materials change, they reformulate to lower costs. This trend could lead to higher levels of plasticizers in LVT.

Non-PVC Resilient Flooring and Recycling of Materials (Circular Material Systems). Most U.S. and European flooring companies have projects to move out of PVC for resilient flooring or have commercial products in the market. Reducing pressure from NGOs is a key motivator. Manufacturers are focused on using polyolefin polymers for these products.

Interface and Mohawk, producers of LVT flooring, are recycling their reclaimed vinyl tile into carpet backing. Tarkett in Europe is using polyvinyl butyral (PVB) instead of PVC for resilient flooring (and carpet backing), from the PVB coating from recycled car windshields. The PVB is plasticized with a glyceride plasticizer from hydrogenated castor oil.

Conclusions – Why did substitution occur?

Four factors were major contributors:

1. **Brand Action.** Tarkett, a major brand, became motivated to design its vinyl flooring, including LVT, with non-phthalate plasticizers, out of safety concerns. The actions of

this “lead user” of non-phthalate plasticizers for vinyl flooring paved the way for other flooring companies.

2. **NGO Pressure.** A group of NGOs collaborated to create a campaign that focused on phthalates in vinyl flooring and worked together to convince retailers to commit to eliminating phthalates in the vinyl flooring sold in their stores.
3. **Retailer Action.** Major U.S. retailers committed to phasing out phthalates in their vinyl flooring.
4. **Availability of alternatives.** There was a track record of acceptable performance of non-phthalate plasticizers in toys, which gave confidence to Tarkett to make needed investments to convert production. The fact that flooring manufacturers manage much of the compounding process eased the transition.
5. **Cooperation along the value chain.** Tarkett and other LVT manufacturers were able to work closely with the suppliers of DEHT/DOTP and DINCH to solve technical issues that arose during the switch.

CASE STUDY ON SCREEN-PRINTED APPAREL

The elimination of plasticizers in screen-printing inks is complicated because different approaches were chosen based on the brand. Some leading brands, including Nike, H&M, Zara, Levi Strauss, and Patagonia, eliminated PVC from their products, which by default included plastisol ink. Others still use plastisol inks, but the phthalate plasticizer has been replaced with a non-phthalate plasticizer. Whatever the pathway, the goal is for the replacement to resemble plastisol ink from an aesthetic perspective and maintain ease of use during manufacturing.

Product description

Screen-printed textiles, especially finished garments, are commonly printed with plastisol ink, which is a suspension of PVC or other polymer particles in a liquid plasticizer. The colored PVC is mixed with enough plasticizer, up to 40%, to make the ink resemble and flow like a thick viscous liquid. Commonly used plasticizers were phthalates, especially DEHP, due to its excellent plasticizer performance, availability, and cost.

The invention of plastisol ink enabled screen printers to run more complex designs, print on any type of garment, and run mass production effectively. Plastisol inks will not dry at room temperature and require curing at 180 °C, either with a flash dryer or oven. When the curing temperature is reached, the PVC dissolves, and the mixture turns into a viscous gel that forms a flexible, permanently plasticized solid product when cooled to 60°C.

Plastisol inks offer many advantages to the printer, the brand, and the consumer. They are not water-soluble and will not dry if left on the screen for extended periods. Ink can be quickly flashed and stacked on top of itself, thus producing complex designs. Printed garments do not need to be washed after printing, and plastisol inks are often used to print on colored fabric due to the high-quality resulting print.

Types of plasticizers used historically

Plastisol inks were introduced in the 1970s as an alternative to water-based inks. The most common plasticizers were DEHP and DINP, due to low cost and effective plasticizer function[1].

Other plasticizers that were used historically, and may still be used today, include some dihexyl phthalates such as Dicyclohexyl phthalate (DCP or DCHP), Diisohexyl phthalate (DHP or DIHxP), and Di-heptyl phthalates such as Diisoheptyl phthalate (DIHP).

Phthalates are not specifically restricted in apparel, and their use in apparel is left somewhat to interpretation. Some are, however, categorized as substances of very high concern (SVHC), and some are specifically regulated in children's toys and other childcare products.

[1] DEHP (di(2-ethylhexyl) phthalate) and DOP (di-octyl phthalate) refer to the same chemical compound also recognized as BEHP (bis(2-ethylhexyl) phthalate).

Analysis of drivers and barriers

Table Key:

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Factor column is blank = Driver or enabler was not a factor

Drivers	Factor	Key Developments
Brand culture & action	✓	**Brand reputation**. Nike phased out PVC in all products, which included plastisol inks. This was in response to a Greenpeace campaign targeting PVC, and some negative press with regards to labor issues. Plasticizers were not the primary reason for the phase-out. This occurred in the late 1990s to early 2000s. Other brands, including Marks and Spencer, H&M, Zara, etc., restricted phthalates in the early 2000s once they were regulated in toys. The concern was that a child could chew on screen printed apparel printed with plastisol. Brands must meet all applicable chemical regulations in the countries where they sell their products. Many proactively manage chemicals to protect their brand reputation and to meet corporate social responsibility initiatives. **RSLs play a role**. Nike, Levi Strauss, Adidas, and a few other brands developed RSLs in the early 2000s. Many contained regulated chemicals and chemicals with some health or environmental concerns. Some phthalates were added to these lists before REACH or the CPSIA regulations. Given the number of phthalates and scientific and regulatory debates about them, some brands proactively placed all ortho-phthalates and PVC on their RSLs, rather than track each phthalate and update their list with each new requirement or change in the science (what can be termed list fatigue). **Industry collaboration**. Stakeholder engagement and collaboration is common in the apparel industry. Several organizations in the sector such as the ZDHC, AFIRM Group®, and Sustainable Apparel Coalition convene brands, suppliers, and other stakeholders in supply chain actions that drive more sustainable products in the sector. ZDHC and AFIRM Group® were started by brands to address chemicals of concern in textile processing. These stakeholder groups could be considered as drivers for substitution given that they develop and manage restricted chemical lists on behalf of their membership and encourage the phase-out of priority chemicals. However, as their membership has grown, they may also be considered as enablers for change, and even serve as advisors to industry and governments on better chemistry. Additionally, these groups track global chemicals regulations and help their members adhere to regulations by providing tools, training, and guidance documents.
NGO pressure	✓	Greenpeace USA started its PVC: The Poison Plastic campaign that was a key factor initiating plastisol reduction in screen printing. In 2011, the Greenpeace Detox Fashion Campaign tasked brands to meet "zero discharge of hazardous chemicals" by 2020. 11 classes of chemicals were targeted for substitution, including all ortho-phthalates.
Retailer action		No retailers are specifically targeting plasticizers in apparel. Some brands that are also retailers, however, are acting on ortho-phthalates.
Regulations/Other government action	✓	In 1986, Proposition 65 passed and required California to publish a list of chemicals known to cause cancer, birth defects, or other reproductive harm. This list, which is updated annually, includes some ortho-phthalates.

		In 1999, the EU restricted the use of six ortho-phthalate plasticizers in toys and childcare items. Screen-printed apparel could potentially fit into these regulations, although apparel was not addressed specifically. In 2008, some phthalates were added to the REACH SVHC list. Since July 7, 2020, seven ortho-phthalate plasticizers are restricted in the EU. The U.S. Consumer Product Safety Improvement Act (CPSIA) is the primary regulatory driver affecting the use of textile inks for products made and sold domestically (though it does not specifically ban or restrict the use of PVC or plastisol inks). Certain phthalates in children's products and child-care articles are targeted.
Consumer pressure		As a result of advocacy campaigns, consumers are increasingly asking questions about chemicals in fashion and apparel products but in this case, consumer pressure was not a direct driver for substitution.
Industry standards	I	American Association of Footwear and Apparel (AAFA) is a U.S. trade association that tracks regulations and publishes and updates an RSL annually. Some ortho-phthalates are included in their RSL. The AFIRM Group®, started in 2004, is a brand-led membership group, whose purpose is to advance the global management of restricted substances in apparel and footwear. It created a guidance list of chemicals in 2012 and a full RSL in 2015. This RSL has been adopted by many brands and is updated annually by a task force. ZDHC, formed in 2011, a textile-related stakeholder group, was a result of the Greenpeace Detox campaign. ZDHC developed a manufacturing restricted substance list in 2013 that includes all phthalates.
Green Stds & Certs	I	bluesign® is a voluntary textile eco-standard introduced in 2000. It has a restricted substance list of chemicals, the BSSL, and identifies hazardous chemicals that should not be used or present on products. bluesign® initially gained adoption by outdoor brands but today its use in footwear and apparel has grown since it has been integrated into the ZDHC MRSL chemical conformance strategy. OEKO-TEX® 100 is a voluntary standard for finished products that limits the presence of certain restricted chemicals on products. It is also popular with many brands, especially in Europe.
Enablers/Barriers		**Key Issues**
Alternatives & Switching: • **Performance/ track record** • **Safety/availability of safety data** • **Cost** • **Scale** • **Multiple suppliers** • **Switching process, costs & time**	✓	**Performance/track record.** **Alternative plasticizers.** DEHT/DOTP has largely replaced DEHP, although it is approximately 7% less efficient, which means that more of the plasticizer is required, and some reformulation may have been necessary. **Alternatives to plastisol inks.** High solid acrylic inks and polyurethanes are "PVC-and phthalate-free" inks and acceptable substitutions. They were developed to combat some of the problems associated with water-based inks (thin, runny, too transparent). A thickening binder creates a consistency more akin to plastisol ink. PolyOne was awarded a patent in 2011 (U.S. patent 2011/0206907 A1) for a ***plastisol-like ink*** made from a methacrylate core shell copolymer, a non-phthalate ester plasticizer, a pigment, filler, and a thixotropic agent. Dibenzoates were used as the high solubility parameter plasticizer and DINCH was used as the low solubility parameter plasticizer. High solid acrylic inks act more like plastisol in that they don't dry quickly on the screen and can stretch and stack on top of each other, which makes them ideal for more complex printing techniques, such as halftones and simulated process printing. Initially, they were difficult to work with compared to plastisol, but most of the common printing techniques could be accomplished. Today, the performance closely mimics plastisol inks, but this took a lot of development work by printers and was not a straightforward switch.

		Safety/availability of safety data. If a replacement chemical is not on an RSL, it is generally acceptable for use. Some brands, such as Nike, conduct due diligence via hazard-screening of alternatives, but this is not common. Apparel brands typically do not specify what chemicals to use, but rather what not to use. Eco-standards and certifications, such as bluesign® or OEKO-TEX®, are used by many brands and if a chemical or product is certified, it is considered acceptable to use. **Cost.** Alternative plasticizers are slightly more expensive than DEHP. High solid acrylic inks and polyurethanes are a little more costly than standard plastisol and are substantially more expensive than other water-based inks, but they mimic plastisol inks better than other water-based inks. **Quantity/Scale/Multiple Suppliers.** No issues were identified with either type of replacement. **Switching process, costs, & time.** The same equipment can be used with either type of replacement; however, for alternatives to plastisol inks, extra effort is required by the screen printer. These inks do not offer the same wet-on-wet print and bleed-blocking capabilities as PVC inks and because water-based inks eventually dry on the screen, many printers have two sets of screens that are rotated. As one set is used, the other is washed to remove drying ink. Another challenge was color variation on very fine mesh screens. Again, this was due to the drying effects of the inks and clogging meshes. This was largely overcome by the rotating of the two sets of screens.
Transparency		Apparel brands and even screen printers often do not know the specific plasticizers being used in the inks that they use.

Segments of this market where substitution has not yet occurred and why

For the U.S. and European markets, the switch to alternative plasticizers in plastisol ink, or a switch to non-plastisol inks, is considered to be fairly complete, especially in the EU where the softer feel of water-based inks is preferable to plastisol. Approximately 90% of the products and goods sold in Europe are printed with water-based prints. The substitution can be verified in most cases because many inks meet eco-standards that do not allow phthalates, and ink manufacturers test for the presence of phthalates. However, it is hard to identify and quantify if complete substitution has occurred for a few reasons:

- Screen printing is a highly fragmented sector. It is not possible to determine if all screen printing occurs with alternative plastisol or PVC and phthalate-free inks.
- A significant amount of production occurs in Asia where chemicals regulations are often not as strict, and enforcement may be lacking. However, for domestic and European manufacturing, this is not the case.
- The apparel industry manages chemicals by managing restricted lists. This means that they restrict chemicals (such as PVC and phthalates) rather than specify what chemicals can be chosen. Some brands have addressed this by restricting the use of plastisol ink entirely, which by its very nature means that phthalates are restricted as well. This strategy has been adopted by some, but not all, companies.

Conclusions – Why did substitution occur?

Three main drivers led to the substitution of plasticizers in this case:

1. **Brand action:** Brands are concerned about their reputation and therefore a move away from regulated phthalates and PVC entirely was one way to ensure their reputation remained intact. The same regulations that changed the makeup of plastisol inks motivated many industry-leading apparel companies to look for alternatives to plastisol altogether so as not to potentially tarnish their reputation.
2. **Regulations:** The move away from a plastisol-dominant market has been gradual but decisive, with incentives and pressure coming predominantly from outside ink manufacturers and printers. The CPSIA caused major shifts in manufacturing requirements and, more recently, a move away from regulated phthalates. The U.S. regulations are specific to childcare products and toys and include "anything that aids sleep." Based on these criteria, manufacturers interpreted this to mean that screen - printed children's apparel products should be free from regulated phthalates. In addition to U.S. regulations, the EU regulated some phthalates as SVHCs, and many brands try and avoid SVHC concern as much as possible.
3. **NGO pressure:** The most important NGO campaign targeting the apparel industry is the Greenpeace Detox campaign. As a result, ZDHC was formed to tackle hazardous chemicals in textile manufacturing. ZDHC, coupled with pressure from Greenpeace, catalyzed action to phase out of chemicals of concern. ZDHC membership includes 30 signatory brands, 101 value chain affiliates, and 19 associates.

CASE STUDY ON INFLATABLE PVC TOYS

Brand image is critical in the toy industry, with iconic products, such as Barbie, often representing the brand. This is not the case in inflatable PVC toys, where no one brand or company dominates the market. Therefore, well-known brands are not needed to drive a lot of volume. Inflatable children's toys are sold in big-box retailers such as Target, Walmart, and others, but generally not by well-known toy companies. Nonetheless, corporate brand image does remain important and even specific inflatables brands can be recognized by visual cues.

Product description

Inflatable PVC products are manufactured through the calendaring of PVC resin in combination with plasticizers and dyes. Thin, PVC sheets are cut, and RF welded together to form airtight seals that allow toys and other merchandise to take form through inflation. These products are intended to be used in a wide variety of applications, including airbeds, boats, pool floats, children's ball pits, and so forth.

Scalability and consistency are very important to many inflatable toy manufacturers because often the same PVC sheet is used for entirely different products, such as an adult airbed or a child's inflatable toy. As a result, the same plasticizer is typically used regardless of the product application.

Types of plasticizers used historically

DEHP was used historically as the primary plasticizer for inflatable PVC toys. For some companies, this was replaced as early as 1999 with dioctyl terephthalate (DEHT/DOTP) because the two plasticizers are similar in cost and performance and because DEHT/DOTP was readily available in the market. In addition to DEHT/DOTP, DINCH and ATBC are used.

Analysis of drivers and barriers

Table Key:

✓ **=** Driver or enabler was a factor, **I =** Driver or enabler was an indirect factor

Factor column is blank = Driver or enabler was not a factor

Drivers	Factor	Key Developments
Brand action	I	Some toy companies replaced DEHP as early as 1999 because of increasing NGO attention and some regulatory pressure from the EU. Many toy companies sell globally and to minimize company risk, would replace a chemical across all products if it was being watched.

		To minimize company risk, some toy companies specify what plasticizers to use and restrict and often designate to suppliers where to purchase chemicals (i.e., name the chemical company).
NGO pressure	I	Greenpeace started a campaign against PVC in the mid- 1990s, with phthalates and toys being a major focus. NGO pressure dropped off because the substitution of DEHP with a safer alternative in this product category occurred as early as 2005.
Retailer action	I	To meet the requirements of the CPSIA regulations and avoid reputational risks, some ortho-phthalates are on retailer RSLs, particularly for children's products. Retailers in countries outside of the EU have adopted standards modeled after EU 2005/84/EC (see below). Retailers expect their suppliers to meet all regulations.
Regulations/Other government action	✓	In 1999, the EU introduced a temporary phthalate restriction on six phthalates, which was implemented as a permanent restriction in 2005 by Directive 2005/84/EC. This Directive was transferred into Annex XVII, 51 and 52 of REACH (Regulation (EC) 1907/2006) and prohibits the use of certain phthalates in the manufacturing of toys and childcare articles. The phthalate restrictions in Annex XVII where extended to cover seven phthalates in 2018 (Reg (EU) 2018/2005), effective since July 7, 2020. The CSPC's 2008 restrictions restrict phthalates in children's toys and childcare articles. These regulations catalyzed the phase-out of DEHP in this product type.
Consumer pressure	I	While consumers were beginning to question major brands and retailers about the use of phthalates in toys by the end of the 1990s and some companies were labeling their toys as phthalate-free, consumer pressure was not a significant reason for substitution in this product category. This may be due to the following: inflatables are not made by known companies/brands, and the substitution was already complete before increasing awareness around this issue in the mid-2000s.
Industry standards	✓	American Society for Testing and Materials (ASTM) F963 is a voluntary toy safety standard that included the ortho-phthalate regulation that became mandatory in 2009. Its importance in motivating substitution increased after regulations were passed.
Green Stds & Certs		DEHT/DOTP is listed in CleanGredients for two commercial brands as a safer alternative plasticizer.
Circular economy		
Enablers		**Key Issues**
Alternatives & Switching: • **Performance/ track record** • **Safety/availability of safety data** • **Cost**	I	**Performance**. DEHT/DOTP is not a regulated or restricted chemical in this product category, which is a key reason for using it. From a manufacturing standpoint, the switch to DEHT/DOTP was fairly seamless, offering no additional challenges. It offered the required performance, i.e., airtight, and had the same consistency as DEHP. **Safety/Safety data.** Most toy manufacturers relied on their chemical suppliers to conduct the necessary risk assessment and toxicological studies. No additional data were requested. It should be noted that Eastman Chemical Company manufactures DOTP and was instrumental in the substitution by providing technical support to manufacturers. **Cost**. Product cost initially increased because the cost of DEHT/DOTP was slightly higher and new supply networks had to be established.

• **Scale** • **Multiple suppliers** • **Switching process, costs & time**		**Scale.** DEHT/DOTP has been available for 40 years and therefore scaling was not an issue. This application is a small part of the plasticizer market, and several suppliers manufacture DEHT/DOTP. **Switching Process**. There were significant resources dedicated to trial production and testing to ensure that the required performance attributes were met. This included the ability of the product to hold air without breaking. Scale and increased efficiencies have improved, thus stabilizing cost.
Transparency		Full transparency of the formulation was available.

Segments of this market where substitution has not yet occurred and why

In the U.S. used elsewhere, phthalate substitution in this product class is widespread as the CPSIA regulation bans specific ortho-phthalates in specific product categories including children's toys.

There may be instances when smaller non-branded factories sell some items on an original equipment manufacturer (OEM) basis. Those items would most likely not make their way into major retailers; however, they could enter the distribution network through online sales and regional shops. For PVC inflatable toys manufactured in Asia, DEHP is still the most important plasticizer, with products likely targeted towards an internal market given the regulations in the EU.

Conclusions – Why did substitution occur?

There were two main reasons for substitution:

1. **Regulations**. The main drivers toward successful substitution were the EU and CPSIA phthalate regulations, given that they were specific to children's toys. The EU market had taken the first step towards regulating phthalates in toys at the end of the 1990s and the U.S. followed suit several years after. Several U.S. states also issued policies on chemicals in children's products in the mid-2000s. Global manufacturers found it necessary to adapt global production to meet these standards to maintain competitive scale.
2. **Brand image and risk**. While inflatables manufacturers are not recognized as iconic brands, as manufacturers of children's products, brand reputation, including consumer safety concerns are important motivators for action.

Some toy manufacturers phased out ortho-phthalates well before the European and U.S. regulations were finalized and before the ASTM toy standard became mandatory. This was mainly done to reduce company risk and perhaps simplify supply chains. It can take up to 18 months to transition towards new formulations and getting a head start on "watch" chemicals is a strategy adopted by many companies in an effort to proactively manage company risk.

CASE STUDY ON GARDEN HOSES

Product description

Garden hoses are typically made from rubber or soft plastic, usually PVC. The exterior is smooth, and the interior is often reinforced with an internal network of fibers to provide toughness, reinforcement, and strength.

PVC garden hoses are made with multiple layers of PVC. The PVC pellets, which contain a plasticizer and other additives are mixed with pigments and then homogenized, melted, and extruded to form a tube that is cooled in a water bath. It is then cut to the desired length.

Garden hoses are designed to be flexible and smooth to facilitate pulling them past obstacles such as trees, posts, and steps. They must also be tough enough to withstand being stepped on, run over by a vehicle, or scraped against outside obstacles without causing leakage and damage. In addition, they must be able to survive a range of temperatures from -30F to 120F and resist sunlight and biodegradation.

Some garden hoses are designed to carry potable water, and these are typically made from materials that have been tested and shown not to leach harmful materials into the drinking water. If a garden hose is NSF/ANSI 61 or NSF/ANSI 372 certified, it means the product meets certain safety standards to be used for drinking water.

Types of plasticizers used historically

The specific plasticizer that is used in garden hoses depends on the product manufacturer and it may depend on the location in which the product is made.

Approximately 20 years ago almost all PVC garden hoses were made with DEHP, given its excellent plasticizer performance and cost. However, about 10 years ago, there were concerns from the media and NGO's that people, especially children, may be drinking out of garden hoses. This led to a new certification called NSF drinking water safe that tested for the presence of many chemicals, including phthalates and metals.

Today, some U.S. manufacturers have transitioned away from DEHP to either DEHT/DOTP or DPHP, given that the cost and plasticizer performance are very similar to DEHP.

Analysis of drivers and barriers

Table Key:

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Factor column is blank = Driver or enabler was not a factor

Drivers	Factor	Key Developments
Brand culture & action	I	Garden hoses are not dominated by one brand, and brand recognition is not required to drive a lot of volume. In 2014, Teknor Apex, both a manufacturer and brand, moved away from DEHP to reduce brand risk given ongoing consumer awareness about phthalate exposure.
NGO pressure	I	The Ecology Center published 3 reports on chemicals in garden hoses, including reports in 2012 and 2013 that tested 90 garden hoses. The 2016 report tested 32 different garden hoses purchased from big-box retailers. Several product names were included. Of these, 24 were PVC, five were polyurethane, one was rubber, and two were other polymers. Ten were labeled drinking water safe. Results showed that PVC hoses frequently contained lead, bromine, antimony, and phthalates. Phthalates were found in 75% of PVC hoses. Phthalates included DIBP, DBP, DEHP, DINP, B2PHP, DIDP, DNUP (phthalates were not found in drinking water safe garden hoses). DEHT/DOTP and TOTM were also found in several hoses.
Retailer action	I	Most retailers that sell garden hoses have not requested that they be free from phthalates despite the Ecology Center reports. In addition, these products are not specifically called out by the Mind the Store campaign.
Regulations/Other government action	I	California's Prop 65 may have been a factor in transitioning away from DEHP for some manufacturers so that Prop 65 product labeling could be avoided. Other phthalate regulations are not applicable to garden hoses and hence this is not a big driver for change.
Consumer pressure	N/A	Consumers are gaining awareness that some phthalates pose a risk to human health although it is not clear if consumers associate garden hoses with phthalates. Purchasing decisions for garden hoses may be driven by performance and cost rather than brand loyalty and safety. Consumers tend to associate "chemicals" with personal care, household cleaning products, and cosmetics rather than plastic hoses.
Industry standards	N/A	NSF Drinking water safe which tests for the presence of several priority chemicals.
Green Stds & Certs	N/A	
Circular economy	N/A	
Enablers/Barriers		**Key Issues**
Alternatives & Switching: • **Performance/ track record**		**Performance/track record.** For Teknor Apex, there was a track record of acceptable performance of alternatives (DEHT/DOTP and DPHP). Minimal reformulation was required. **Safety/availability of safety data.** DEHT/DOTP is not listed under Prop 65 and the safety data that is available is adequate, even though there is much more history with DEHP. Teknor Apex selected non-phthalate plasticizers that were already used in other product categories such as toys, for which toxicological studies existed and showed no risk for their applications.

• **Safety/availability of safety data** • **Cost** • **Scale** • **Multiple suppliers** • **Switching process, costs & time**		**Cost.** As the demand and use of DEHP continues to decline and the demand of DEHT/DOTP continues to rise, the difference in cost between the two chemicals is almost negligible. **Quantity/Scale/Multiple Suppliers.** Producers scaled up quantities of DEHT/DOTP for use in toys and children's products and therefore scaling was not an issue. **Switching process, costs & time.** For at least one manufacturer, Teknor Apex which sells branded garden hoses**,** all of the processing (i.e., compounding) is done in-house, and the company verified that no new equipment was needed to produce garden hoses with new plasticizers. Some reformulation was required in some cases.
Transparency		Companies that manufacture and sell branded products have access to ingredient information, though retailers may not have this information.

Segments of this market where substitution has not yet occurred and why

Based on the 2016 report by Ecology, it appears that a little more than 25% of the market has made the substitution. However, this figure may be higher given that "drinking water safe" hoses do not contain regulated phthalates and many garden hoses are also made from polymers other than PVC.

Conclusions – Why did substitution NOT occur?

It appears that substitution has not occurred because there are insufficient drivers in place, even though the Ecology reports raise concerns. As there are no strong regulatory drivers and no specific campaign that targets PVC hoses, there is little incentive for brands to protect their reputation. Further, as there is no strong "brand" in the garden hose product area, the brand reputation concern is minimal.

Alternative plasticizers to regulated phthalates do exist and are feasible, as shown by the substitutions by Teknor Apex.

Other barriers to substitution may include the following:

- **Incumbency**. Much of the garden hose production is in Asia, where there is a long history of DEHP use, given its low cost and effectiveness. Since DEHP-plasticized PVC garden hoses are not under significant consumer pressure or regulation, there is little incentive to switch either plasticizer or polymer. Additionally, manufacturers may not have much power over reformulation as they are often not manufacturing the hose material but rather purchasing long lengths of spool from China that are cut to length and fitted with special fittings and sold as consumer garden hoses.
- **Safety**. There is limited concern for safety. Some manufacturers believe that DEHP is safe to use in garden hoses given that it is not regulated in this product category.

CASE STUDY ON IV FLUID DELIVERY PRODUCTS

Overview

For IV fluid delivery products (FDPs), in some instances, drivers have led to the successful substitution of phthalates with alternatives. This includes a powerful, far-reaching NGO campaign and the public commitment of leading hospitals to phasing out IV FDPs made from DEHP and PVC. Yet, in nearly 20 years, the product category has only reached between 30 and 35% substitution, according to GHX data[2].

Product description

Intravenous therapy delivers fluids (electrolytes, colloids, and blood) directly into a vein through injections or infusions using IV FDPs and accessories such as tubing, needles, and others. The fluid, which must be safe, clean, and sterile, is stored in an IV FDP.

The four main U.S. companies that make IV FDPs[3] are Baxter, ICU Medical, Fresenius Kabi, and B. Braun. The products must be made in an FDA-approved facility, which may take years to complete given the high degree of complexity associated with manufacturing medical devices. The plastic resin is blended, melted, and extruded into sheets that are fabricated into the FDP, IV fluid is added, and the bag is sealed. It is then sterilized, packed, distributed, and stored. Numerous quality assurance checks are completed before shipment.

Performance is critically important for FDPs. They should be visually clear, transparent, soft, and flexible to prevent kinking. They must be sterilized with steam and radiation, be biocompatible, and appropriate for the application in question. Because FDPs may be stored for many weeks or months prior to use, they must be able to withstand storage conditions, prevent leaching, and ensure the solution remains clean and safe for administration.

FDPs are purchased by large hospitals and/or Group Purchasing Organizations (GPOs) that effectively negotiate prices based on scale. Based on the purchased volume, they are inexpensive devices generally used only once before disposal. They are often used by clinicians, doctors, nurses, and other medical personnel in life and death situations, where ease of use is crucial.

[2] GHX is a global healthcare exchange and data automation company. It maximizes industry savings using cloud-based supply chain technology exchange platform, solutions, analytics, and services.

[3] FDPs come in different sizes, but typically large volume products carry 250 – 1000 ml of solution and small products carry 25 to 150 ml solution. In addition to IV FDPs there are irrigation bags that are used to clean and irrigate wounds, which are typically 2 to 5 liters in size.

Types of plasticizers used historically

Very early FDPs were made from glass with a rubber stopper and tubing, and a steel cannula. In the early 1970s, glass was replaced with an FDA approved bag made from PVC and DEHP.

Types of plasticizers used in PVC that replace DEHP

There are replacements to PVC and DEHP. The two main approaches are:

1. Use PVC but replace the DEHP with another plasticizer such as terephthalates, carboxylates, adipates, citrates, and trimellitates. DEHT/DOTP, DINCH, DOA, ATBC, TOTM, and polyester (polyadipate) are options. Substitute phthalate plasticizers, such as DINP, are also used.
2. Eliminate PVC and DEHP and replace it with a different polymer system such as polypropylene, polyethylene, or other types of plastics that do not require a plasticizer.

Analysis of drivers and barriers

Table Key:

✓ = Driver or enabler was a factor. **I** = Driver or enabler was an indirect factor

Factor column is blank = Driver or enabler was not a factor

Drivers	Factor	Key Developments
Brand culture & action		Typically, IV FDPs are not associated with a particular brand, but rather a medical device manufacturer. A patient (consumer) will not usually know who manufactures medical devices, and they will likely not have a choice in the type of IV device that is used. This is entirely up to the hospital. The assumption is that the equipment used in hospitals is safe and will not injure a patient. Therefore, this driver is not relevant.
NGO pressure	I	Health Care Without Harm (HCWH), a global NGO, started a campaign in the late 1990s targeting hazardous chemicals used in hospital settings, including IV FDPs made from PVC and DEHP. They met with manufacturers to identify alternatives and encouraged hospitals to switch due to the risk of DEHP, especially for certain populations, such as infants in the NICU. The campaign has reduced its pressure on hospitals to replace DEHP/PVC FDPs in recent years. However, HCWH continues to be a valuable resource for health care providers and has a section on their website about PVC and phthalates that shows potential health concerns. A list of alternatives is also provided, although the list may be out of date. Their communication specifically mentions "PVC IV bags and tubing". HCWH encourages hospitals to "take action to reduce PVC and DEHP" by enrolling in the Healthier Hospitals Initiative Safer Chemicals Challenge or joining Practice Greenhealth, and both initiatives encourage PVC elimination. The PVC medical products that HCWH suggests replacing are: *1. breast pumps and accessories, 2. enteral nutrition products, 3. enteral tubes, 4. general urological, 5. gloves, 6. parenteral infusion devices and sets, 7. respiratory therapy products, and 8. vascular catheters*.

Retailer action/Hospitals/GPOs	✓	This driver is not applicable to this product category. However, it could be assumed that a hospital can play the role of a retailer. In this case, many hospitals have taken action to find and use alternatives. Reducing hazardous chemicals in hospitals would be part of their company culture. By 2006, Dignity Health completed the phase-out of PVC and DEHP IV FDPs and replaced them with non-PVC alternatives manufactured by B. Braun. Dignity Health creates contractual obligations with manufacturers to avoid chemicals of concern and uses goals and metrics to measure progress and evaluate results. It is the 8th largest hospital provider in the U.S. In 2012, Kaiser Permanente agreed to the phase-out of PVC/DEHP IV medical equipment. In 2011, the company purchased 9.2 million bags.
Regulations/Other government action	**I**	Medical equipment, including IV FDPs, is FDA-regulated. Those made from PVC and DEHP are approved for use by the FDA, though the agency has raised concerns about chronic exposures to some vulnerable populations. In 2002, the FDA published a public health notification about the concern with DEHP released from PVC used in medical devices. This led to additional impetus and action by some hospitals such as Kaiser Permanente and Dignity health. Although medical device manufacturers developed alternatives, some such as Baxter continue to make PVC and DEHP IV FDPs. To add additional complexity, some IV FDPs may have parts made with a different material, while other parts may have continued to be made with plasticized PVC.
Consumer pressure	N/A	IV FDPs are not consumer-facing products and consumers (patients) do not have any input into the type of FDP that is used. Patients assume that medical devices are safe and may not be aware of the issues with PVC/DEHP.
Industry standards	N/A	
Green Stds & Certs	N/A	Vizient, a group purchasing organization, (GPO) has an environmentally preferable purchasing initiative (see fact sheet) on preferred sourcing of medical-surgical products and how to purchase them. This includes a section on PVC/DEHP and suggests auditing the facility to determine which purchased medical devices contain PVC/DEHP.
Circular economy	N/A	
Enablers/Barriers		**Key Issues**
Alternatives & Switching: • **Performance/ track record** • **Safety/availability of safety data** • **Cost** • **Scale** • **Multiple suppliers** • **Switching process, costs & time**	✓	**Performance/track record.** Alternatives to PVC and DEHP FDPs exist. B. Braun, Baxter Healthcare, Cryovac, and others make IV FDPs from polymers other than PVC, thus eliminating the need for DEHP. Other plasticizers including terephthalates, carboxylates, adipates, citrates, and trimellitates. DEHT/DOTP, DINCH, DOA, ATBC, TOTM, and polyester (polyadipate) are the primary alternatives to DEHP. Initial challenges with compatibility between the different sections of the IV FDP occurred but this was eventually resolved by all manufacturers. **Safety/availability of safety data.** By far the most safety data are available for DEHP. As such, some companies may believe that not enough data exists on different plasticizers to support a change. Companies assume that available alternatives have the necessary toxicity testing and FDA approvals because some have been on the market for over 30 years and some hospitals have already transitioned over to them. **Cost.** PVC and DEHP-free bags are more expensive to make than their PVC counterparts. Hospital purchasers are very cost-conscious and are reluctant to pay more. Therefore, the

		manufacturers have reduced their margins so that costs remain similar. As such, cost should not be a barrier to adoption. **Quantity/Scale/Multiple Suppliers.** If all PVC and/or DEHP devices were replaced today, there could be a capacity issue. Nonetheless, for one non-PVC/DEHP alternative, B. Braun has one facility in the U.S. and is building another that will double their capacity. However, this could be a few years away given the time it takes for FDA approval that is required for each facility that manufactures medical equipment. **Switching process, costs, & time.** For a manufacturer to switch to non-PVC materials, requires a significant financial investment and time commitment to establish manufacturing. However, at least two companies already produce PVC and DEHP-free IV FDPs, so this should not be a problem except for new capacity coming online.
Transparency		Manufacturers of IV FDPs fully disclose what chemicals are used.

Segments of this market where substitution has not yet occurred and why

For the U.S. market, based on analysis of the product codes in the GHX system, up to 70 % of IV FDPs still contain PVC and DEHP. Many alternatives exist and there is some knowledge about exposure concerns with PVC and DEHP in medical devices.

Why substitution has not occurred

Hospitals that have successfully switched to alternatives have done so in a methodical way by communicating the problem, involving clinical staff, testing alternatives, and educating internal purchasers.

Given that there are some cost-neutral, readily available alternatives[4], coupled with the HCWH initiative, it is hard to determine why the adoption rate is so low. The answer is likely multi-factoral. A few possible explanations include:

- There is a long history of IV FDPs made from PVC and DEHP with extensive data supporting their use. With the FDA approval and no restriction, there is little incentive to change.
- NGOs, including HCHW, are not placing the same pressure as previously on hospitals, manufacturers, and GPOs to substitute. While HCWH undertook an additional campaign targeted at parents with children in the NICU to demand safer alternatives, this approach was tricky given the sensitive nature of the children's health situation.
- Substitution in a hospital setting is not easy. The medical professionals using these devices may be comfortable with the status quo and reluctant to make a change, especially if the replacement is not quite as easy to use, works differently, or requires new training. Nurses, in particular, carry a lot of weight in purchasing decisions.

[4] Alternatives include: Non-DEHP PVC, Polypropylene/Polyethylene copolymer, Polypropylene/Polyethylene copolymer, polyester, elastomer laminate, Ethylene vinyl acetate, Polyolefin, Polypropylene, Multi-layer polyethylene, polypropylene

- There may be a lack of awareness by hospital purchasers that using PVC IV FDPs may be unsafe, resulting in little cost-incentive to switch.
- Non-PVC IV FDPs are not being offered as an alternative to hospital purchasing agents.
- Many assume the transition to safer alternatives is complete and the issue has been resolved.
- Existing "PVC-free" policies may not include IV FDPs, but rather focus on other medical devices that typically use PVC such as breast pumps or gloves.
- Hospitals may not want to scare patients by acknowledging the switch to safer IV FDPs.