Chapter 7. DEHP

Five Chemicals Alternatives Assessment Study

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7.1 Overview for DEHP

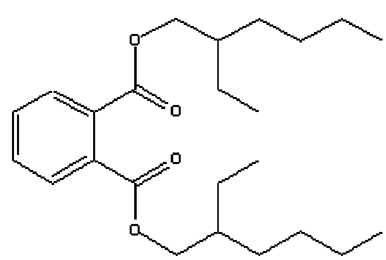
Plasticizers are additives to otherwise rigid plastics that impart the flexibility required for certain applications. Phthalates are a class of plasticizers that are commonly used in a variety of applications, from consumer products to medical devices to industrial equipment. They are organic chemicals produced from petroleum and are the most commonly used plasticizers in the world. Over 90% of the phthalates produced are used specifically for their plasticizing function, giving plastics, primarily polyvinyl chloride (PVC), strength, flexibility and durability. The purity requirements for commercial plasticizers are very high; phthalate esters are usually colorless and are mostly odorless. Although the various kinds of plasticizers in use today have some structural similarity, each one is different in the way it performs.

Phthalates are products of simple esterification reactions, which can be carried out readily in heated kettles with agitation and provision for water take-off. While some manufacturing facilities produce plasticizers by such batch methods, newer, highly automated plants operate continuously, particularly if they emphasize a single product. Esterification catalysts speed the reaction and are neutralized, washed and then removed. The reaction usually requires an excess of alcohol, which is readily recycled. Analogous syntheses yield aliphatic dicarboxylic acid esters, benzoates and trimellitates (Stanley 2006).

Di (2-ethylhexyl) phthalate (DEHP) is the international standard PVC plasticizer and properties of other plasticizers are usually reported relative to those of DEHP. As a plasticizer for PVC, DEHP generally offers excellent compatibility, desirable fusion properties and a set of performance properties that, for many uses, require little modification with other types of plasticizers.

The chemical structure of DEHP *(*$C_{24}H_{38}O_4$*)* is illustrated in Figure 7.1A:

Figure 7.1 A: Chemical Structure of DEHP



DEHP (CAS No 117-81-7) is also known as di-octyl phthalate (DOP) or bis (sec) ethylhexyl phthalate. It is the most commonly used phthalate plasticizer with an estimated annual production in Western Europe of 500,000 metric tons per year (Greens 2004) and an estimated global annual production of between 1 and 4 million metric tons per year (Swedish Chemicals Inspectorate (KemI) 2003). The U.S. production of DEHP was 120,000 metric tons in 2002. This represented 18% of the total U.S. consumption of phthalate plasticizers (Bizzari et al. 2003).

7.1.1 Characteristics

DEHP is a colorless liquid with almost no odor. It represents one of the most versatile and widely used plasticizers in industrial applications primarily because of its overall performance characteristics and its wide range of appropriate properties for a great many cost-effective, general purpose products (Phthalates Information Centre Europe 2005).

Table 7.1 A: Chemical/Physical Characteristics of DEHP (USEPA 2005)	
Melting/Boiling Point	-50°C / 230 °C
Vapor Pressure	1.32 mm Hg at 200 °C (1.4×10^{-6} mm Hg at 25°C)
Octanol/Water Partition Coefficient	Log Kow = 4.89
Specific Gravity	0.99 at 20 °C
Solubility[15]	0.285 mg/L at 24 °C (slightly soluble in water)
Soil Sorption Coefficient	Log Koc = 4 to 5; low mobility in soil
Bioconcentration Factor	Log BCF = 2 to 4 in fish and invertebrates, Log BCF = 2.93 in fathead minnows; expected to bioconcentrate in aquatic organisms
Henry's Law Coefficient	1×10^{-4} atm-m^3/mole
Biodegradation	Half-Life in water = 2 to 3 weeks

7.1.2 Health and Environmental Impacts

Summary

DEHP is present in many products that require the use of flexible plastics. With a relatively low vapor pressure and water solubility, the amount of DEHP in plastic products that will be released is fairly low relative to the amount in products. The amount released is affected by the medium it is in. In non-aqueous environments (*e.g.,* fats) more DEHP will be released. Many studies indicate that the human body burden of DEHP has been increasing over the decades as flexible plastics find new uses. In addition, more recent studies that look at the presence of metabolites of DEHP excreted by humans provide supporting evidence that DEHP exposure to humans is in fact occurring. The following sections detail some of the more recent knowledge and generally accepted understanding of the health and environmental effects of exposure to DEHP.

Human Health Effects

Based on our current scientific knowledge, human exposure to DEHP during manufacture or consumer use occurs primarily through inhalation and oral exposure. There has been only limited study of dermal exposure to DEHP, but it is thought to be an insignificant mechanism for adverse human health effects. This is due to low absorption rate and limited human exposures through dermal contact. Exposure may also occur during medical fluid injection if DEHP leaches into the medical fluids as a result of direct contact with the DEHP-plasticized PVC materials used in some medical devices. When these fluids have high lipid content the likelihood of DEHP leaching into the fluids increases.

[15] Other sources estimate water solubility as 0.00249 mg/L at 25°C (Staples 2003), which is several orders of magnitude lower than what is reported by EPA.

Information on the oral toxicity of DEHP in humans is limited to gastrointestinal symptoms (mild abdominal pain and diarrhea) based on the evidence of two individuals who ingested a single large dose of the compound (Agency for Toxic Substances and Disease Registry (ATSDR) 2002). Because of the dearth of scientific studies that have been conducted on humans, only limited information is available relative to the health effects of DEHP in humans following inhalation or dermal exposure, although recent studies are exploring the potential for effects (*e.g.,* asthma) associated with inhalation of dusts containing DEHP (Børnehag et al. 2004).

When DEHP enters the human body, the compound is rapidly metabolized into various substances that are more readily excreted. The first of these metabolites to be created is mono-ethylhexyl phthalate (MEHP), which is thought to be responsible for much of DEHP's toxicity. MEHP is primarily formed by the hydrolysis of DEHP in the gastrointestinal (GI) tract and then absorbed (Centers for Disease Control and Prevention (CDC) 2005). The enzymes (lipases and esterases) that break down DEHP into MEHP are found mainly in the GI tract, but also occur in the liver, kidney, lungs, pancreas, and plasma.

MEHP is subsequently further metabolized by different oxidation reactions, creating a number of other metabolites, the most significant of which include (Koch et al. 2006):

- 2-ethyl-5-hydroxyhexyl phthalate (5OH-MEHP)
- 2-ethyl-5-oxy-hexylphthalate (5oxo-MEHP),
- 2-ethyl-5-carboxy pentylphthalate (5cx-MEPP), and
- (2-(carboxymethyl)-hexyl) phthalate (2cx-MMHP).

These secondary metabolites of DEHP represent the majority of DEHP metabolites (approximately 70%) excreted in urine versus MEHP, which is present in urine at approximately 6% of the total amount excreted (Koch et al. 2006). 5OH-MEHP and 5oxo-MEHP are produced by the oxidative metabolism of MEHP and are present at roughly three-to ten-fold higher concentrations than MEHP in urine (Koch et al. 2003). Because the majority of conversion of DEHP to MEHP occurs in the GI tract, exposures to DEHP by ingestion may be more hazardous than by intravenous exposure, which largely bypasses the GI tract. The primary purpose of studying these secondary metabolites is that the long half-times of elimination of the carboxy metabolites (5cx-MEPP and 2cx-MMHP) make them appropriate parameters for measuring time-weighted body burden of DEHP, while 5OH-MEHP and 5oxo-MEHP appear to more accurately reflect short-term human exposure to DEHP (Koch et al. 2006). However much less is known about the potential human effects of exposure to these secondary metabolites.

The initial metabolism of DEHP to MEHP is qualitatively similar among mammalian species, so that animal studies are likely to be useful in understanding the consequences of human exposure. The similarity of secondary metabolite creation among non-human species is less well known. There are a number of animal studies that have been conducted over the past several decades looking at potential health effects associated with exposure to DEHP. The primary studies have involved rodents (rats and mice) while more recently studies have been conducted on primates (such as marmosets and cynomolgus monkeys) and pigs. Studies of rats represent the most prevalent source of information on potential health effects associated with varying doses and exposure routes. Studies of primates focused on common marmosets (Kurata et al. 1998) and cynomolgus monkeys (Pugh et al. 2000).

Cancer Risk

DEHP is currently classified by the USEPA as a Class B2 carcinogen. This determination is based entirely on liver cancer in rats and mice. In 2000 IARC changed its classification for DEHP from "possibly carcinogenic to humans" to a Class 3 carcinogen "cannot be classified as to its carcinogenicity to humans," because of the differences in how the livers of humans and primates respond to DEHP as compared with the livers of rats and mice (ATSDR 2002).

Reproductive/Developmental Effects

No studies are currently available that directly indicate reproductive effects in humans after oral exposures of humans to DEHP, but many animal studies of this potential have been conducted. Studies in rodents exposed to doses in excess of 100 mg/kg/day DEHP clearly indicate that the testes are a primary target organ, resulting in decreased testicular weights and tubular atrophy. Weights of the seminal vesicles, epididymis, and prostate gland in rats and mice are also reduced by oral exposure to DEHP (Gray and Butterworth1980; Lamb et al. 1987).

Studies suggest that nonhuman primates are less sensitive than rodents to the effects of DEHP on the degree and permanence of testicular damage (Kurata et al. 1998). Evidence suggests that MEHP might be the toxic metabolite in the testes. A review of various studies indicates that MEHP generally produces developmental, reproductive and hepatic toxicity in laboratory animals (ATSDR 2002). In one study, 1,055 mg/kg/day of DEHP administered for 5 days to rats did not affect testicular weight or structure, but an equimolar dose of MEHP had a significant effect (Sjoberg et al. 1986).

Based on current studies, and in accordance with the conclusions drawn by the NTP (ATSDR 2002), the developing organism is more sensitive to exposure to DEHP than the juvenile or adult organism. The age at first exposure to DEHP appears to have a clear influence on the degree and permanence of testicular damage (Gray and Butterworth 1980). Based on the multiple studies evaluated by the CERHR panel as part of its review of the reproductive toxicity of DEHP, they have determined that exposure of neonates to DEHP is a "serious concern" (National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) 2005).

While there was insufficient human data to directly demonstrate reproductive effects in human, the Panel concluded that animal data suggest there is sufficient evidence that DEHP causes reproductive toxicity in female rats (decreased numbers of corpora lutea and growing follicles), in female marmosets (increased ovary weight and uterine weight) and in male rats for exposures that included gestational and/or peripubertal periods (NTP-CERHR 2005). The recent update of the NTP study of the toxicological effects of DEHP indicates that DEHP is considered to be of serious concern when critically ill infants are exposed to products containing this chemical (NTP-CERHR 2005). In particular, the NTP Panel has serious concern that intensively medically treated male infants may experience adverse affects on their reproductive tract development and function.

As a result of its review of associated studies, the NTP has determined a LOAEL for exposure to DEHP of 38 – 144 mg/kg bw/day and a NOAEL for males of 3.7 mg/kg bw/day (*NTP 2005*).

Exposure Routes

The ATSDR has determined that because DEHP's effects are exerted in animals in a dose-related manner and exhibit threshold responses, and because concentrations of DEHP in the environment are expected to be well below the established effect thresholds, DEHP is not expected to pose a serious public health concern for the vast majority of the population (ATSDR 2002). It is important to note that this opinion was offered prior to the availability of pertinent studies of the potential for exposure to DEHP in dust found in indoor environments. Specifically, studies have identified a somewhat elevated presence of DEHP in household dusts in homes with DEHP/PVC surfaces such as flooring and wall coverings (Børnehag et al. 2005). While this and related studies are preliminary and do not clearly indicate associated health effects, they do suggest that the general public may be exposed to DEHP in indoor environments.

Because DEHP has a very low vapor pressure, little is found in air. DEHP molecules that are present in air will adsorb onto dust particles and will be deposited on surfaces through gravity, rain or snow. Indoor releases of DEHP to the air from plastic materials, coatings, and flooring in home and work environments, although small, can lead to higher indoor levels than are found in the outdoor air (Børnehag et al. 2005).

In its evaluation of the potential for reproductive toxic effects, the CERHR determined that there is some cause for concern relative to exposure of DEHP by the general population of infants and toddlers, and serious concern for neonates undergoing intensive medical treatment (NTP-CERHR 2005). The variation in level of concern is most closely related to the potential for exposure of sub-populations to have different weight-related doses due to body size and duration of exposure.

One of the primary routes of exposure to the general population is associated with the use of DEHP in flexible PVC medical devices. Parenteral[16] medical exposure to DEHP of critically ill infants has been shown to exceed general population exposures by several orders of magnitude. Numerous studies have been conducted to determine or estimate the exposure level of neonates and infants to DEHP due to various medical procedures. Figure 7.1B presents a compilation of human exposure data associated with a variety of common medical procedures, as presented in the report entitled "Preventing Harm from Phthalates, Avoiding PVC in Hospitals" (Ruzickova et al. 2004). In it, the mean and range of exposure levels of DEHP measured in various studies are summarized based on specific medical procedures. Based on these data, one of the primary potential sources of exposure on a body weight basis is extracorporeal membrane oxygenation[17] (ECMO) in infants.

[16] Procedures where medical fluids are taken into the body in a way other than the digestive tract, usually subcutaneously or intravenously

[17] ECMO is used in infants who are extremely ill due to breathing or heart problems. The purpose of ECMO is to provide adequate oxygen to the baby while allowing time for the lungs and heart to "rest" or heal.

Potential Exposures to DEHP from Medical Procedures and Nutrition

Source of DEHP Exposure	Exposure (mg DEHP/kg body weight)	Unit	Total Exposure or Concentration in Product	Source
Artificial ventilation in preterm infants (PVC respiratory tubing; not polyethylene)	NR	Hour (inhalation)	0.001-4.2 mg (estimated exposure)	Roth et al., 1988 [42]
Neonatal blood replacement transfusion; short-term, acute	0.3 (0.14-0.72)	treatment period	NR	Sjoberg, et al. 1985a [43]
Neonatal blood replacement transfusion; double volume; short term, acute	1.8 (0.84-3.3)	treatment period	NR	Sjoberg, et al. 1985a [44]
Platelet concentrates in newborns	1.9	treatment	NR	Huber et al., 1996 [45]
Enteral feeding	0.035	day	0.14 mg/kg (estimated exposure for 4 kg neonate)	US FDA, 2001 [46]
Extracorporeal membrane oxygenation (ECMO) in infants	42-140	treatment	NR	Schneider et al., 1989 [47]
ECMO in infants	4.7-34.9	Treatment	NR	Karle et al, 1997 [48]
Congenital heart repair (neonates)		1-4 hours	0.3-4.7 µg/mL/hr (change in level in whole blood during procedure)	Barry et al., 1989 [49]
IV glucose solution	0.005 (maximum)	one liter of solution	NR	Roksvaag et al., 1990 [50]
Total parenteral nutritional formula (TPN)	NR	NR	3.1 µg/mL (concentration in TPN formula)	Mazur et al., 1989 [51]
TPN/IV Tubing	5	day	10 mg/2-kg baby/day	Loff et al., 2000 [52]
Multiple IV Sources: packed red blood cells, platelet rich plasma, fresh frozen plasma, and medications	5	day	10 mg/2-kg baby/day	Loff et al., 2000 [53]
Breast milk	0.0015-0.0165	Day	0.01-0.11 mg/kg (concentration in breast milk)	Pfordt and Bruns-Weller, 1999 [54]
Infant formula	0.015	Day	0.004-0.06 mg/kg wet weight	Petersen and Breindahl, 2000 [55]
Infant formula	0.0087-0.035	NR	0.33-0.98 mg/kg dry weight	MAFF, 1998 [56]

NR = Not Reported

Figure 7.1 B: Compilation of Various Peer-Reviewed Scientific Data Sources from the report "Preventing Harm from Phthalates, Avoiding PVC in Hospitals" June 2004 (Ruzickova et al. 2004)

In its 2002 report entitled "EAP on DEHP in Medical Devices MDB Report: An Exposure and Toxicity Assessment" (Health Canada 2002), the Medical Devices Bureau of Health Canada concluded that exposures of infants to DEHP occur as follows:

1. Infants undergoing routine replacement blood transfusions may be exposed to doses of DEHP 1-2 orders of magnitude above general population exposures. Infants undergoing intensive therapies may be exposed to levels up to 3 orders of magnitude above general exposures.
2. Infants receiving double volume exchange transfusion, which is the short-term procedure reported to give the highest acute exposure – up to 23 mg/kg body weight/day.
3. ECMO for infants, which is the sub-acute medical treatment that results in one of the highest daily DEHP exposures per kg body weight and the highest daily exposure over a prolonged period of time – up to 14 mg/kg/day during the 3 to 30-day treatment period.

Other medical procedures that result in very high exposures relative to the general population exposure include cardiac bypass procedures, total parenteral nutrition therapy, infusion of lipophilic drugs using PVC bags and tubing (which is contraindicated in the directions for use), and possibly, respiratory therapy.

Environmental Hazards

DEHP is not chemically bound to the PVC polymer matrix and can therefore be released throughout the lifecycle of polymer products. Release of DEHP to the environment potentially occurs not only during the production, distribution and incorporation into PVC but also when the PVC material is heated or comes into contact with certain media. Consequently, DEHP may be lost from the finished products during their use or disposal. In general this is a relatively slow process as indicated by common flexible PVC products' (*e.g.,* vinyl flooring) ability to maintain flexibility.

The half-lives of DEHP and of phthalates in general in the environment are relatively short. Phthalates typically spend hours in the atmosphere and months in soil. However, phthalates adsorbed to soil and sediments can persist in the environment for years. Although DEHP has a low bioconcentration factor, it will preferentially bioconcentrate in aquatic organisms rather than remain in water due to its low water solubility. However, DEHP does not significantly bioaccumulate in the food chain, nor is it expected to bioconcentrate in terrestrial organisms.

DEHP has a strong tendency to adsorb to soil and sediments. Experimental evidence demonstrates strong partitioning to clays and sediments (USEPA 2005). DEHP released to water systems will biodegrade fairly rapidly, exhibiting a half-life of 2 to 3 weeks.

DEHP enters the environment through releases from manufacturing facilities that make or use DEHP and from consumer products that contain it. Over long periods of time, it can also migrate out of plastic materials and into the environment. Therefore, DEHP is widespread in the environment; about 291,000 pounds were released in 1997 from industries (USEPA 2005). According to EPA, it is often found near industrial settings, landfills, and waste disposal sites. Based on the TRI report, a large amount of plastic containing DEHP is buried at landfill sites (USEPA 2005). When DEHP is released to soil, it usually attaches strongly to the soil and does not move very far away from where it was released. DEHP has also been found in groundwater near waste disposal facilities (USEPA 2005). When DEHP is released to water, it dissolves very slowly into underground water or surface waters that contact it.

DEHP can break down in the presence of other chemicals to produce MEHP and 2-ethylhexanol. Many of the properties of MEHP are like those of DEHP, and therefore its fate in the environment is similar. In the presence of oxygen, DEHP in water and soil can be broken down by microorganisms to carbon dioxide and other simple chemicals. DEHP does not break down very easily when deep in the soil or at the bottom of lakes or rivers where there is little oxygen.

7.1.3 Use and Functionality

As a plasticizer, the primary function of DEHP used in products is to soften otherwise rigid plastics and polymers, such as PVC. Most industry analysts agree that an estimated 90% of DEHP is used as a plasticizer for PVC. DEHP exhibits good gelation, plasticizing efficiency and adequate viscosity properties in PVC emulsions making it ideal for most plasticized PVC applications (Ecobilan 2001).

As a result of DEHP's plasticizing performance as well as its reasonable cost, DEHP is found in a wide variety of products in every day use. DEHP not only softens the PVC but enhances the color-fast, durable, low-maintenance qualities that make PVC desirable and useful in building materials, autos, toys, and medical devices. Table 7.1B presents a summary of information on the various uses of DEHP. Information about amounts used in products in the EU (and assumed to apply to the US) or manufactured in Massachusetts is provided when available.

Table 7.1 B: Survey of Uses of DEHP

Major Use Category	Uses/Applications	Used in Product in EU **	Used in Mfg in MA (lb/y)	Important Considerations
Polymer Uses	**Consumer Products**			
	Toys	(US producers generally no longer use DEHP)		Permanently banned in EU; Potentially vulnerable population exposed
	Sheet/Film (e.g. food contact)	15% of total use (for all sheet materials)	180,600 (otherwise used) 734,000 (incorporated into product)	FDA approved for applications not touching food.
	Vinyl Shower Curtain			Large consumer usage; ubiquitous
	Vinyl Wall Covering			Large consumer usage; ubiquitous
	Car Undercoating	1% of total use		Alternatives available
	Footwear	8% of total use		Alternatives available
	Upholstery			High consumer exposure potential; large usage; ubiquitous
	Medical Devices (approximately 25% of total US consumption of DEHP) (Bizzari et al. 2002)			
	Plastic sheet materials (e.g. bags)	15% of total use (figure for all sheet materials, not just medical devices)	566,300 (typically 20-40% DEHP)	High usage; Potentially vulnerable population exposed; Many alternatives possible
	Tubing (e.g. IV tubing)		minimal	High usage; Potentially vulnerable population exposed; Many alternatives possible
	Industrial/Commercial Uses (approx 45% of total US consumption of DEHP (Bizzari et al. 2002)			
	Resilient flooring (also residential uses)	15% of total use	1,049,500	Used in MA; High occupational exposure potential
	Roofing			
	Aluminum Foil Coating/ laminating			Alternatives available
	Paper Coating			Alternatives available
	Extrudable PVC Molds/Profiles	1% of total use	649,000	Used in MA
	Electronic Component Parts		58,600	Used in MA

Table 7.1 B: Survey of Uses of DEHP

Major Use Category	Uses/Applications	Used in Product in EU **	Used in Mfg in MA (lb/y)	Important Considerations
	Wire/Cable Coating/Jacketing	15% of total use	21,200 (manufactured) 70,000 (incorporated into product)	Used in MA
Non-Polymer Uses	Lighting Ballasts & Electric Capacitors			Minimal use
	Vacuum Pump Oil			Minimal use
	Perfumes/Cosmetics			Other phthalates used preferentially in this industry
	Pesticides			Little information on use
	Printing Inks (e.g. lithographic)	<1% of total use		Potential consumer exposure to printed films
	Paints & lacquers	<1% of total use		Potential occupational and environmental exposure
	Adhesives & Coatings	2% of total use	13,500	Used in MA; Potential occupational and environmental exposure
	Ceramics	<<1% of total use		Limited information on use

*** Based on 2003 KemI study of EU uses of DEHP in 1997 – assumed to apply in the US (KemI 2003).*
Note: if a cell is blank this indicates that no data is available

7.2 DEHP Use Prioritization

Chemical Uses

The uses of DEHP in Massachusetts manufacturing are presented based on the 2003 TURA data (Toxics Use Reduction Institute (TURI) 2003). Over 3.5 million pounds of DEHP were used in Massachusetts in 2003. Further details are outlined in Table 7.2A below:

Table 7.2 A: Total DEHP Use in Massachusetts in 2003

CAS	Chemical Name	TOTAL USE (lbs)	Generated as a Byproduct (lbs)	Shipped in/as Product (lbs)	Total Emissions
117-81-7	DEHP	**3,593,614**	320,631	3,260,296	3,300

Thirteen companies reported DEHP use in 2003 (TURI 2003). These include companies manufacturing various flexible PVC products such as flooring, molded products and medical devices, plastic compounders and chemical distributors. The company reporting the highest use of DEHP makes rubber and plastic commercial and industrial flooring products.

Uses in Products

TURI developed a list of products and/or applications where DEHP is used utilizing sources from both the EU and the US. Table 7.1B outlines the major known uses and applications of DEHP in products today. As shown, the primary products using DEHP for its plasticizer functionality include:

- Adhesives and coatings;
- Extrudable PVC molds and profiles (*e.g.,* bumpers for marine applications);

- Food packaging applications;
- Footwear (in soles and in PVC design appliqués);
- Medical devices (in a variety of bags and tubing devices);
- Resilient PVC-based flooring materials;
- Toys;
- Vinyl wall coverings (as part of the PVC emulsion used to provide water resistance); and
- Wire and cable coating and jacketing compounds.

In order to identify the priority uses of DEHP, a more comprehensive list of uses was presented to Massachusetts stakeholders, for their input (see Appendix B for this list of uses associated with DEHP). Stakeholders discussed the routes of DEHP exposure including oral exposure (*e.g.,* mouthing toys, film covering foods), inhalation (*e.g.,* off-gassing), dermal exposure, exposure from DEHP in dust, injection after leaching of DEHP into medical bag devices, etc.

Priority Uses

Table 7.2B summarizes the major uses of DEHP which were discussed with the stakeholders and their general comments.

Table 7.2 B: DEHP Uses and Stakeholder Discussion

Uses/Applications	Stakeholder Discussion
Consumer Products	
Toys	Permanently banned in EU; Potentially vulnerable population exposed; DEHP not currently used in toys in the US because of consumer relations; concern with imported products
Sheet/Film (e.g. food packaging)	FDA limits use of DEHP in packaging that touches food
Vinyl Shower Curtain	Not recommended for study because other applications with similar manufacturing process will be evaluated
Vinyl Wall Covering	High consumer exposure potential; large usage; ubiquitous
Car Undercoating	Alternatives available
Footwear	Alternatives available; further research to determine manufacturing in MA and US and potential consumer exposure.
Upholstery	High consumer exposure potential; large usage; ubiquitous
Medical Devices	
Plastic sheet materials (e.g. bags)	High usage; potentially vulnerable population exposed; many alternatives possible; Serious health issue; High concern to many stakeholders
Tubing (e.g. IV tubing)	High usage; potentially vulnerable population exposed; many alternatives possible; serious health issue; High concern to many stakeholders
Industrial/Commercial Uses	
Resilient flooring (also residential use)	Used in MA; high occupational exposure potential; alternatives available on the market
Roofing	Most roofers do not want or use products containing DEHP; alternatives available (stakeholder discussion 10/21)
Aluminum Foil Coating/ Laminating	Alternatives available
Paper Coating	Alternatives available
Extrudable PVC Molds/Profiles	Used in MA; 1% of total DEHP use; not identified as priority
Electronic Component Parts	Used in MA; less than 1% of total DEHP use; not identified as priority
Wire/Cable Coating Compounds	Used in MA; DEHP has been greatly reduced in MA due to use of alternative plasticizers

Table 7.2 B: DEHP Uses and Stakeholder Discussion

Uses/Applications	Stakeholder Discussion
Others: Lighting Ballasts and Electric Capacitors; Vacuum Pump Oil; Perfumes/Cosmetics; Pesticides; Printing Inks (e.g. lithographic); Paints and lacquers; Adhesives and Coatings; Ceramics	Very small amount of DEHP used in each of these products – not identified by stakeholders as applications of concern.

The priority uses of DEHP were selected based on predetermined criteria (refer to Appendix A) including:

- Quantity of DEHP in products and manufacturing in Massachusetts;
- Potential environmental and occupational exposure; and
- Availability of viable alternatives.

According to the criteria, the major DEHP uses that warranted further research in our alternatives assessment included:

Table 7.2 C: DEHP Preliminary List of Priority Uses

Use	Criteria Applied to Determine as Priority
Medical Sheet/Bag Devices in Neonatal Care	Potential public exposure; Many device manufacturers in Massachusetts; Many alternatives available
Medical Tubing Devices in Neonatal Care	Potential public exposure; Many device manufacturers in Massachusetts; Many alternatives available
Resilient Flooring	Largest DEHP manufacturer in Massachusetts; Potential occupational and public exposure; Many alternatives available
Footwear	Potential occupational and public exposure; Many alternatives available
Vinyl Wall Coverings	Potential occupational and public exposure; Many alternatives available

The Institute originally identified footwear as a priority industry for analyzing alternatives to DEHP. However, after further investigating DEHP use among Massachusetts footwear manufacturers, the Institute did not find any firms using DEHP in footwear. The one Massachusetts firm that manufactures footwear in the Commonwealth, New Balance, was contacted to discuss its use of DEHP. According to New Balance representatives, they phased DEHP out of their products several years ago. Several other footwear companies, including Timberland, Nike, and Adidas, have eliminated DEHP from products. Although there is likely some footwear imported into the Commonwealth containing DEHP, the Institute decided to focus its alternative analysis resources on vinyl wall coverings as the more pertinent consumer product use of DEHP.

This list of priority uses does not include two products that are of particular interest to certain stakeholders – toys and wire and cable coating compounds. Toys were not included because further research showed that DEHP has been eliminated from toys manufactured in the US in almost all applications. One of our stakeholders commented, "The global market is moving away from phthalates in toys." In addition, our conversations with toy manufacturers and their suppliers of plasticizers indicate that the US market has voluntarily moved away from the use of DEHP in response to the 1999 EU temporary ban on phthalates that was made permanent in 2004 (EU Marketing and Use Directive 76/769/EEC as amended) for certain phthalates present at greater than 0.1% for all toys and childcare articles. The Toy Manufactures of America (TMA) have stated that most manufactures of pacifier and toys have discontinued the use of the DEHP and DINP in their products (Hileman 2005).

The TMA set DEHP standards to less than 3% in pacifiers and teethers. This was done as part of an agreement with the U.S. Consumer Product Safety Commission (CSPC) in 1986. The CPSC stated that the projected cancer risk associated with exposure to DEHP has declined greatly after the phase of out of the chemical in pacifiers. However there is currently no federal US regulation restricting the use of DEHP in toys. Stakeholders expressed concern about imported products still containing DEHP. However, overall stakeholders saw little benefit from including this application in the alternatives assessment.

Wire and cable coating compounds were also not included because further research with local companies as well as the stakeholders indicates that DEHP use in wire and cable has already been greatly reduced in Massachusetts. This reduction is largely due to the availability of a number of viable alternatives The alternatives are also being simultaneously assessed by an EPA sponsored Design for the Environment project, which is performing a life cycle assessment of alternative constructions for three wire and cable applications[18].

Further research on the major DEHP uses was completed, presented and discussed at the third meeting with stakeholders. Additional feedback from the stakeholders was requested in order to identify the applications of DEHP to be examined for alternative applications. The final list of priority uses selected for further study is:

- Resilient Flooring
- Medical Devices (including sheet and tubing uses, with a specific focus on the use of these devices in neonatal care)
- Vinyl Wall Coverings

7.3 DEHP Alternatives Identification and Prioritization

For the priority uses that have been selected, DEHP is used for its functionality as a plasticizer. Therefore, when considering alternatives to DEHP there are two distinct strategies that can be employed:

1. Substitute an alternative plasticizer; or
2. Substitute an alternative material or technology that does not require the use of a plasticizer.

These alternatives are referred to herein as plasticizer and material alternatives. Technological alternatives will be addressed on a use-specific basis as appropriate. As described within the methodology for this project (Appendix A), factors leading to determining priority alternatives include:

- Performance criteria;
- Availability of alternatives;
- Manufacturing location;
- Environmental, health and safety considerations;
- Cost;

[18] Go to http://www.epa.gov/dfe/pubs/projects/wire-cable/index.htm for information on this program.

- Global market effects; and
- Other issues pertinent to that particular use.

These factors are not necessarily weighted the same for each use. The Institute determined which factors present the most significant role in determining preferred alternative plasticizers and materials. For material alternatives the Institute has also taken into account significant life cycle considerations when determining priority alternatives. Technological alternatives often require a more in depth life cycle assessment to evaluate how the alternative compares to the original technology. Therefore, unless existing life cycle assessments are available for technological alternatives (*e.g.,* painting rather than covering walls with a material), the Institute did not focus its efforts on these alternatives to uses of DEHP.

7.3.1 Alternatives Associated with Resilient Flooring

Available Alternatives

This study focuses on alternatives to DEHP/PVC residential resilient flooring. Resilient flooring is defined as tile and sheet materials which have the ability to return to their original form after compacting (Vinyl by Design (VBD) 2006). When considering alternatives to DEHP in resilient flooring the comparison must include different materials as well as different plasticizers. Based on our evaluation, no specific technological alternatives are associated with this use.

Plasticizer alternatives in resilient flooring that were identified from stakeholder conversations, discussions with industry experts and literature research include:

- DINP (di isononyl phthalate)
- DIDP (di isodecyl phthalate)
- DEHT (di(2-ethylhexyl)terephthalate)
- BBP (butyl benzyl phthalate)
- DGD (dipropylene glycol dibenzoate)
- DEGDB (diethylene glycol dibenzoate)
- DEHA (di(ethylhexyl) adipate)
- DEHPA (di(2-ethylhexyl) phosphate)
- DHP (di isohexyl phthalate)
- BOP (butyl, 2-ethylhexyl phthalate)
- DBP (dibutyl phthalate)
- TCP (tricresyl phosphate)
- TEGDB (triethylene glycol dibenzoate)
- ATBC (o-acetyl tributyl citrate)
- DBS (dibutyl sebacate)
- DIHP (di (isoheptyl)phthalate)
- 97A (hexanadedioic acid, di-C7-9-branched and linear alkyl esters)
- TXIB (butane ester 2,2,4-trimethyl 1,3-pentanediol di isobutyrate

Material alternatives were also considered as replacements for the DEHP/PVC blend used as resilient flooring in residential, industrial and commercial settings. The following list, developed based on literature and market research and discussions with industry experts, presents the material alternatives that were considered at this stage of the process:

- Bamboo
- Natural Linoleum
- Cork
- Polyolefin
- Polyethylene/limestone blend
- Rubber
- Concrete
- Terrazo
- Concrete and recycled glass blend
- Wood

Alternatives Screened Out for Resilient Flooring

The methodology for screening potential alternatives presented in Section 2 (and is presented in more detail in Appendix A) was applied to the plasticizer alternatives. Table C5 (in Appendix C) presents the information used to determine if any of the plasticizer alternatives had to be screened out based on being carcinogenic, on the list of more hazardous substances or a PBT. It is important to note on Table C5 that in several instances no data were available for one of the criteria for a specific alternative. In this case, the chemical was not eliminated from further study.

Based on this analysis, the following chemicals were screened out for further analysis:

- DIHP (di (isoheptyl) phthalate) - Failed due to sediment persistence and aquatic toxicity
- 97A (hexanadedioic acid, di-C7-9-branched and linear alkyl esters) – Failed due to sediment persistence and aquatic toxicity
- TXIB (butane ester 2,2,4-trimethyl 1,3-pentanediol di isobutyrate) – Failed due to sediment persistence and aquatic toxicity (also exhibits high bioaccumulation, though it does not exceed the screening level)

Several material alternatives were eliminated from further evaluation because they did not meet the resiliency criterion (*i.e.,* able to return to their original form after compacting) associated with this specific use category. Those materials include:

- Concrete
- Terrazo
- Concrete and recycled glass blend
- Wood
- Bamboo

Materials were not screened out from further evaluation because of other performance, environmental and human health, or economic considerations.

Priority Alternatives for Resilient Flooring

Based on our initial review of available alternatives it was apparent that there were a large number and variety of potential plasticizer alternatives available for resilient flooring. Therefore, in order to arrive at a manageable number of alternatives to assess fully, the Institute conducted a tiered approach to determining the priority alternatives.

Plasticizer Alternatives for Resilient Flooring

As part of the initial screening effort to determine alternatives to eliminate, several plasticizer alternatives were identified as having persistence, bioaccumulative or toxic values that exceeded the screening criteria (indicated as red on Table C5, Appendix C), with one of the other PBT criteria approaching a level of concern (indicated as orange on Table C5, Appendix C). Hence they were not screened out as PBTs, but have been flagged as being of concern because they approach the associated PBT screening levels.

These "P, B or T" alternatives include:

- DHP (di isohexyl phthalate)
- BOP (butyl, 2-ethylhexyl phthalate)
- DBP (dibutyl phthalate)

- BBP (butylbenzyl phthalate)
- TCP (tricresyl phosphate)
- DEGDB (diethylene glycol dibenzoate)
- TEGDB (triethylene glycol dibenzoate)
- ATBC (o-acetyl tributyl citrate)
- DBS (dibutyl sebacate)

Because there are numerous plasticizer alternatives available for this use that did not approach levels of concern, none of these alternatives were evaluated further.

Institute staff met with a resilient flooring manufacturer in Massachusetts to tour their production facility and discuss the manufacturing process and the use of DEHP in its products. The manufacturer's representative did indicate that alternative phthalates would potentially be appropriate alternatives to DEHP from a technical standpoint, but added that this would mean certain financial impacts associated with raw material costs and required process modifications. He further indicated that in today's very competitive market, economic factors become primary operating considerations in this industry sector when choosing materials.

Several parameters were evaluated when determining which alternative plasticizers would be prioritized for further assessment. Specific performance considerations included the substance's compatibility with PVC. According to industry experts, the volatility of the plasticizer should not be higher than that of DEHP to assure similar processability. Adoption of alternative plasticizers that approach the technical and economic profile of DEHP/PVC would likely be more attractive to industry for adoption.

According to plasticizer and flooring manufacturers, plasticizer cost is the most important consideration when designing and marketing a product. The flooring market is so competitive today that increasing the cost of a product by a few cents could determine whether a product sells.

Table 7.3.1 A summarizes the considerations that the Institute used in determining if a plasticizer alternative would be eliminated from further evaluation.

Table 7.3.1 A: Considerations for Resilient Flooring Alternative Plasticizers

Environmental	Processability	Cost
Plasticizer alternative should not exceed any levels of concern for environmental screening criteria	Plasticizer alternative should not be significantly more difficult to process than DEHP	Plasticizer alternative should be no more than 10% greater than DEHP on a processed per pound basis

Table 7.3.1 B summarizes the cost, performance and environmental prioritization considerations for plasticizers that were factored into determining the alternatives to assess. Particular attention was paid to an alternative's ability to approach the technical and economic profile of DEHP.

Based on the considerations evaluated on Table 7.3.1B, the following alternative plasticizers appear to be suitable for further study for resilient flooring: DEHT, DINP, DGD, and DEHA.

Table 7.3.1 B: Resilient Flooring Plasticizer Prioritization Summary

Plasticizer	Performance and Cost Considerations									Environmental Considerations						Comments
	Processability				Physical Properties		Cost			Persistence				Bio-accum-ulation	Aquatic Toxicity	
	Vapor Pressure (mm Hg)	PVC Com-patibility	Com-pounding	Calender-ing	Emissions	Tensile Elongation	Raw material ($/lb)	Subst. Factor (phr)	Adj. Cost	Water	Soil	Sed.	Air	BCF	Chronic Fish ChV (mg/L)	
DEHP Di-2-ethylhexyl phthalate	**1.4 x 10^{-6}**	**Ref.**	**Ref.**	**Ref.**	**Ref.**	**Ref. MW 390**	**$0.70**	**1**	**$0.70**	**15**	**30**	**140**	**0.75**	**310 580**	**No effect at 0.0025 mg/1**	
DINP Di isononyl phthalate	5.4 x10^{-7}	Good	Similar to DEHP	Higher process temp >2 C°	Similar to DEHP	higher MW 418	$0.73	1.06	$0.77	15	30	**140**	0.67	3.2	**>0.14** mg/L @ 96 hr	
DIDP Di isodecyl phthalate	3.7 x 10^{-7}	Good	Similar to DEHP	Higher process temp >2 C°	Similar to DEHP	Higher MW 446	$0.77	1.1	$0.85	38	**75**	**340**	0.62	3.2	Not Est.	Exceeds two **P** criteria; Cost 10% greater than DEHP
DEHT Di 2-ethylhexyl terephthalate	2.14 x 10^{-5}	Good			Similar to DEHP	Same MW 390	$0.72	1.03	$0.74	15	30	**140**	0.75	25	> **0.015** mg/L	
BBP Butyl benzyl phthalate	7.7 x 10^{-6}	Good			Similar to DEHP	Lower MW 312	$0.70	0.94	$0.66	15	30	**140**	**1.5**	880	**0.081**	Exceeds **P** and **T** criteria
DGD Dipropylene glycol dibenzoate	5.2 x 10^{-6}	Good	Easier than DEHP	No issues identified	Similar to DEHP	Lower MW 342	$0.73	0.98	$0.72	15	30	**140**	0.46	190	**0.55**	
DEHA Di 2-ethylhexyl adipate	8.5 x10^{-7}	Fair	More difficult than DEHP	Similar to DEHP	Somewhat lower volatility	Similar to DEHP MW 371	$0.74	0.94	$0.70	8.7	17	**78**	0.62	61	>100 mg/L at 96 hr.	

Table 7.3.1 B: Resilient Flooring Plasticizer Prioritization Summary

Plasticizer										Environmental Considerations						Comments
					Physical Properties		Cost			Persistence				Bio-accumulation	Aquatic Toxicity	
		PVC Compatibility	Compounding	Calendering	Emissions	Tensile Elongation	Raw material ($/lb)	Subst. Factor (phr)	Adj. Cost	Water	Soil	Sed.	Air	BCF	Chronic Fish ChV (mg/L)	
DEHP Di-2-ethylhexyl phthalate		**Ref.**	**Ref.**	**Ref.**	**Ref.**	**Ref. MW 390**	**$0.70**	**1**	**$0.70**	**15**	**30**	**140**	**0.75**	**310 580**	**No effect at 0.0025 mg/l**	
DEHPA Di 2-ethylhexyl phosphate	4.7×10^{-7}	Good	Difficult	Similar to DEHP	Similar to DEHP	MW 322	$2-3	1	$2-$3	15	30	**140**	0.25	49	Not Est.	Significantly more expensive

Notes: *Refer to Appendix C for specific references for the environmental considerations*
Cost data obtained from industry sources, and reflect current US prices in March 2006
Processability data obtained from various industry sources, including trade organization data, individual chemical technical data sheets and MSDS
Comments based on review of presented data and stated prioritization criteria

Alternative Materials for Resilient Flooring

Considerations for alternative resilient flooring materials are outlined in Table 7.3.1 C. Material alternatives that do not satisfy any of these considerations are deemed less feasible as alternatives to DEHP/PVC flooring. As noted, the Institute included maintenance and durability as key considerations for comparing material alternatives to DEHP/PVC in addition to cost and performance considerations.

Table 7.3.1 C: Considerations for Resilient Flooring Material Alternatives

Performance	Maintenance /Durability	Cost	Environmental
Avoid the following: • Limited stock available • Lifetime less than 1 year	Materials should not require daily polishing and/or waxing	Cost should not be significantly higher than DEHP/PVC (*i.e.,* >$15/sf)	Materials should not be petrochemical based, preferentially from renewable resources, do not require the use of toxic chemicals in their manufacture or installation, and do not off-gas VOCs.

Table 7.3.1 D summarizes the cost, performance and environmental prioritization considerations for materials that were factored into determining the alternatives to assess. Particular attention was paid to an alternative's ability to approach the technical and economic profile of DEHP/PVC.

Based on the information presented in Table 7.3.1D, natural linoleum, cork and polyolefin all came through as priority alternatives for DEHP/PVC.

Both the polyethylene/limestone blend and rubber are feasible alternatives to DEHP/PVC flooring based on the majority of the factors considered. However the Institute identified limitations for each of these materials that made them less favorable alternatives compared to the other materials identified and they were therefore not considered further in this study. Specifically, although the polyethylene/limestone blend looked like a very viable alternative to DEHP/PVC from a performance and cost standpoint, it is not manufactured or readily available in the US at this time. The one distributor identified was contacted and is apparently not actively marketing this product. While rubbers have clear applicability in certain industrial and high traffic commercial applications (*e.g.,* in health care settings) at consistent cost and performance to DEHP/PVC, the limited nature of color alternatives makes rubber a less attractive alternative for light commercial (*e.g.,* office) or residential applications. It should be noted however that the range of colors and patterns available in synthetic rubber floorings is increasing.

Table 7.3.1 D: Resilient Flooring Material Prioritization Summary

Material	Performance			Availability (No. of suppliers/mfgr)	Cost (purchase & install.) $/sf	Environmental		Comments
	Maintenance / Durability	Lifespan (years)	Colors/ Patterns			Hazards	Benefits	
DEHP/PVC	Clean with water and ammonia when needed. Many require routine stripping and wax reapplication.	25+	Many	Many	$3-8	Ref.	Ref.	
Natural Linoleum	Dust mop, vacuum or sweep with a broom to remove grit and dust from the surface	40+	Many patterns and colors	Many	$3-6	Outgases linseed oil VOCs	Rapidly renewable, decomposes in dump, may be compostable	
Cork	Sweep or vacuum floor frequently. Wet maintenance is entirely forbidden. Recoat with polyurethane 4-8 yrs or when floor starts to show wear	80+	Limited solid colors	Many	$6 - $11.50	Some manufacturers use urea formaldehyde binders (*see section on formaldehyde*)	Rapidly renewable, biodegradable at end of useful life	
Polyolefin (Stratica)	Sweep or vacuum floor frequently; mop with water when necessary		Wood and stone prints	Many	$6.50/sf	Petrochemical based	Low VOC, solvent free adhesive, limited recycling	
Polyethylene / Limestone (LifeLine)	Moist or wet-cleaning method with mildly alkaline cleaner should be used	30-50	Many colors stone prints	Despite printed literature, does not appear to be available in the US	$5-$6	Installed with a regular acrylic based adhesive	Recycled during production, disposed of by burning and used as an energy waste since contains no PVC	Not currently available in the US
Rubber	Sweep or vacuum to remove loose dirt, spot clean and use damp mop		Limited colors and prints	Many	$3-10	Some outgas of VOCs – varies between differing products	Recyclable but no infrastructure to take back	Limited colors and prints; more of a niche product for high traffic industrial & commercial installations.

Alternatives to be Assessed for Resilient Flooring

Table 7.3.1 E presents the list of alternatives that were assessed more fully for resilient flooring uses:

Table 7.3.1 E: Priority Alternatives for Resilient Flooring

Priority Alternative Plasticizer	Priority Alternative Material
DEHT	Natural linoleum
DINP	Cork
DGD	Polyolefin
DEHA	

7.3.2 Alternatives Associated with Medical Devices for Neonatal Care

Available Alternatives

Information on available alternatives was obtained from technical experts in the manufacturing and health care industries, public health organizations, and academia and from literature searches. Because the focus was on medical devices for neonatal care, stakeholders pointed out the importance of a careful evaluation of alternatives, both to ensure reliable performance, and to minimize the risk to a sensitive population. One Massachusetts stakeholder is currently working on manufacturing non-DEHP devices, and specifically requested that the Institute assess DINCH, which is an alternative plasticizer that has received limited review by other sources. To obtain additional insight into the toxicology of DEHP and some of the alternatives, a meeting was held in Lowell with experts from industry, health care and academia.

There are two distinct categories of medical devices used for infants in neonatal intensive care facilities that were the focus of this study: bag/sheet devices containing plasticizers, and tubing containing plasticizers. As with the resilient flooring use, alternatives that are investigated for these applications include alternative plasticizers and alternative materials. For this use, process changes were not evaluated. Specifically, the option of foregoing medical procedures in order to avoid exposure to medical devices that contain DEHP is not an acceptable alternative.

Much work has been done to evaluate the material properties and processing of alternatives to DEHP plasticizers and PVC (one of the primary materials used) in the healthcare industry. The Danish Environmental Protection Agency has conducted significant research into alternatives for healthcare applications (Danish Environmental Protection Agency (DEPA) 2003), including conducting research to confirm certain technical parameters of a variety of alternative plasticizers in PVC. Health Care Without Harm (HCWH) is a leading advocacy and policy research organization concerned with identifying and promoting the use of safer materials in the healthcare environment. It has reported on alternatives, focusing primarily on alternative materials to PVC, in several reports, including "Neonatal Exposure to DEHP and Opportunities for Prevention" (Rossi 2002). While this report emphasizes alternatives to PVC, it includes detailed research and discussion on the use of DEHP in PVC-based products. Concurrently, many companies that manufacture medical devices have been developing products made from alternative materials. These represent some of the major sources of information the Institute used when identifying and prioritizing alternatives for medical devices used for neonatal applications.

Plasticizer Alternatives

The Danish EPA was interested in evaluating the performance and environmental issues associated with representative plasticizer alternatives. The suite of alternative plasticizers identified as warranting further investigation by this Danish agency includes:

- DINP
- DEHA
- DEHS, di(2-ethylhexyl) sebacate
- TOTM, triethylhexyl trimellitate
- ATBC, acetyltributyl citrate
- Benzoates (potentially DGD)
- Polymeric adipates
- Ethylene-acrylate-carbon monoxide terpolymer (Elvaloy®)

The HCWH evaluations were more focused on the use of alternative materials; however, they also assessed the availability, performance and EHS implications of various alternative plasticizers used in the US. Two alternative plasticizers they identified as being used or available in the US that were not identified as warranting further evaluation by the Danish EPA were:

- DBS (di butyl sebacate)
- BTHC (butyryl trihexyl citrate)

Finally, one of the study stakeholders, a manufacturer of medical devices in Massachusetts, specifically requested that the Institute include di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH) in its alternatives assessment for medical device applications as it represents an emerging alternative plasticizer that they are considering.

Materials Alternatives

The options available for alternative materials in medical device applications are more limited. Again, the Institute relied on existing and timely research conducted by other organizations, as well as research into alternative materials hospitals and medical device manufacturers are currently using, to determine potentially suitable alternative materials. Five materials were identified:

- Ethyl Vinyl Aacetate
- Polyolefins (Polyethylene and Polypropylene)
- Thermoplastic Polyurethane
- Glass
- Silicone

Priority Alternatives for Medical Devices for Neonatal Applications

When determining which plasticizer and material alternatives to prioritize for further study, the Institute relied heavily on existing and timely studies conducted by other organizations (primarily the Danish EPA and HCWH), and the feedback received from our stakeholders.

Plasticizer Alternatives

The Institute was interested in focusing on a representative set of alternatives that approaches the cost and performance characteristics of DEHP while not approaching levels of concern from an EH&S standpoint. Each of the alternatives listed above has been identified by the Danish EPA, HCWH and/or stakeholders because they are feasible alternatives from a performance basis. The Institute focused its research at this stage on EHS and cost considerations, and on choosing representative plasticizers when determining the final list of priority alternative plasticizers to assess for medical devices.

Of the plasticizer alternatives listed above, there is a wide range of plasticizer types represented, including phthalates (DINP), adipates (DEHA and polymeric adipates), sebacates (DEHS and DBS), trimellitates (TOTM), citrates (ATBC and BTHC), benzoates (DGD), a terpolymer (Elvaloy®) and carboxylates (DINCH).

A review of PBT data (see Table C5 in Appendix C) indicates that the following plasticizers exhibit chronic aquatic toxicity and sediment persistence levels that approach or exceed levels of concern: ATBC, DGD and DBS. Therefore, these alternatives were not assessed further.

From a cost standpoint, many of the plasticizer alternatives are in a cost range that would likely be acceptable for the medical device industry. However other alternative plasticizers exhibit costs that may not be acceptable in this industry.

Alternative plasticizers with higher costs (based on creating a functional plastic with a hardness rating of 70 Shore A[19]) include:

- DINCH (cost ~$0.91 /lb – March 2006 industry data)
- TOTM (cost $1.11 /lb – March 2006 industry data)
- BTHC (cost ~$1.12 /lb – March 2006 industry data)
- Elvaloy® (cost ~$4.10 /lb – based on Danish EPA information)
- DEHS (estimated cost ~$4.50 /lb – based on Danish EPA information)
- Polymeric adipate (cost ~$6.00 /lb – based on Danish EPA information)

Based on these figures, Elvaloy®, DEHS and polymeric adipate appear to be in a range that is significantly greater than the estimated cost of DEHP (~$0.70/lb) and therefore will not be assessed further.

Material Alternatives

Based on our review of the above-mentioned studies, the Institute determined that all five of the alternative materials to DEHP/PVC (*i.e.,* ethyl vinyl acetate, polyethylene, polyurethane, glass, and silicone) warranted further assessment.

Alternatives to be Assessed for Medical Devices for Neonatal Applications

Table 7.3.2 A summarizes the final list of high priority alternatives for full assessment for medical device applications.

[19] 70 Shore A is a standard hardness rating for flexible plastics, and allows for a functionally equivalent cost comparison

Table 7.3.2 A: Final Alternatives for Medical Device Neonatal Applications

Priority Alternative Plasticizer	Priority Alternative Material
TOTM	Ethyl vinyl acetate
DEHA	Polyolefins
BTHC	Glass
DINP	Silicone
DINCH	Thermoplastic Polyurethane

7.3.3 Alternatives Associated with Wall Coverings

This study focuses on alternatives to DEHP/PVC, or vinyl, residential wall covering. When considering alternatives to DEHP in vinyl wall coverings the comparison must include different materials as well as different plasticizers. Process alternatives such as painting or paneling are alternatives that are also available for vinyl wall coverings.

Available Alternatives for Wall Coverings

Plasticizer alternatives for vinyl wall coverings that were identified from stakeholder conversations, discussions with industry experts and literature research include:

- DINP
- DIDP
- TOTM
- DEHA
- DEHPA
- TOP (tri (2-ethylhexyl) phosphate)

Material alternatives for DEHP/PVC blend used in wall coverings, developed based on literature and market research and discussions with industry experts, include:

- Glass Woven Textiles
- Wood Fiber/Polyester
- Polyethylene
- Cellulose/Polyester
- Polyester
- Biofibers
- Polyolefins
- Recycled Paper
- Wool/Ramie

Finally, there are viable process alternatives to vinyl wall coverings, including painted wall surfaces or different wall materials (such as pine paneling). They differ significantly from wall coverings in terms of aesthetics, but can be functionally equivalent. These technological alternatives have many issues associated with them throughout their life cycle. Because a full life cycle assessment is beyond the scope of this study, and because many plasticizer and material alternatives are available for assessment, the Institute is not evaluating technological alternatives in the full assessment. However, it is important to note that painting and other wall materials are indeed viable alternative to the use of vinyl wall coverings.

Alternatives Screened Out

None of the plasticizer or materials alternatives identified above were screened out due to EH&S issues. However, the plasticizers that were screened out as discussed in the resilient flooring section (Section 7.3.1) were also not considered for this application.

Priority Alternatives for Wall Coverings

Based on our initial review of available alternatives it is apparent that there is a large number and variety of potential plasticizer alternatives available for wall coverings. Therefore, in order to arrive at a manageable number of alternatives to assess fully, the Institute conducted a tiered approach to determining the priority alternatives.

Plasticizer Alternatives for Wall Coverings

Several criteria were considered when determining which alternative plasticizers would be prioritized for further assessment. Plasticizers should exhibit equal or improved characteristics from an environmental and human health standpoint than DEHP. Adoption of alternative plasticizers that approach the technical and economic profile of DEHP/PVC will be more attractive to industry for adoption. Substances that are incompatible will not plasticize PVC properly. In addition, the volatility of the plasticizer should not be higher than that of DEHP in order to assure similar processability. According to plasticizer and wall covering manufacturers, plasticizer cost is the most important consideration when designing and marketing a product.

Table 7.3.3 A summarizes the considerations that the Institute used in determining if a plasticizer alternative would be eliminated from further evaluation.

Table 7.3.3 A: Considerations for Wall Covering Plasticizer Alternatives

Processability	Cost	Environmental
Plasticizer alternative should not be significantly more difficult to process than DEHP	Plasticizer alternative should not be more than 10% greater than DEHP on a processed per pound basis	Plasticizer alternative should not exceed any levels of concern for environmental screening criteria

The plasticizer alternatives to DEHP vinyl wall coverings are listed in Table 7.3.3 B. These DEHP plasticizer alternatives include other phthalates, as well as trimellitates, adipates and phosphates. Each of these plasticizers is known to be an available alternative to DEHP in vinyl wall covering.

Table 7.3.3 B: Wall Covering Plasticizer Prioritization Summary

Plasticizer	Performance and Cost Considerations									Environmental Considerations						Comments
	Processability				Physical Properties		Cost			Persistence				Bio-accum-ulation	Aquatic Toxicity	
	Vapor Pressure (mm Hg)	PVC Com-patibility	Com-pounding	Calender-ing	Emissions	Tensile Elongation	Raw material ($/lb)	Subst. Factor (phr)	Adj. Cost	Water	Soil	Sed.	Air	BCF	Chronic Fish ChV (mg/L)	
DEHP Di-2-ethylhexyl phthalate	**1.4 x 10^{-6}**	**Ref.**	**Ref.**	**Ref.**	**Ref.**	**Ref. MW 390**	**$0.70**	**1**	**$0.70**	**15**	**30**	**140**	**0.75**	**310**	**No effect @ 0.0025 mg/L**	
DINP Di isononyl phthalate	5.4 x10^{-7}	Good	Similar to DEHP	Higher process temp >2 C°	Similar to DEHP	higher MW 418	$0.73	1.06	$0.77	15	30	**140**	0.67	3.2	>0.14 mg/L at 96 hr	
DIDP Di isodecyl phthalate	3.7 x 10^{-7}	Good	Similar to DEHP	Higher process temp >2 C°	Similar to DEHP	Higher MW 446	$0.77	1.1	$0.85	38	**75**	**340**	0.62	3.2	Not Est.	Exceeds two **P** criteria; Cost 10% greater than DEHP
TOTM tri-2-ethylhexyl trimellitate	4.5 x 10^{-8}	Good	Slightly harder than DEHP	Similar to DEHP	Lower than DEHP	Higher MW 546	$0.95	1.17	$1.11	8.7	17	**78**	0.5	3.2	>100 mg/L at 96 hr.	Sediment **P** above level of no concern; Significantly lower volatility; Cost significantly higher than DEHP
DEHA Di 2-ethylhexyl adipate	8.5 x10^{-7}	Fair	More difficult than DEHP	Similar to DEHP	Similar to DEHP	Similar to DEHP MW 371	$0.74	0.94	$0.70	8.7	17	**78**	0.62	61	>100 mg/L at 96 hr.	
DEHPA Di 2-ethylhexyl phosphate	4.7x 10^{-7}	Good	Difficult		Similar to DEHP	MW 322	$2-3	1	$2-$3	15	30	**140**	0.25	49	Not Est.	Significantly more expensive

Table 7.3.3 B: Wall Covering Plasticizer Prioritization Summary

Plasticizer	Performance and Cost Considerations									Environmental Considerations						Comments
	Processability				Physical Properties		Cost			Persistence				Bio-accum-ulation	Aquatic Toxicity	
	Vapor Pressure (mm Hg)	PVC Com-patibility	Com-pounding	Calender-ing	Emissions	Tensile Elongation	Raw material ($/lb)	Subst. Factor (phr)	Adj. Cost	Water	Soil	Sed.	Air	BCF	Chronic Fish ChV (mg/L)	
DEHP Di-2-ethylhexyl phthalate	**1.4 x 10^{-6}**	**Ref.**	**Ref.**	**Ref.**	**Ref.**	**Ref. MW 390**	**$0.70**	**1**	**$0.70**	**15**	**30**	**140**	**0.75**	**310**	**No effect @ 0.0025 mg/L**	
TOP tri(2-ethylhexyl) phosphate	1.5 x 10^{-5}	Fair	Difficult	Unknown	Somewhat higher than DEHP	Higher than DEHP MW 434.7	$2.10	1	$2.10	8.7	17	**78**	0.16	3.2	Not Est.	Sediment **P** above level of no concern; Processing difficult and only fair compatibility with PVC; Cost significantly higher than DEHP

Notes: *Refer to Appendix C for specific references for the environmental considerations*
Cost data obtained from industry sources, and reflect current US prices in March 2006
Processability data obtained from various industry sources, including trade organization data, individual chemical technical data sheets and MSDS
Comments based on review of presented data and stated prioritization criteria

Based on the information presented in Table 7.3.3C, the following plasticizer alternatives were identified to be assessed further: DEHA and DINP.

Alternative Materials for Wall Coverings

For material alternatives the Institute included maintenance/durability considerations as a key consideration for selecting alternatives to DEHP/PVC in addition to cost and performance considerations. Table 7.3.3 C summarizes the undesirable attributes for wall covering material alternatives.

Table 7.3.3 C: Considerations for Wall Covering Material Alternatives

Performance	Maintenance /Durability	Cost	Environmental
Material should have a variety of colors and patterns available. The estimated life time usability should not be significantly shorter than for DEHP /PVCwall covering.	Material should not be easily stained or damaged. It should not be especially difficult to clean.	Materials should not be significantly higher than DEHP/PVC (>$25/yd)	Materials should not be petrochemical based, preferentially from renewable resources, do not require the use of toxic chemicals in their manufacture or installation, and do not off-gas VOCs.

The material alternatives to DEHP/PVC wall coverings are listed in Table 7.3.3 D. The table summarizes reasons why particular materials were eliminated from further study.

Table 7.3.3 D: Wall Covering Material Prioritization

Material	Performance		Cost (1) (purchase & installation) ($/yard)	Global Market Effect (e.g. restrictions)	Other	Environmental		Comments
	Maintenance / Durability	Lifespan (years)				Hazards	Benefits	
DEHP/PVC (Vinyl)	**Scrubbable and washable**	**25+**	**$3 -5 low end; $14- $22 high end**	**Some architects and designers are voluntarily moving away from DEHP/PVC products**		**Ref.**	**Ref.**	
Glass Woven Textiles	Clean with damp cloth, can be scrubbed if necessary. Can repaint up to 10 times to change appearance or cover scuffs.	20+	$13-$15		Used in Europe for over 60 years. Mold/mildew resistant		Made from sand (woven glass) and recycled glass. Can be covered with any latex or special finish paint.	
Wood Fiber/ Polyester	Scrubbable using soft bristle brushes only	1 year warranty	$13		Not recommended for high-moisture areas; Not scrubbable; Not good for high traffic areas		50% wood pulp and 50% spun-woven polyester fibers; No heavy metals or formaldehyde; Water soluble inks	
Polyethylene	Periodic vacuuming; Aggressively scrubbable	20+	$28-30 (material only)	Petrochemical product very durable; Low VOCs	Water repellant, stain resistant; Anti-bacterial, antifungal and non-toxic.		Contains no PVC, no Chlorine, is plasticizer free, heavy metal free and inherently flame retardant.	High cost
Cellulose/ Polyester	Scrubbable	10-15	$18-$22 (material only)	Product take-back program available. Duraprene uses recycled products	Can be used in all areas "similar to vinyl" except this product breathes reducing mold and mildew		Cellulose totally chlorine free. Does not emit any VOC's; Waterbased inks; Wood from sustainably managed forests	
Polyester	Occasional vacuuming recommended; Keeping the product clean is a problem		$30-$35				100% recycled and poly blends with natural fibers; Both post consumer and post industrial polyester used.	High cost, difficult maintenance

Table 7.3.3 D: Wall Covering Material Prioritization

Material	Performance		Cost (1) (purchase & installation) ($/yard)	Global Market Effect (e.g. restrictions)	Other	Environmental		Comments
	Maintenance / Durability	Lifespan (years)				Hazards	Benefits	
DEHP/PVC (Vinyl)	**Scrubbable and washable**	**25+**	**$3 -5 low end; $14- $22 high end**	**Some architects and designers are voluntarily moving away from DEHP/PVC products**		**Ref.**	**Ref.**	
BioFibers	Light brushing and occasional vacuuming is recommended.						Contains post-consumer recycled material;, Releases minimal pollutants (including VOCs); Rapidly renewable Biodegradable	
Polyolefins	Will not absorb stains		$18-$22 (material only)			Teflon finish to enhance "cleanability" and ensure adhesives do not seep thru surface	100% Polyolefin and 85% polyolefin/ 15% polyester blend treated with Teflon finish.	
Recycled Paper	All stains should be treated ASAP with clean water. Harder stains can be treated with a mild detergent. Avoid rubbing. Occasional vacuuming	1 year warranty	$15.00 (> 200 yards) $16.50 (≤ 200 yards) plus installation		Installation by professional textile wall cover installer recommended (per web site)		Made from Japanese phonebooks (50-75% recycled books and the rest paper pulp).	Short life span, difficult maintenance
Wool/Ramie			$50-$67				Custom high end fabric which has low impact manufacturing.	Very high cost

Notes: (1) Cost includes $7 to $10 per yard for installation
Comments based on review of presented data and stated prioritization criteria

Alternatives to be Assessed for Wall Coverings

Our prioritization evaluation of alternatives resulted in the following list of alternatives that will be assessed more fully (Table 7.3.3 E):

Table 7.3.3 E: Final Alternatives for Wall Coverings

Priority Alternative Plasticizer	Priority Alternative Material
DEHA, di (2-ethylhexyl) adipate	Glass Woven Textiles
DINP, di(isononyl) phthalate	Cellulose/Polyester Blends
	Wood Fiber/Polyester Blends
	Biofibers
	Polyolefins

7.4 DEHP Alternatives Assessment

This section reviews the various priority plasticizer and material alternatives to DEHP identified using the criteria and methods described in Section 7.3. The following sections outline the assessment of these potentially viable alternatives. The alternatives assessment for each use is organized by plasticizer and material alternatives, with specific discussions of EH&S, technical and economic factors for each use within that overall heading. However, there are also common issues for plasticizers that apply to all the applications. These issues are discussed in a separate section, below.

Common Issues for DEHP Plasticizer Alternatives

Various plasticizer alternatives were identified through a literature review and discussions with industry manufacturers, processors, and end users. The Institute established desired criteria for cost, performance, environmental health and safety and cost for each alternative plasticizer that were used in assessing the feasible alternatives. Table 7.4 A summarizes these criteria.

Table 7.4 A: DEHP Plasticizer Alternative Assessment Criteria

Category	Assessment Criteria
Performance	The following performance criteria are important when substituting plasticizers in flooring and wall covering operations: • Lower plasticizer volatility, measured by plasticizer's vapor pressure, increases a product's expected lifetime. Ideally, the volatility of a substitute plasticizer should be equal to or lower than DEHP. • Compatibility measures how well a plasticizer is suited to PVC. Plasticizers with low compatibility are known to migrate out of plastic over the life of a product. • Molecular weight is a good indication of tensile elongation. Higher molecular weight plasticizers tend to result in longer product life • Compounding and calendaring processability compared to DEHP. These processes are most common when manufacturing flexible PVC. Alternatives should ideally process as well as or better than DEHP. The following additional performance criteria are important when substituting plasticizers in medical device applications: Sheet applications: Tensile strength, cold flexibility (because solutions must be cold-storable) and clarity are key considerations. Tubing applications: In addition to the considerations for sheet applications, elastic recovery is an essential consideration to assure that tubing does not kink during use. Solvent cementability to assure sound bonds between parts.
Financial	Cost data from industry sources in March 2006, based on a hardness rating of 70 Shore A. Cost estimates use plasticizer substitution factors to determine the relative amount of plasticizer, compared to DEHP, needed to obtain a particular level of hardness. For example, a factor of 1.1 indicates to achieve similar hardness; 1.1 times the amount of DEHP used is required.
Environmental Health and Safety	• Critical criteria were associated with the initial screen (*i.e.,* no PBT, Class 1 or 2 carcinogens or TURA SAB more hazardous chemicals). No chemicals that exceeded these criteria were put forward for further assessment. • If a plasticizer exhibits PBT values that approach levels of concern, as identified by the EPA in its PBT Profiler methodology, it will be considered less favorably in the assessment phase. • Additional parameters that are considered when assessing plasticizer alternatives have been identified based on the characteristics of DEHP and specific concerns relative to the likelihood of an effect occurring. These additional health criteria include: water solubility, octanol-water partition coefficient (a measure of hydrophobicity), organic carbon partition coefficient (sediment affinity indicator), lethal dose value (using the oral rat value as the benchmark), immediately dangerous to life and health (IDLH) value, permissible exposure limit, reference dose, carcinogen classification, toxicity (EU R-phrase or present on the California Proposition 65 list), and vapor pressure. For medical device applications particular attention needs to be paid to the ability of the plasticizer to migrate out of the polymer matrix and into the contained solution, thereby increasing the likelihood of exposure and associated health impact. Associated generation of metabolites of concern (based on associated environmental and human health effects) when the plasticizer enters the body must also be considered

Technical Issues Associated with Plasticizer Alternatives

As indicated in Table 7.4A, some of the technical issues associated with plasticizer alternatives are common regardless of the application for the plasticizer. Below is a discussion of those common technical issues.

PVC Compatibility

One of the most important factors determining the feasibility of a plasticizer as an alternative to DEHP is its overall compatibility with PVC. Plasticizers are assessed on their PVC compatibility based on their ability to create a stable compound (*i.e.,* create a single phase). An incompatible plasticizer will exude to the surface of the plastic making it more easily extracted by either volatilization into the air, or solubilization into the contact solution. In effect, this will result in a less flexible plastic than originally designed. In addition, the plasticizer needs to be compatible with any other additive that may be compounded into the plastic product. An indication of a poorly compatible plasticizer would be the loss of flexibility and/or a sticky or oily surface of the product.

To process well, plasticizers must be absorbed into the PVC resin particles during the blending process (DEPA 2003). Known as processability, PVC resin, plasticizer(s), stabilizers and lubricants should blend together readily in a compounding operation.

Migration or Permanence of Plasticizer

DEHP can migrate out of the PVC matrix because it is not permanently or covalently bound to the plastic molecule, therefore exposure to DEHP from the polymer matrix is a possibility. The mechanisms that control migration from a plastic, excluding the effects of plastic weathering, are surface-controlled losses (such as volatility and aqueous solubility) and diffusivity. Most plasticizers have extremely low water solubility and therefore their losses into aqueous environments are controlled by surface mechanisms rather than by being drawn out of the plastic (diffused). Volatile losses of plasticizer are influenced by vapor pressure, solvency strength for the polymer and oxidative degradation of the plastic. Plasticizers like DEHP are highly lipid soluble and therefore, when in the presence of oily or fatty solutions, their losses from the plastic are controlled by diffusivity.

Financial Factors Associated with Plasticizer Alternatives

Because of extreme price competition in the PVC flooring and wall covering industry, even slightly more expensive plasticizers find difficulty gaining widespread acceptance.

Depending on the application, the concentration of plasticizers in the polymer matrix can be up to 40% of the product by weight. In this case, and when dealing with low margin industries, the cost premiums associated with some of the alternatives to DEHP may be unacceptable from an industry standpoint. A mitigating factor here is that the plasticizers typically do not replace each other on a 1:1 basis. Some plasticizers are more efficient, and therefore less is required to achieve the same level of hardness of the plastic product. This "substitution factor" will be presented throughout the discussion to normalize the costs as much as possible.

Table 7.4B presents estimates of plasticizer costs based on data obtained from industry sources in March 2006, and includes estimated substitution factors, which allow for a normalized comparison of costs based on how they are used to create a comparably flexible product (70 Shore A). For instance, DINP, with a substitution factor of 1.06, requires more plasticizer and DEHA with a 0.94 substitution factor requires less plasticizer to achieve the same hardness as DEHP.

It is important to note also that some of the plasticizer alternatives are relatively new, and cost may decrease as production increases. This trend, however, is limited by the molecular composition of the plasticizers; compounds with more carbon chains and more complex chemistries will necessarily be more expensive than simpler plasticizer molecules.

Table 7.4 B: Plasticizer Cost Estimates

Plasticizer	Cost Estimate ($/lb)	Substitution Factor (SF)	Normalized Cost (raw cost x SF)
DEHP	*$0.70*	*1*	*$0.70*
DEHA	$0.73	0.94	$0.70
DGD	$0.73	0.98	$0.71
DEHT	$0.74	1.03	$0.76
DINP	$0.74	1.06	$0.77
DINCH	$0.91	unknown	$0.91
TOTM	$0.95	1.17	$1.11
BTHC[20]	$1.15	0.975	$1.12

Data from Industry Sources, March 2006

Environmental and Human Health Issues Associated with Plasticizer Alternatives

As discussed in Section 7.2, the health and environmental impacts associated with the use of DEHP as a plasticizer relate first to potential exposures in manufacturing, and second to potential exposures due to leaching out of the PVC matrix. Other plasticizers may also produce exposure to humans or the environment by leaching out. The environmental and human health impact assessment of the use of alternative plasticizers will begin by examining the inherent hazards of the substances, followed by a review of the likelihood of migration out of a product, and continue with a discussion of the potential impacts associated with a resulting exposure. Specific criteria that will be focused on in our assessment have been identified in Table 7.4A.

7.4.1 Alternatives Assessment for Resilient Flooring

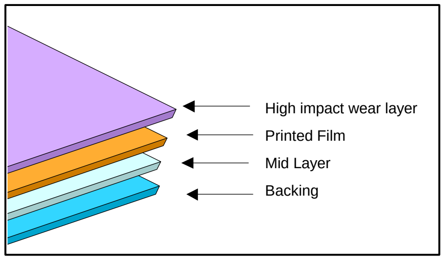
DEHP/PVC or vinyl flooring has been one of the most popular flooring types found from kitchens and bathrooms to hospitals and schools. In general, there are two types of DEHP/PVC flooring: sheet flooring (typically 6' or 12' wide) and tile (typically 12"x12" or 9"x9").

Composition

Vinyl sheet is made with a felt or vinyl backing and can be either rotogravure (printed) or inlaid. In rotogravure vinyl, a printed image is sandwiched between the backing, a mid layer and a top wear layer (see Figure 7.4.1A). Inlaid vinyl uses tiny vinyl granules from the backing all the way to the wear surface making it highly durable but available in fewer patterns and colors. DEHP/PVC flooring can also be finished with a polyurethane layer which increases wear resistance. The backing may be made up of cellulose fibers, glass fiber, styrene butadiene latex, or acrylic latex, along with inorganic fillers such as limestone and talc. The backing adheres to the plastisol PVC layer. Inlaid sheet DEHP/PVC may have a felt backing.

[20] Substitution Factor from manufacture's literature (http://www.morflex.com/pdf/bul101.pdf)

Figure 7.4.1 A: Common Rotogravure DEHP/PVC Sheet Construction



Vinyl composition tile (VCT) construction is very different from vinyl sheet. VCT contains a high proportion of inorganic filler (limestone) to increase its dimensional stability and reduce its elasticity.

Vinyl flooring varies widely in grade and quality with thinner grades priced lower. Figure 7.4.1 B shows several DEHP/PVC flooring samples.

Figure 7.4.1 B: Typical DEHP/PVC Tile Samples

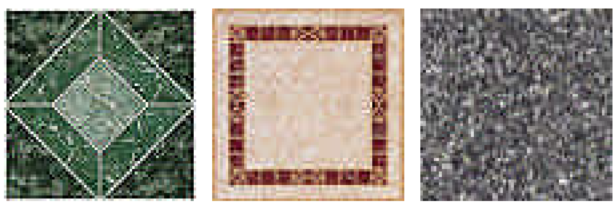


Table 7.4.1 A: Common Vinyl Flooring Compositions

DEHP/PVC Sheet Flooring Composition[21]		
Wt. %	Material	Origin/Precursor Materials
50%	PVC	Ethylene dichloride, vinyl chloride
30%	Plasticizer DEHP	Phthalic anhydride, 2-ethylhexyl alcohol
15%	Limestone	Mineral
~3%	Heat stab.	Barium zinc, calcium zinc[23]
~2%	Other ingredients	(e.g. titanium dioxide pigments, linseed oil)

DEHP/PVC VCT Flooring Composition[22]		
Wt. %	Material	Origin/Precursor Materials
12%	PVC	Ethylene dichloride, vinyl chloride
5%	Plasticizer DEHP	Phthalic anhydride, 2-ethylhexyl alcohol
80%	Limestone	Mineral
2%	Vinyl acetate	Ethylene, acetic acid
1%	Other ingredients	Stabilizers, etc.

Installation/Cleaning/Maintenance

Vinyl floors can be installed over wood, concrete or, in some cases, existing flooring. However, sub-flooring should be clean, smooth, of high quality and as flat as possible. Professional installation is often recommended to ensure long life. Daily sweeping or dust-mopping is recommended to

[21] Source: (Potting and Blok 1995)

[22] Source: (Environmental Works Community Design Center (EWorks) 2002)

[23] According to the Resilient Floor Covering Institute, cadmium and lead based stabilizers are no longer used in vinyl flooring. Mixed metal stabilizers dominate the market in this application (see comments to USGBC LEED TSAC PVC Study Information Outreach Forum on stabilizers: http://pvc.buildinggreen.com/comments.php).

remove grit and dirt. Floors should be damp-mopped with a neutral detergent. Spills should be wiped up before they dry with a damp, clean white cloth. Many manufacturers recommend stripping and refinishing vinyl floors on a routine basis.

Resilient Flooring Financial Considerations

Typically, commercial vinyl composition floor tile has an installed cost of between $1.40 to $8.70 per square foot, depending on the thickness and pattern (this includes materials, equipment and labor). Commercial sheet vinyl has an approximate installed cost of $2.64 to $5.50 per square foot (VBD 2006). Higher quality vinyl flooring is thicker and is expected to last nominally from 25 to 30 years with proper cleaning and maintenance.

Environmental and Human Health Issues

The principal environmental and human health issues associated with DEHP/PVC flooring are outlined in Table 7.4.1 B. The PVC supply chain, including intermediates manufacturing and the various processing steps from crude oil and rock salt extraction through vinyl chloride monomer production, plays a major role in PVC impacts. Other impacts include energy use impacts from manufacturing and transport and a lack of end-of-life recycling and recovery options.

Table 7.4.1 B: General DEHP/PVC Alternative Material Assessment Criteria

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of DEHP/PVC
Raw Materials	• Extraction and refining of petroleum based feedstocks. • Ethylene feedstock is non-renewable • Few suppliers offer recycled content • A minority of DEHP/PVC is manufactured from chlorine made using the mercury cell process	• Some vinyl sheet manufacturers use up to 25% post-industrial recycled DEHP/PVC and reclaimed wood fibers in product.
Manufacture	• Human health impacts of PVC precursor chemicals • Energy use impacts: greenhouse gas, particulate, other • Potential worker exposure to DEHP during manufacture	• Post industrial vinyl scrap is recyclable
Installation	• Volatile organic compounds emitted from styrene butadiene floor adhesives	• Adhesives typically water-based, safer than older solvent-based types
Use and Maintenance	• DEHP exposure, though this is expected to be low due to the low vapor pressure • VOC emissions (rate depends on product type) • Most varieties require routine stripping and waxing, which may have associated VOC emissions	• Waxing and cleaning with mild detergent
End of Life	• Potential for chlorine derivative (dioxin and furan) emissions from improper combustion (accidental fire, backyard burning) • Chlorine derivatives may be found in fly ash of properly controlled incinerators • Not compostable • Lack of recycling infrastructure to recycle DEHP/PVC flooring	• Recyclable

Even though there is a great deal of information in the literature concerning life cycle impacts of using DEHP/PVC blends, there is no scientific consensus. This assessment attempts to lay out the key potential issues, allowing readers to draw their own conclusions.

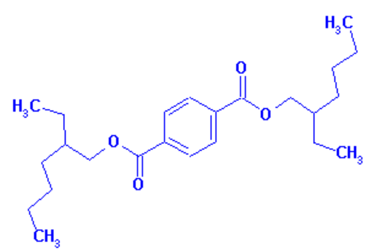
Specific Plasticizer Alternatives Assessed for Resilient Flooring

While DEHP is not the only plasticizer used in resilient flooring applications, it is the most commonly used plasticizer. Plasticizer alternatives that were prioritized for resilient flooring include DEHT, DINP, DGD and DEHA. These plasticizers represent a terephthalate, a phthalate, a dibenzoate and an adipate, as discussed in more detail below.

Di 2-Ethylhexyl Terephthalate (DEHT)

DEHT (di(2-ethylhexyl) terephthalate) is called a "phthalate like" plasticizer whose specific chemical structure is shown in Figure 7.4.1 C. DEHT has an isomeric structure of DEHP, which means that it has the same elements but has a different arrangement of the atoms. Although DEHT and DEHP are structurally similar, giving them almost identical physical-chemical properties, they have distinctly different toxicological properties. The performance of DEHT is similar to DEHP and its low cost often makes it a good alternative plasticizer. It is made by Eastman Chemical and known as Eastman 168 Plasticizer.

Figure 7.4.1 C: Chemical Structure of DEHT



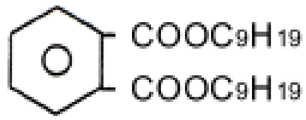
Rubber mat manufacturers have tried substituting DEHT and found that it does not work. There were issues because DEHT does not 'take up' fast enough and slows the process down (Biltrite 2005). DEHT used in rubber or PVC applications can, if not formulated properly, exude to the surface under warm and humid conditions when used in tightly coiled (Teknor Apex 2006). In addition, DEHT is slightly more volatile than DEHP, indicating that more may be required to make up for fugitive emissions during processing.

There are no workplace air exposure standards for DEHT. In a study conducted in 2002, the NOAEL for reproductive toxicity associated with exposure of rats to DEHT was considered to be 10,000 mg/kg bw/day. The NOAELs for parental toxicity and neonatal toxicity were considered to be 3,000 mg/kg bw/day (Faber et al. 2002). The persistence of DEHT in sediments and air is estimated as 140 days using the PBT Profiler methodology. Based on these few sources of information on impacts to human and environmental health due to exposure to DEHT, it appears that DEHT is of low concern.

Diisononyl Phthalate (DINP)

DINP is a mixture of phthalates with branched alkyl chains of varying length (C8, C9 and C10). The chemical structure of DINP is depicted in Figure 7.4.1 D. The plasticizing efficiency of DINP is somewhat lower than DEHP and therefore more plasticizer is required to gain the same softness. Because the molecular weight of DINP (418) is greater than DEHP (390), DINP has better high temperature performance and extraction resistance. Because DINP is less volatile than DEHP, processing with DINP leads to lower plasticizer losses during compounding and calendaring, reducing emissions and occupational exposure. According to one industry source, when compared with DEHP, DINP processing emits noticeably lower levels of plasticizer mist from process equipment.

Figure 7.4.1 D: Chemical Structure of DINP



DINP is a "drop in replacement" for DEHP. Because DINP has a lower volatility (5.4×10^{-7} mm Hg) than DEHP (1.4×10^{-6} mm Hg) the emissions from the operation using DINP may be lower. In one Massachusetts factory, line workers observed a clearer room (less haze) when running with DINP compared with DEHP (Biltrite 2005). DINP's processability is similar to DEHP's.

Exposure to DINP during processing or use of resilient flooring is expected to be minimal due to the lower emissions relative to DEHP. During use there is little likelihood of DINP migrating out of the polymer matrix and causing exposure. In the event that humans do become exposed to DINP from this use however, there may be associated health effects.

Workplace air exposure standards have not been established for DINP, which although considered an animal carcinogen, has not been completely classified as to human carcinogenicity (CDC 2005).

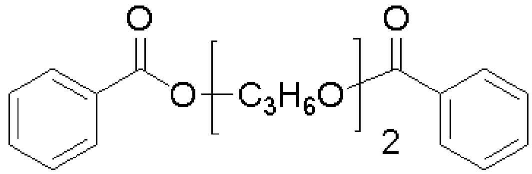
According to the Chronic Health Advisory Panel, exposure to DINP results in potential acute toxic effects (Chronic Hazard Advisory Panel (CHAP) 2001). The NOAEL for systemic toxic effects induced in laboratory animals by exposure to DINP is estimated between 15 mg /kg bw/d and 88 mg/kg bw/d. To put this into context, a study by the Consumer Council Austrian Standards Institute (Fiala n.d.) used the lowest NOAELs for DINP and DEHP to determine a total daily intake level for these plasticizers (this study focused on the use of DINP and DEHP in children's toys that would be mouthed, using a risk factor of 100) of 150 μg/kg bodyweight /day for DINP and 37 μg/kg bodyweight /day for DEHP. Based on this study, DINP is less toxic than DEHP.

According to its review of relevant studies, the CHAP concludes that DINP is clearly carcinogenic to rodents, inducing hepatocellular carcinoma in rats and mice of both sexes, renal tubular carcinoma in male rats, and mononuclear cell leukemia in male and female rats. The studies they reviewed also suggest possible carcinogenicity in the testis, uterus, and pancreas in rodents (CHAP 2001). DINP has not been categorized by EPA or IARC as to its carcinogenicity.

Dipropylene Glycol Dibenzoate (DGD)

DGD is a benzoate plasticizer with great affinity for PVC; as a result, vinyls containing DGD show good resistance to solvent extraction and perform well in volatility tests. Figure 7.4.1 E illustrates its chemical structure. The volatility of DGD is only slightly higher than DEHP, indicating relatively similar plasticizer losses and emissions during processing. The compatibility with PVC is reported as good due to a vapor pressure that is similar to that of DEHP. Velsicol Chemical Corporation makes and markets this plasticizer under the name Benzoflex® 9-88.

Figure 7.4.1 E: Chemical Structure of DGD



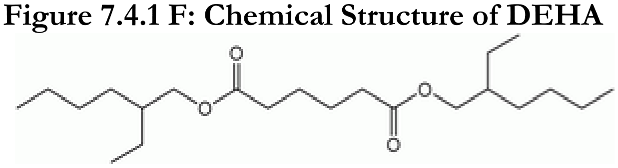
Benzoate alternative plasticizers have been known for years as effective PVC plasticizers. Although they represent effective plasticizer substitutes, benzoates, and specifically DGD, have not been widely used. Serious consideration has been revived due to the search for substitutes caused by the ongoing phthalate controversies.

DGD is estimated as persistent in sediments for 140 days, and produces a chronic aquatic toxicity at 0.55 mg/L. While neither of these levels exceed methodology thresholds, they do suggest that precaution should be used when using DGD. The primary routes of exposure potentially associated with DGD are inhalation and dermal. According to the MSDS for this product, there is virtually no human toxicity anticipated based on rodent studies (Velsicol Chemical Corporation 2002). They estimate an oral LD50 of greater than 5000 mg/kg. However, this product does have a Risk Phrase of R-51/53 associated with it, indicating that it may cause long term toxic effects in the aquatic environment[24]. The MSDS also indicates that there may be irritation associated with inhalation, ocular and dermal contact to DGD. DGD is not a listed carcinogen, nor is there a specific water quality criterion established for this chemical.

Di (2-Ethylhexyl) Adipate (DEHA)

DEHA is an adipate plasticizer whose specific chemical structure is shown in Figure 7.4.1 F. Adipates are classified as low temperature plasticizers and are all relatively sensitive to water (DEPA 2001). Its low temperature properties make DEHA a potentially favorable plasticizer for materials used to store cold solutions (*e.g.,* blood). DEHA is less compatible with PVC than DEHP, which can lead to exudation (*i.e.,* plasticizer migrating to the surface). DEHA is known to be slightly more difficult to process compared to DEHP, though it exhibits relatively lower volatility than DEHP.

Figure 7.4.1 F: Chemical Structure of DEHA



The Danish EPA determined that DEHA has the potential to migrate from the PVC matrix into fatty solutions. They conducted a review of toxicological data associated with a number of plasticizers, including DEHA. A NOAEL of 610 mg/kg bodyweight/d has been reported (DEPA 2001), which is orders of magnitude higher (*i.e.,* indicating lower toxicity) than the NOAEL for DEHP. However the Institute did not determine if any studies evaluating the impact of exposure on the male reproductive system have been conducted. The Chronic Health Advisory Panel for the US Consumer Product Safety Commission quotes a study that indicates a fetotoxicity issue associated with oral exposure to DEHA (CHAP 2001).

[24] Note that DEHP has risk phrases of R-60 and 61, which indicate may impair fertility and may cause harm to the developing fetus, respectively

Summary of Plasticizer Alternatives Assessed for Resilient Flooring

Table 7.4.1 C summarizes the comparative assessment of plasticizer alternatives to DEHP for use in PVC resilient flooring. Refer to Table 7.3.1 B for associated data.

Table 7.4.1 C: Summary of Plasticizer Alternatives Assessment for Resilient Flooring

Assessment Criteria		DEHP (Reference)	Comparison Relative to DEHP			
			DEHT	DINP	DGD	DEHA
Technical/ Performance Criteria	Volatility	**1.4 x 10^{-6} mm Hg**	-	+	=	+
	Compounding	**Good**	?	=	=	=
	Tensile Elongation (life of product)	**MW 390**	=	=	=	=
	PVC Compatibility	**Good**	=	=	=	-
	Loss of Plasticizer (Manufacture, Use)	**Acceptable** (M, U)	=	= (M) - (U)	=	-
Cost	Cost /lb applied	**$0.70** (March 2006)	=	=	=	=
Environmental Criteria	Persistence	**Sediment** (140 days)	=	=	=	+
	Bioaccumulation	**BCF = 310**	+ (BCF = 25)	+ (BCF = 3.2)	+ (BCF = 190)	+ (BCF = 61)
	Aquatic (Fish) Toxicity	**> 0.0025 mg/l**	= (>0.015 mg/L)	= (>0.14mg/L)	= (0.55 mg/L)	+ (>100 mg/L)
Human Health Criteria	Carcinogen	EPA **B2**, IARC **3**	?	= (indicated in rodents – *CHAP 2001*)	?	?
	Reproductive Toxicity	**Yes** (Prop 65, EU; NOAEL = 3.7 - 100 mg/kg bw/d)	+	+	+	= (pot. feto toxicity)
	Occupational Exposure to Emissions (mfg)	**Yes**	=	=	?	-
	LD50	**34 g/kg**	?	+	+	-
	Irritation	**Yes** (Dermal, Ocular, Respiratory)	= (D,O) + (R)	+	=	+ (D) = (O,R)

Comparison Key + Better = Similar - Worse ? Unknown

Material Alternatives for DEHP/PVC Resilient Flooring

Flooring Material Alternative #1: Natural Linoleum

A natural product is a non-petroleum based, biodegradable product. Linoleum products are typically available in sheet and square form. While natural linoleum can be found in hundreds of colors and patterns (see Figure 7.4.1 G), there are currently fewer choices than for DEHP/PVC.

Figure 7.4.1 G: Typical Color Choices for Linoleum

Source: *Marmoleum 2006*

Construction

Natural linoleum is made from linseed oil, wood flour, resin, jute and limestone and calendared onto a natural jute backing. The table below lists materials commonly used in natural linoleum.

Table 7.4.1 D: Composition of Natural Linoleum Flooring[25]

Wt. %	Material	Origin/Precursor Materials
30	Wood powder	From wood sawdust, provides the unique characteristic of being able to bind with pigment; gives linoleum products colors and ensures long-term color-fastness.
25	Linseed oil	Obtained by pressing the seeds of the flax plant are linoleum's most important raw material (and the origin of its name).
20	Limestone	Found all over the world in large quantities; used in very finely ground form.
10	Jute	Spun from the fibers of jute plants in India and Bangladesh, it is the preferred backing of many natural linoleum products.
5	Resin	Typical resin sources include pine and spruce trees. Other resins include balsam or copal resins Balsam resin is obtained in a similar way to rubber, by tapping from plantation trees. Copal is a fossilized resin found in the ground in wooded environments in Africa, South America and Asia.
5	Cork flour	Ground bark of the cork oak. The bark is peeled every seven to ten years without damaging either the lifespan or the health of the tree.
5	Pigments	Manufacturers typically avoid the use of heavy metals pigments such as lead, hexavalent chromium and cadmium.

Installation/Cleaning/Maintenance

Professional installation is recommended since over 95% of reported complaints are due to faulty installation (Forbo Holding 2006). Most manufacturers offer a line of finishing and cleaning products. Manufacturers recommend that natural linoleum flooring be protected with a wax type finish or polish 2-3 days after installation. Everyday cleaning includes keeping floor dirt-free with a dry dust mop and/or dust cloth and spot removal with a neutral cleaner and damp cloth.

[25] Sources: Gunther and Langowski1997; Forbo Holding 2006, Armstrong, Inc. website (www.armstrong.com/resflram/na/linoleum/en/us/)

Financial

Natural linoleum's cost depends not only on the product and design, but also on the quantity of product purchased (as volume discounts are often available). Installation costs will vary according to contractor and location. Natural Linoleum flooring is expected to last between 25 and 40 years.

Table 7.4.1 E: Typical Costs Associated with Linoleum Flooring

Total Cost ($\$/ft^2$)	Material ($\$/ft^2$)	Installation ($\$/ft^2$)
~5.00	2 to 2.50	2.5

Environmental and Human Health Issues

The chief environmental impact associated with natural linoleum is eutrophication from the use of nitrogen and phosphate fertilizers used to grow linseed. However the amount of eutrophication depends upon the growing conditions. For example, flax in the US is primarily grown in North Dakota in 3 to 6 year rotations with other crops and requires no added nitrogen. VOCs, generated during the manufacturing process, are another concern with linoleum. While most VOCs are emitted during the manufacturing and drying process, residual VOCs can off gas following installation.

Other manufacturing-related pollution includes energy combustion and the associated greenhouse gases, particulate emissions and other air pollutants. Like DEHP/PVC, installation involves the use of water-based styrene butadiene floor adhesives. Linoleum is not recyclable but is compostable, however there is no infrastructure to collect and compost it at the end of life.

Table 7.4.1 F: Environment and Human Health Issues Associated with Natural Linoleum

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Natural Linoleum
Raw Materials	• Eutrophication and global warming impacts from the use of nitrogen based fertilizers to cultivate flax • Sustainability of natural ingredients not assured • Does not contain recycled content • Manufactured in Europe • No recycled content	• Derived from natural ingredients
Manufacture	• Energy use and associated greenhouse gas, particulate and other related emissions. • VOC generation during the manufacturing process	
Installation	• Styrene butadiene floor adhesive off-gas VOCs • Surface topcoat of acrylic usually applied	
Use and Maintenance	• Cleaning, waxing VOC off gassing potential	• Can be cleaned with a mild detergent
End of Life	• Not recyclable • Compostable but no infrastructure	• Biodegradable raw materials • Compostable • No chlorine products generated if incinerated

Environment, Health, and Safety Comparison of DEHP/PVC and Linoleum

There are numerous fact sheets and studies comparing linoleum and DEHP/PVC flooring. Studies and reports that use a hazards based analysis rank linoleum as safer than both VCT and vinyl sheet, citing the hazards of PVC precursor chemistry, plasticizers, and dioxin formation in manufacture and end-of-life combustion under suboptimal conditions. Studies based on life cycle generally conclude that linoleum has comparable or slightly fewer environmental impacts when compared with PVC sheet flooring of equivalent quality in the production phase (VBD 2004). Several studies point to the importance of detergent or chemical use in cleaning and maintenance, since across the useful life of the product the use of the associated maintenance chemicals/materials can lead to significant impacts (VBD 2004). One study that focuses solely on the use phase suggests that in PVC might have advantages over linoleum in this phase. This result is dependent on the frequency of cleaning, and type of cleaning (wax or polish) process used (Paulsen 2003). However this study did not examine indoor air quality issues. Regardless of the floor type (*e.g.,* DEHP/PVC or linoleum), wax-based systems are preferable to polish systems in many applications (Paulsen 2003). Higher quality products that require less use phase maintenance can significantly lower life cycle impacts (VBD 2004). The forthcoming US Green Building Council combined life-cycle risk assessment of VCT, vinyl sheet, linoleum and cork should provide additional insight into the tradeoffs between these materials.

Table 7.4.1 G: Summary of Comparison between DEHP/PVC and Linoleum

Life Cycle Assessment	Hazards Analysis
• Linoleum has comparable or lower environmental impacts compared to DEHP/PVC flooring of equivalent quality in the production phase. • In the use phase, the differences between DEHP/PVC and linoleum will depend more on the cleaning regime used more than the flooring material.	• Strong preference for natural linoleum over DEHP/PVC tile and sheet flooring

Flooring Material Alternative #2 - Natural Cork

Cork oak trees grow in forests in Portugal, Algeria, Spain, Morocco, France, Italy and Tunisia (Jones 1999). Bark is first stripped when trees are roughly 25 years old and approximately every nine years thereafter. No more than 50% of the bark is removed, and most cork oak trees survive many generations. After being removed from the tree, workers cut large slabs into strips that are stored in the forest for seven months or more to cure (Expanko 2006).

After harvest, the best cork is punched out to make bottle stoppers. The remaining is ground into granules, combined with binders, and baked in molds. Various temperatures produce different colors of cork and dyes are never used for coloring. To produce floor tiles, the blocks of baked cork are cut into slabs, sanded and varnished. Color variations are achieved by varying baking temperature (Jones 1999). Table 7.4.1 H lists the main constituents in cork flooring and their origins or component materials.

Table 7.4.1 H: Composition of Cork Flooring

Material	Origin/Precursor Materials
Cork granules	Cork oak trees
Binders	Urea-formaldehyde, urea melamine, phenol formaldehyde, polyurethane, or natural proteins

Installation/Cleaning/Maintenance

Any experienced hardwood and /or ceramic tile flooring installer can install cork (Expanko 2006). Regular cleaning includes vacuuming and light cleaning with a damp sponge mop. Ammonia-based cleaners or chemicals must not be used to clean cork floors. For routine care, sweep or vacuum to remove lose dirt before it can scratch or be ground into the floor’s surface.

Financial

Cork's cost depends not only on the product and design, but also on the quantity of product purchased (as volume discounts are often available). Installation costs will vary according to contractor and location. Current cost estimates for cork flooring are:

Cost of material (per square foot):	$4 - $6
Installation (per square foot):	$ 6
Overall cost (per square foot):	$10 - $12

Cork flooring is expected to last up to 80 years, which should factor into its overall cost when compared to other materials.

Environmental and Human Health Issues

There are relatively few environmental impacts associated with the growing and harvesting of cork. No fertilizers or pesticides are used to promote tree growth or kill pests. Cork forests are managed carefully in many countries (Jones 1999). The main issue associated with cork flooring manufacturing is the binders use to hold together the cork granules. Binder types include urea-melamine, phenol-formaldehyde (see Chapter 4 for discussion of EH&S issues associated with formaldehyde binders), or polyurethane.

During the installation phase, indoor air quality problems can exist with the adhesives, finishes, or sealers used. Both water-based and polyurethane-based adhesives are used. Cork is also finished similarly to wood, using wax or polyurethane. Off-gassing will depend on the type of finish applied. Pre-finished cork tiles are on the market, eliminating the need for on-site finishing, but this results in a lack of sealing around the individual tile joints (Jones 1999). Unlike with other floorings, cork can be installed as a floating floor, with no adhesive use required.

Table 7.4.1 I: Environment and Human Health Issues Associated with Cork

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Cork
Raw Materials	• Binder manufacture • Cork imported from Spain, Portugal and Africa	• Very few impacts associated with cork growing and harvesting • Renewable resource
Manufacture	• Worker exposure to binders	
Installation	• Off-gassing of adhesives	
Use and Maintenance	• Off-gassing of polyurethane maintenance coatings	• Hypoallergenic
End of Life	• Not recyclable • Compostable but no infrastructure	• Compostable • No chlorine products generated if incinerated

Environment, Health, and Safety Comparison of DEHP/PVC and Cork

There are numerous fact sheets and studies comparing cork and DEHP/PVC flooring. Studies and reports that use a hazards based analysis rank cork as safer than both VCT and vinyl sheet, citing the hazards of PVC precursor chemistry, plasticizers, and dioxin formation in manufacture and end-of-life combustion under sub-optimal conditions.

A combined life-cycle risk assessment of VCT, vinyl sheet, linoleum and cork has been conducted by Georgia Technical Research Insitute (Jones 1999) using the EPA BEES (Building for

Environmental and Economic Sustainability) software. It is an extensive assessment that can be viewed at the Georgia Tech website[26]. In general, it indicates that cork has a better life cycle profile than the vinyl flooring alternatives. Another study compared cork flooring to cork finished with a PVC top laminate to protect the cork surface. This study found that cork flooring with a PVC top laminate had significantly higher ecological impacts than cork without the laminate, even if cork polyurethane refurbishing interval was assumed to be every 2 years (Althaus and Richter 2001).

Table 7.4.1 J: Summary of Comparison between DEHP/PVC and Cork

Life Cycle Assessment	Hazards Analysis
Cork exhibits better life cycle impact profile than VCT	Strong preference for cork over DEHP-PVC tile and sheet flooring.

Flooring Alternative #3 – Polyolefin Flooring

A combination of synthetic copolymer resins and limestone, this material is manufactured by Amtico Company, based in Coventry, United Kingdom, under the name Stratica. This flooring material was specifically designed for large, high-traffic commercial areas and is used in health care facilities, ships, shopping centers, and airports. According to the Stratica website[27], the product offers the convenience and durability of DEHP/PVC flooring and is easy to install.

Construction

Polyolefin flooring consists of two layers of polymers. The bottom layer is made from ethylene copolymers and includes chalk and clay as filler materials. The top layer consists of an ionomer coating called Surlyn™, created from ethylene/methacrylic acid copolymers.

Table 7.4.1 K: Composition of Polyolefin Flooring

Material	Origin/Precursor Materials
Polyethylene	Ethylene from natural gas or oil
Chalk	Abundant naturally occurring mineral
Clay	Abundant naturally occurring mineral
Suryln	Ethylene/methacrylic acid

Source: *Fisher 1999*

Installation/Cleaning/Maintenance

Polyolefin flooring is installed using VOC-free adhesives. Cleaning and maintenance are simple. Flooring can be swept or vacuumed and mopped with water when necessary. Amtico says the flooring is scuff-resistant and that in abrasion tests, it performed 10 times better than linoleum, and twice as well as quality vinyl tiles and laminates (Fisher 1999).

Financial

Polyolefin flooring comes in a variety of patterns that mimic natural flooring, including solids, marbles, granites, stones, terrazzos, and woods. Polyolefin flooring is priced slightly higher than high-end vinyl flooring. The manufacturer claims that the cost savings in installation and maintenance over the long term result in significant overall cost saving. Purchase and installation

[26] http://maven.gtri.gatech.edu/sfi/resources/pdf/TR/Resilient_flooring.pdf

[27] www.stratica.com

costs are estimated to be $5 to $6 per square foot. The lifespan of polyolefin flooring is anticipated to be higher than DEHP/PVC flooring, though less than that of cork (Lent 2006).

Environmental and Human Health Issues

The chief environment and human health issues associated with polyolefin center around the extraction and processing steps. Impacts include extraction and refining of ethylene and mineral feedstocks and the greenhouse gas and other air pollutants associated with these activities. One of the chief benefits of polyolefin flooring is during the use phase due to its durability and ease of maintenance. Polyolefin flooring can be cleaned with a mild detergent. No polishing or waxing or other finishing (unlike DEHP/PVC tile and sheet, linoleum or cork) is required. In addition, unlike DEHP/PVC tile and sheet and linoleum, polyolefin flooring has very low VOC emissions associated with it once installed.

Table 7.4.1 L: Environment and Human Health Issues Associated with Polyolefin Flooring

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Polyolefin
Raw Materials	• Extraction and refining of petroleum based feedstocks • Ethylene feedstock is non-renewable • No recycled content	
Manufacture	• Energy use • Associated greenhouse gas, particulate and other related emissions	
Installation	• Styrene butadiene floor adhesive off gas VOCs	
Use and Maintenance		• Can be cleaned with a mild detergent • No polishing or waxing required • Very low VOC emissions
End of Life	• No recycling infrastructure in place	• Recyclable • No chlorine products generated if incinerated

Environment, Health, and Safety Comparison of DEHP/PVC and Polyolefin Flooring

There are several green building websites and fact sheets comparing polyolefin and DEHP/PVC flooring. Studies and reports that use a hazards-based analysis rank polyolefin preferably to VCT and vinyl sheet, citing the hazards of PVC precursor chemistry, plasticizers, and dioxin formation in manufacture and end-of-life combustion under sub-optimal conditions. According to Environmental Building News, the German Frauenhoffer Institute prepared a LCA comparing polyolefin and vinyl flooring. It appears that this is the only LCA study on polyolefin flooring that has been conducted to date. The study found that the production of polyolefin flooring requires 30% less energy and 29% less water than the production of vinyl, resulting in 33% less contribution to global warming and 54% less acidification (Healthy Building Network (HBN) 2005). The Institute was unable to independently review the Frauenhoffer study to examine boundary conditions and other important study assumptions.

Summary of Material Alternatives Assess for Resilient Flooring

Table 7.4.1 M summarizes the Institute's assessment of material alternatives to DEHP/PVC resilient flooring.

Table 7.4.1 M: Materials Alternatives Assessment Summary for Resilient Flooring

Assessment Criteria		DEHP/PVC Reference	Comparison of Materials to DEHP/PVC		
			Linoleum	Cork	Polyolefin
Performance Criteria	Color/Pattern Choices	**Large**	=	-	=
	Ease of Maintenance	**Easy**	=	=	=
	Recyclable	**Yes**	-	-	=
Cost	Purchase and Installation Cost	**$2 - $10/ft^2**	=	=	=
	Expected Lifespan of Material	**25+ years**	+	+	+
Environmental Criteria	Derived from Sustainable Material	**No**	+	+	=
	Use Environmentally Preferred Materials for Installation	**Possible**	=	+	=
	Energy Use/ GHG emissions (mfg)	**Ref .**	+	?	=
	Biodegradable/ Compostable	**No**	+	+	=
Human Health Criteria	Emissions of VOCs • Manufacture • Installation • Use	**Yes (M, I, U)**	=	=	= (M, I) + (U)

Comparison Key + Better = Similar - Worse ? Unknown

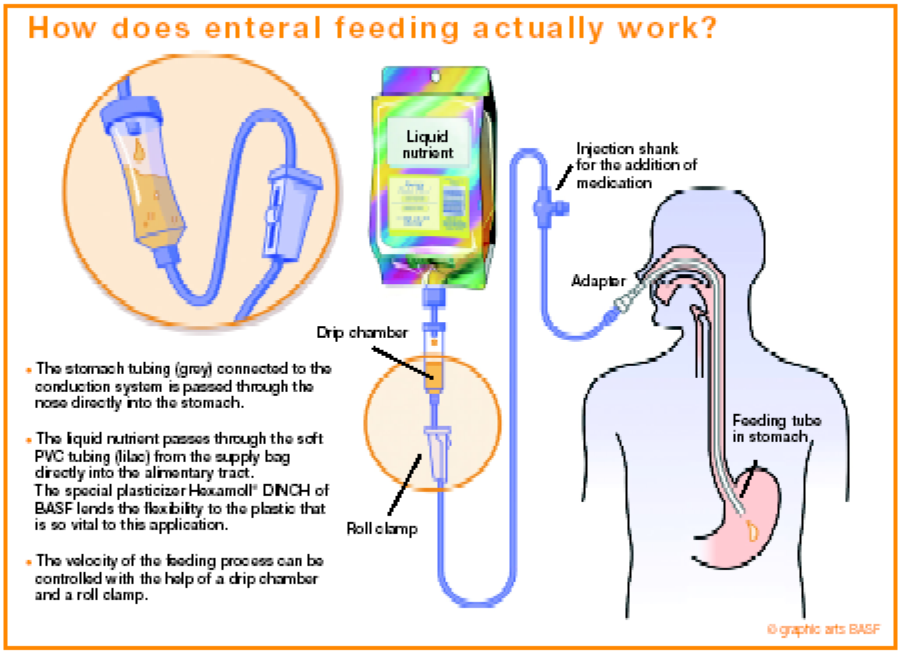
7.4.2 Alternatives Assessment for Medical Devices for Neonatal Care: Sheet and Tubing Applications

PVC is widely used as a plastic in medical sheet and tubing type devices. Studies suggest that as much as 25% of all plastics used in hospital environments are PVC. Regardless of the material or plasticizer used in a medical device, however, there are certain characteristics that are desirable for these applications.

Figure 7.4.2 A, created by BASF[28] illustrates a common use of both sheet and tubing in medical applications, in this case enteral feeding.

[28] Go to www.corporate.basf.com and click on "Science Around Us"

Figure 7.4.2 A: Example of medical sheet and tubing application



Technical Considerations for Medical Devices in General

Medical devices used in neonatal procedures include bags used to store a variety of medical solutions, and tubing used to transfer those solutions to the neonate.

An interesting issue associated with DEHP as the plasticizer is that it apparently functions as an inadvertent preservative for blood platelet storage. It is now well established that red blood cells can be stored for up to 72 hours in DEHP plasticized blood bags. The required shelf life of red blood cells in storage is a 75% survival for 24 hours after infusion on the last day of storage. DEHP improves red blood cell storage by reducing haemolysis and membrane loss (Hill et al. 2001). The result is that red blood cells stored in PVC bags plasticized with DEHP have a shelf-life of up to 42 days (American Association of Blood Banks (AABB) 2006). Baxter, the leading manufacturer of blood bags in the United States, introduced a non-DEHP PVC red blood cell bag in 1991 (Plastics Week 1992). That bag, plasticized with butyryl-trihexyl citrate (BTHC) performs as well the DEHP bag, with the same shelf life as the DEHP bags (Food and Drug Administration (FDA) 1999).

One study looked at the effect of DEHP plasticizer on stored platelets (Racz and Baroti1995). They found that platelet aggregation was the only parameter that was slightly inhibited in DEHP-plasticized bags indicating that the presence of DEHP had no harmful effect during storage especially if bags are manufactured to assure higher gas permeabilities. However, the majority of platelets used in the US today are stored in non-DEHP bags. For platelets, a 40% recovery after 72 hours of storage is generally considered acceptable (FDA 1999).

In vitro studies showed that DEHP reduced platelet functions such as aggregation responses and the percentage of hypotonic shock responses. It also prevented morphological changes in platelets which are frequently seen in TOTM and BTHC plasticized PVC bags (Racz and Baroti 1995). These changes have been explained on the basis of the migration of DEHP into the plasma stabilizing platelet membrane and thereby preventing changes. This apparent preservative function seems to only be a factor in the storage of blood platelets, and therefore will not be described in more detail here.

Characteristics that are important to consider for medical device applications include aesthetic properties and physical properties. Desirable aesthetic properties of materials used in medical devices include color, clarity and odor. When choosing a material for medical devices it is important to also consider tensile strength, cold flexibility and elastic recovery. In addition, the choice of material or plasticizer must consider post manufacture technical issues, primarily its ability to withstand harsh sterilization procedures.

Aesthetic Properties of Medical Devices

Color is considered important in that it conveys "purity of product" to the user. Plasticizers are therefore more desirable if they result in colorless compounds and articles. PVC additives that produce materials that are semi-opaque or yellow in appearance may be perceived by medical staff and hospitals to be imperfect or contaminated.

In general, medical device manufacturers and users prefer that the devices be colorless and clear or transparent. Transparency allows for the end user to see the contents of any article or device made from the material, which is not only important from a perception standpoint, but also from a safety standpoint, so that medical staff can visually confirm that they have the solution they intend to be using, that the amount they need is present, and that there are no obstructions or contaminants present.

For the purposes of this assessment the Institute focused its assessment of aesthetic properties purely on color and clarity.

Physical Properties of Medical Devices

For medical device manufacturing, the design of the device must consider physical properties that influence processing and use.

Medical device materials need to have sufficient tensile strength to ensure that the article remains durable and intact throughout its intended service life. Issues can arise around potential mishandling or inappropriate storage of the device. Therefore the tensile strength of the material used should be sufficient to allow the medical device to be maintained throughout the intended service life of the product.

The material needs to retain its flexibility at low temperatures, as products are likely to be used or stored in low temperature environments. In particular, blood storage must be maintained at temperatures ranging from 2°C (for whole blood and red blood cells) to 20°C (for platelets) when not in use. The cold flexibility of the material needs to be maintained throughout the service life of the product to avoid breakage due to embrittled materials.

The rate or degree at which a material returns to its original shape after being deflected – its elastic recovery – is another important physical property of a medical device for many applications, though especially in flexible PVC tubing (*e.g.,* for use in peristaltic pumping applications). The possibility of a kink developing in a tubing device could result in inefficient delivery of the intended medical solution thereby potentially endangering the health of the patient.

One of the primary considerations of choice of plasticizer or material for medical devices relates to its ability to be sterilized as a whole unit. Sterilization of medical devices must reach 121°C to meet FDA criteria (for IV solutions), and is done through three basic mechanisms: gamma radiation, ethylene oxide and steam (autoclaving). Another sterilization process used by some healthcare facilities is electron beam sterilization, however this is much less widely practiced. Specific considerations associated with sterilization using the three primary mechanisms are summarized in Table 7.4.2 A.

Table 7.4.2 A: Medical Device Sterilization Requirements

Sterilization Mechanism	Functional Requirements
Gamma Radiation (R)	• The plasticizer should be sufficiently stable towards the energy disposition associated with the radiation sterilization process. • No sweating should occur
Ethylene Oxide (EO)	• The plasticizer should be sufficiently stable towards the heat, humidity and chemicals associated with the ethylene oxide sterilization process. • No sweating should occur
Steam (S)	• The plasticizer should be sufficiently stable towards the heat and humidity associated with the steam sterilization process. • No sweating should occur. • A low vapor pressure is desirable so the plasticizer does not distil away.

Designing a medical device to withstand the sterilizing conditions it will likely be subjected to is essential.

When evaluating plasticizers for PVC, it is also important to consider the potential of the plasticizer to migrate out of the PVC matrix and interact with the substance (*e.g.,* drug, blood, solution) that it will come into contact with. As mentioned previously, DEHP does interact with blood platelets, resulting in a preservative effect. The United States Pharmacopoeia (USP) has created standards that devices must adhere to in order to minimize the potential for undesirable migration into the medical solution. Plasticized materials must meet USP[29] Class VI standards[30]. The goal is to avoid any adverse impact on drug efficiency, and to minimize the potential for the plasticizer to migrate into the substance, thereby entering the body during use. Because of this issue, DEHP/PVC is generally not recommended for packaging certain medications with high lipid content (*e.g.,* Taxol).

Financial Considerations for Medical Devices in General

Several companies market DEHP-free products in the US. In general, the cost of the non-DEHP devices is greater than that of DEHP-containing devices. The status of relative costs may change as the demand for DEHP-free products increases. In addition, some of the alternative materials to DEHP/PVC may have longer shelf lives or allow for multiple usage that would result in an overall cost savings over time. When evaluating alternative plasticizers or materials it is valuable to consider both the raw material costs, the cost savings from increased shelf life and multiple usage, as well as the impact on usage costs such as modified sterilization requirements. Because most of this

[29] United States Pharmacopoeia is a private (non-governmental) organization that "promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies." Those standards include in vivo animal biological reactivity tests for "elastomerics, plastics and other polymeric material with direct or indirect patient contact."

[30] USP Monograph 88 describes the classification of plastics into six classes based on responses to a series of *in vivo* tests for which extracts, materials and routes of administration are specified. Class VI requires the most stringent testing of the six classes. Although USP Class VI testing is widely used and accepted in the medical products industry, some view it as the minimum requirement a raw material must meet to be considered for use in health care applications. USP Class VI testing does not fully meet any category of ISO 10993-1 testing guidelines currently used by the US FDA (General Program/Bluebook Memorandum G95-1) for medical device approval.

information is proprietary, anecdotal or situation-specific, this assessment does not address economic considerations in detail.

Environmental and Human Health Considerations for Medical Devices in General

The primary concerns associated with the use of DEHP in medical devices for neonatal care is its ability to migrate out of the polymer matrix resulting in a direct exposure to a very vulnerable population. Once exposed to DEHP, the human body metabolizes it into chemicals that, along with DEHP, exhibit potential reproductive toxicity, particularly in males. In fact, in its 2002 Public Health Notification the Food and Drug Administration recommended that health providers consider using alternatives to DEHP-containing medical devices when high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males (FDA 2002). When assessing alternative plasticizers, the ability of the plasticizer to migrate, or exude, out of the polymer matrix is particularly pertinent, as is assessing the potential additional effect of metabolites on the neonate.

Specific Plasticizer Alternatives Assessed for Medical Devices

Plasticizer alternatives that were prioritized for medical devices include TOTM, DEHA, BTHC, and DINCH. These plasticizers represent a trimellitate, an adipate a citrate and a carboxylate, which are discussed in more detail below. A short discussion of the technical, economic and environmental, health and safety attributes will be presented for each alternative, then the information for all alternatives will summarized and compared.

Sheet Devices

In its 2000 report entitled "Use of DEHP in PVC Medical Devices: Exposure, Toxicity and Alternatives", the Lowell Center for Sustainable Production reports that the medical sheet or bag market can broadly be divided it into three use categories: 1) IV solution, 2) blood, and 3) other bags, such as collection and specimen bags. IV bags represent the largest end-use, with 55% of the U.S. PVC medical bag market, followed by blood bags (25%) and other bags (20%) (Tickner 2000).

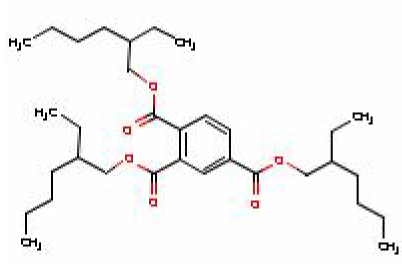
Based on our alternatives prioritization process, the following plasticizers were assessed for medical sheet device applications: TOTM, DEHA, BTHC and DINCH. The following is a summary of these plasticizer alternatives, focusing on the associated technical, cost (when available and not addressed previously) and EHS considerations.

TOTM

TOTM (trioctyl trimellitate, or tri (2-ethylhexyl) trimellitate) is a clear oily liquid that is a high production volume[31] plasticizer in the US. Its specific chemical structure is shown in Figure 7.4.2 B.

[31] Production exceeds 1 million pounds per year.

Figure 7.4.2 B: Chemical Structure of TOTM



TOTM is manufactured in the US by BASF under the brand name Palatinol®. According to the manufacturer, the performance of TOTM as a PVC plasticizer is similar to DEHP. TOTM is significantly less volatile than DEHP, which potentially results in less occupational exposure to fugitive emissions during manufacture. TOTM is therefore used in applications where low volatility is desirable.

TOTM has good PVC compatibility and is resistant to extraction by soapy water (an indication of its lipid solubility). In addition, TOTM plasticized bags possess sufficient gas permeability to be suitable for storage of platelets for over 72 hours (Nair 2002). In the medical device industry, TOTM is currently used primarily in blood and bag infusion sets. While one study reported that trimellitates migrate to the blood faster than DEHP (Yin et al. 1999), the majority of other studies reviewed found that it was more difficult to exude TOTM into lipid-soluble solutions than DEHP.

The manufacturer's literature refers to the cost of TOTM as "relatively low" and March 2006 data obtained from an industry source indicates that the cost is approximately 1.5 times that of DEHP (Teknor Apex 2005). According to the Danish Study, the price of TOTM was significantly lower than they expected. It is not expected that the cost of TOTM will be an insurmountable issue in the use of medical devices.

An industry consortium in Japan conducted a review of data available on the environmental and human health impacts of TOTM in 2002 (*Organization for Ecocnomic Cooperation and Development (OECD) 2002*)[32]. This evaluation indicated that TOTM exhibits weak toxicity in aquatic environments, and may pose a reproductive toxicity concern as evidenced by exposure to male rats. The primary routes of human exposure to TOTM during manufacture are anticipated to be via dermal contact or inhalation of mist. However studies have shown that TOTM is difficult to extract from its polymer matrix (OECD 2002) and is therefore not expected to present a significant exposure concern for patients for whom medical devices containing TOTM are used.

DEHA

DEHA is an adipate plasticizer whose specific chemical structure is shown in Figure 7.4.1F. Adipates are diesters of aliphatic dicarboxylic acids and are produced with varying alcohol groups. The low-temperature properties of DEHA potentially make it a favorable plasticizer for materials used to store cold solutions (*e.g.,* blood). DEHA is known to be slightly more difficult to process compared with DEHP.

DEHA is less compatible with PVC than DEHP, which can lead to exudation (*i.e.,* plasticizer migrating to the surface), increasing the potential for DEHA to enter the medical solution and, through use, the patient's body. The Danish EPA determined that DEHA has the potential to

[32] The "Screening Information Data Set" (SIDS) program operated under the auspices of the Organization for Economic Cooperation and Development (OECD) is a voluntary cooperative international testing program that began in 1989

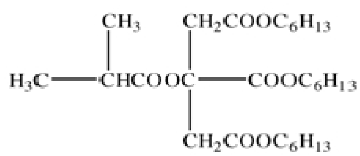
migrate from the PVC matrix into fatty solutions. They conducted a review of toxicological data associated with a number of plasticizers, including DEHA. The most sensitive population potentially exposed to DEHA as a plasticizer in medical devices is neonatal patients (as it is with DEHP). A NOAEL of 610 mg/kg bw/day has been reported (DEPA 2001), which is less toxic than the NOAEL for DEHP. However the Institute did not identify any studies evaluating the impact of exposure on male reproductive system. The Chronic Health Advisory Panel for the US Consumer Product Safety Commission quotes a study that indicates a fetotoxicity issue associated with oral exposure to DEHA (CHAP 2001).

The primary metabolite associated with human exposure to DEHA is 2-ethylhexanoic acid (EHA). The Institute did not identify any specific health hazards associated with exposure to EHA.

BTHC

Butyryl trihexyl citrate (BTHC) is a higher molecular weight plasticizer specifically designed for use in medical articles especially blood storage bags. The chemical structure of BTHC is shown on Figure 7.4.2 C.

Figure 7.4.2 C: Chemical Structure of BTHC



According to the manufacture (Morflex, Inc.), its BTHC plasticizer (Citroflex® B-6) is a component of several FDA approved blood bag systems and provides improved low temperature properties relative to the phthalate plasticizers and superior long-term stability for red blood cells. Citroflex® B-6 has low extractability into lipid media, making it particularly useful for blood products. According to Morflex, Citroflex® B-6 is a specially formulated citric acid ester for use in PVC medical articles such as tubing and IV bags where the content medium is aqueous-based. The manufacturer therefore claims that BTHC nearly duplicates the properties of DEHP for these applications[33].

According to industry experts, the cost of BTHC is significantly higher than DEHP, with raw material costs estimated at $1.15/lb (compared to DEHP's cost of $0.70/lb).

Very little information is available on this plasticizer's migration potential from the PVC matrix or on its potential health effects if patients are exposed to it. BTHC is metabolized to butyric acid, hexanol, and citrate. When exposed to butyric acid humans may experience gastrointestinal, liver and/or skin effects.

[33] http://www.morflex.com/pdf/bul101.pdf

DINCH

Di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH) is manufactured exclusively by BASF under the brand name Hexamoll®. DINCH is the hydrogenated product of the corresponding di C9 phthalate ester (DINP). Its performance characteristics in PVC are expected to be similar to the phthalate counterpart, except for having less solvency for PVC. The manufacturer of DINCH reports that it does not appreciably migrate out of the PVC matrix when used in medical devices.

Manufacturer experience indicates that the plasticizer does not alter the properties of PVC nor change its final characteristics, so that it can be processed on existing processing equipment (Sparrow 2002). Many PVC alternative materials require new production lines or extensive retrofitting, thus increasing overall costs beyond what the marketplace will bear. Processing of PVC plasticized with DINCH only requires fine-tuning the formulation and the processing temperature to achieve the same results.

In a fact sheet prepared by Eastman Chemical (Eastman Chemical Company 2004) a comparison of certain performance characteristics for various plasticizers is presented. In this technical fact sheet, Eastman shows that DINCH is comparable to DEHP and DINP in tensile strength, elongation and modulus, but that it requires more time and energy to fuse with PVC. This may be an issue for certain medical devices, however no other indication of this drawback could be found during our research.

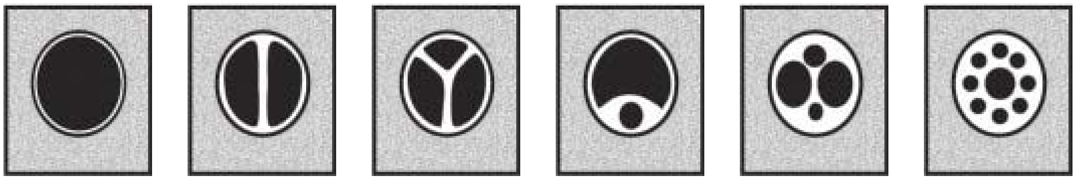
Very little information is available from the manufacturer on the cost, performance or EH&S considerations associated with DINCH, other than what has been discussed above. Other industry sources have provided a cost estimate of $0.21 more per pound than DEHP for 70 Shore A compounds. Bayreuth, a German medical device manufacturer, has switched to manufacturing its medical devices using DINCH. "If you consider the current status of the toxicological tests, then the market will likely be prepared to accept the slightly higher price. Hexamoll® DINCH offers good value for money overall," states Bayreuth's managing director Jürgen Rotter (Sparrow 2002).

In addition, by removing the aromatic ring associated with DINP, the overall toxicity associated with DINCH is expected to be reduced. BASF indicates that it has much lower potential for negative impacts on human or environmental health; consequently, BASF has introduced DINCH as a candidate for medical device applications such as for use with neonates. BASF is currently in discussions with FDA concerning submission of DINCH for approval for use in medical devices (Schaefer 2006).

Tubing Devices

Medical tubing is made from a variety of materials including metal, plastic, and synthetic rubber. Some medical tubing features diameters that measure in the thousandths of an inch, with walls thinner than a human hair. These small, specialty tubes can cost many times more than conventional high-volume tubes, but are well-suited for catheters and other medical devices that are inserted into a patient's cardiovascular system. In general, medical tubing manufacturers seek to reduce the outside diameter (OD) of their products while maintaining as large an inside diameter (ID) as possible. Figure 7.4.2 D illustrates cross-sections of some common tubing configurations.

Figure 7.4.2 D: Common configuration cross-sections of medical tubing devices



The plasticizer alternatives being assessed for tubing uses are limited to DINP and DEHA. Discussions of each chemical are found previously in this section of the report. The primary factor that delineates tubing uses from sheet uses in medical device applications is the requirement for elastic recovery.

DINP

DINP is a mixture of phthalates with branched alkyl chains of varying length (C8, C9 and C10). The chemical structure of DINP is depicted in Figure 7.4.1B.

DINP has been used as a plasticizer in medical tubing devices because it exhibits similar clarity and elastic recovery properties to DEHP.

Workplace air standards for external exposure have not been established for DINP, which although considered an animal carcinogen, has not been classified as to human carcinogenicity (CDC 2005).

When introduced into the human body, DINP is metabolized through similar mechanisms as described for DEHP metabolism. The primary metabolite for DINP is MINP (mono-isononyl phthalate). People exposed to DINP will excrete small amounts of MINP in their urine (CDC 2005). Studies of oral exposures of DINP to rats indicate that it is primarily metabolized in the body, with the majority of the un-metabolized DINP and its metabolites being excreted within days of exposure. The major routes of excretion for orally administered DINP in rats were urine and feces, with about equal amounts excreted by either route at low doses, but more excreted in feces at high doses (Midwest Research Institute (MRI) 1983). Repeated dosing caused no accumulation of DINP or its metabolites in blood or tissue, but resulted in increased formation and elimination of the monoester side-chain oxidation products (MRI, 1983).

According to the Chronic Health Advisory, exposure to DINP results in potential acute toxic effects (CHAP 2001). The NOAEL for systemic toxic effects induced in laboratory animals by exposure to DINP is estimated between 15 mg/kg bw/d and 88 mg/kg bw/d. To put this into context, a study by the Consumer Council Austrian Standards Institute (Fiala) used the lowest NOAELs for DINP and DEHP to determine a total daily intake level for these plasticizers (this study focused on the use of DINP and DEHP in children's toys that would be mouthed and used a safety factor of 100) of 150 μg/kg bw/d for DINP and 37 μg/kg bw/d for DEHP.

According to its review of relevant studies, the CHAP concludes that DINP is clearly carcinogenic to rodents. The studies they reviewed also suggest possible carcinogenicity in the testis, uterus, and pancreas (CHAP 2001). DINP has not been tested for carcinogenicity in young rodents, an important limitation with respect to this assessment, as it is exposure to the very youngest population that the Institute is focusing on for medical device applications. However, DINP has not been listed as an EPA or IARC possible human carcinogen.

DEHA

In addition to the discussion of DEHA for medical sheet uses, it is important to also consider a key performance parameter for DEHA use in tubing – elastic recovery. DEHA is reported to exhibit similar elastic recovery properties to DEHP (DEPA 2003). When exposed to the human body, DEHA can be metabolized into EHA, which does not have clearly identified human health concerns associated with it.

Table 7.4.2 B summarizes the assessment criteria associated with plasticizer alternatives to DEHP in medical devices[34].

[34] Refer to Appendix C for the complete summation of EH&S factors associated with the various plasticizers evaluated for each use of DEHP.

Table 7.4.2 B: Medical Device Plasticizer Alternative Assessment Criteria

Plasticizer Acronym	Performance and Cost Primary Criteria								Environmental Health and Safety Criteria								
	Physical and Aesthetic Properties				Processability			**Cost** per pound (Normalized using SF)	Carcinogen	Reproductive/ Developmental Toxin	Sediment Persistence	Bioaccumulation (BCF)	Other Health Effects		Fish Toxicity (mg/L)	Migration	Metabolite of Concern
	Clar-ity	Tensile Elong-ation	Cold Flexi-bility	Elastic Recov-ery	Steriliz-ability	PVC Compatibility	Emission During Mfg/ Use						LD50 (oral -g/kg)	Irritation (D,O,R)			
DEHP	Exc. (Ref)	Ref (MW 390)	Good (Ref)	Slow but acceptable (Ref)	Ref	Ref	Ref	$0.70	EPA Class B2, IARC Class 3	Listed in Cal Prop 65, EU R43	140	310	34	D, O, R	No effect at 0.0025	Possible migration in lipid soluble drugs	MEHP (repro toxin)
DEHA	Exc.	Similar to DEHP MW 370-390	Good	Slow but acceptable	Similar to DEHP	Fair	Lower volatility than DEHP	$0.70	Not listed	Potential fetotoxicity *(CHAP 2001)*	78	61	5.6	O, R	>100 at 96 h	Migration probable	EHA (not known to be toxic)
DINP	Exc.	Higher than DEHP MW 418	~ better than DEHP	Slow but acceptable	Similar to DEHP; slightly more tolerant of steam than DEHP	good	M: Expected to be similar to DEHP U: Slightly less than DEHP	$0.77	Indicated in rodents *(CHAP 2001)*	Not listed	140	3.2	Unknown	No	>0.14 at 96 h	Expected to be similar to DEHP	MINP (possible repro. toxin)
DINCH	Good	Higher than DEHP MW 514	Better than DEHP	Comparable to DEHP	Unk.	good (per mfgr)	Unknown	$0.91	Not listed	Not listed	Unk.	189	>5000	No	>100 (LC50)	Manufacturer claims low	Unk.

Table 7.4.2 B: Medical Device Plasticizer Alternative Assessment Criteria

Plasticizer Acronym	**Performance and Cost Primary Criteria**								**Environmental Health and Safety Criteria**								
	Physical and Aesthetic Properties				Processability			**Cost** per pound (Normalized using SF)	Carcinogen	Reproductive/ Developmental Toxin	Sediment Persistence	Bioaccumulation (BCF)	Other Health Effects		Fish Toxicity (mg/L)	Migration	Metabolite of Concern
	Clar-ity	Tensile Elong-ation	Cold Flexi-bility	Elastic Recov-ery	Steriliz-ability	PVC Compatibility	Emission During Mfg/ Use						LD50 (oral -g/kg)	Irritation (D,O,R)			
DEHP	Exc. (Ref)	Ref (MW 390)	Good (Ref)	Slow but acceptable (Ref)	Ref	Ref	Ref	$0.70	EPA Class B2, IARC Class 3	Listed in Cal Prop 65, EU R43	140	310	34	D, O, R	No effect at 0.0025	Possible migration in lipid soluble drugs	MEHP (repro toxin)
TOTM	Exc.	Higher than DEHP MW 546	~ worse than DEHP	Slow	Similar to DEHP	good	Significantly lower than DEHP (M & U), by 1:5 ratio	$1.11	Not listed	Potential toxicity in male rats (*SIDS 2002*)	78	3.2	Unknown	D, O	>100 @ 96 h	Difficult to extract from polymer matrix	Unk.
BTHC	Good	Higher than DEHP MW 514	Better than DEHP	Unknown	Similar to DEHP; hydrolysis expected for steam	Probably satisfactory	Good ventilation required (M&U)	$1.12	Not listed	Mfgr literature indicates no toxic effects	78	44	Unknown	No (according to mfgr)	Not Est.	Low extractability into lipid-soluble media	Butyric acid (irritant)

Notes: D = dermal, O = ocular, R = respiratory
Refer to Table 7.4B for cost references
Environmental and human health references from Table C5 in Appendix C
Processing values primarily from Danish EPA study (DEPA 2001), as well as other industry sources

Summary of Plasticizer Alternatives Assessed for Medical Devices

Table 7.4.2 C summarizes the plasticizer alternatives assessment in comparison to DEHP for use in medical devices for both sheet and tubing applications. Recall that only DINP and DEHA were evaluated for tubing applications. Refer to Table 7.4 A for specific information associated with determining the comparative assessment of plasticizer alternatives for this application. Refer to Table 7.4.2B for other data.

Table 7.4.2 C: Summary of Plasticizer Alternatives Assessment for Medical Devices

Key Assessment Criteria		DEHP (Reference)	Comparison Relative to DEHP				
			TOTM	DEHA	BTHC	DINCH	DINP
Technical/Performance Criteria	Clarity	**Excellent**	=	=	=	=	=
	Cold Flexibility	**Good**	-	=	+	+	+
	Elastic Recovery	**Slow** but acceptable	=	=	?	=	=
	Sterilizability • Radiation • EO • Steam	**Good** (R, EO, S)	=	=	= (R,EO) - (S)	?	= (R,EO) + (S)
	PVC Compatibility	**Good**	=	-	=	=	=
	Plasticizer Loss • Manufacture • Use	**Acceptable** (M, U)	+ (M, U)	- (M, U)	- (M + (U)	? (M) + (U)	= (M, U)
Cost	Cost /lb applied (70 Shore A)	**$0.70** (March 2006)	-	=	-	-	=
Environmental Criteria	Persistence	**Sediment** (140 days)	+	+	=	?	=
	Bioaccumulation	**BCF = 310**	+ (BCF = 3.2)	+ (BCF = 61)	+ (BCF = 44)	+ (BCF = 189)	+ (BCF = 3.2)
	Aquatic (Fish) Toxicity	**> 0.0025 mg/L**	+ (>100 mg/L)	+ (>100 mg/L)	?	+ (>100 mg/L)	= (>0.14 mg/L)
Human Health Criteria	Migration (lipid-soluble)	**Yes**	+	=	+	+	=
	Occupational Exposure to Emissions (mfg)	Yes	+	-	-	?	= (M)
	Carcinogen	EPA **B2**, IARC **3**	?	?	?	?	= (indicated in rodents – *CHAP 2001*)

Table 7.4.2 C: Summary of Plasticizer Alternatives Assessment for Medical Devices

Key Assessment Criteria		DEHP (Reference)	Comparison Relative to DEHP				
			TOTM	DEHA	BTHC	DINCH	DINP
	Reproductive Toxicity	**Yes** (Listed on CA Prop 65, EU R60 and R61)	= (pot. toxicity in male rats)	= (pot. feto toxicity)	+	+	+
	LD50	**34 g/kg**	+	-	?	+	+
	Irritation	**Yes** (Dermal, Ocular, Respiratory)	= (D,O) + (R)	+ (D) = (O,R)	+	+	+
	Metabolite of Concern	**Yes** (MEHP, a reproductive toxin)	?	? (no effects identified for EHA)	= (GI, liver and skin effects associated w/ butyric acid)	?	? (no effects identified w/MINP)

Comparison Key + Better = Similar - Worse ? Unknown

Medical Device Material Alternatives

In addition to considering alternative plasticizers for PVC, there are alternative materials that would not require a plasticizer, either because they are inherently flexible, or because they fulfill the function without being plasticized. For materials that are inherently flexible, the potential for the material to become brittle due to loss of plasticizer is eliminated, therefore these materials may have longer shelf lives than their PVC-based counterparts and the possibility of leached plasticizer entering the body is eliminated (important considerations in the medical device industry). Types of alternative materials that are appropriate for medical devices and will be further evaluated include an inorganic substance (glass, which is not a flexible polymer, but the material has been used historically for many medical applications), an elastomer (silicone), a copolymer (ethylene vinyl acetate, EVA), thermoplastic olefins (polyethylene, PE, and polypropylene, PP) and a thermoplastic resins (thermoplastic polyurethane, TPU).

Manufacturers of medical devices such as Hospira and Baxter, who together command approximately 90% of the market, have been in the news lately, touting their new lines of sheet devices (*i.e.,* IV bags) that are 'PVC-free' and therefore, DEHP-free (Waldman 2006). In addition, many large hospital chains have increasingly been making purchasing decisions that include DEHP and/or PVC-free materials[35]. Therefore the availability of feasible alternatives to DEHP in PVC sheet and tubing materials for the medical device industry can be expected to continue to increase in the near future.

The performance criteria discussed for medical devices in the beginning of Section 7.4.2 also apply for material alternatives for medical devices. The following sections summarize the alternatives appropriate for sheet and tubing devices.

[35] View case studies at the Healthcare Without Harm website: www.noharm.org

Sheet Devices

The type of material used for sheet devices is dependent upon the material being stored. There are four broad groups of medical solutions that are packaged in bags:

1. Blood products (whole blood, red blood cells, platelets and fresh frozen plasma)
2. Intravenous (IV) solutions
3. Total parenteral nutrition (TPN) and enteral feeding products
4. Medications

Table 7.4.2 D summarizes the general categorization of materials that are acceptable for these packaged groups.

Table 7.4.2 D: Packaged Medical Solution and Storage Material Alternatives

Medical Solution Product	Storage Materials
Blood – Red Blood Cells	DEHP/PVC, BTHC/PVC
Blood – Platelets	DEHP/PVC, Polyolefin, Polyolefin laminated PVC
Blood – Fresh Frozen Plasma	DEHP/PVC, Polyolefin, Polyolefin laminated PVC
IV Solutions	DEHP/PVC, Polyolefin, Polyolefin laminated PVC
TPN and Enteral Feeding Products	DEHP/PVC, EVA, EVA/Polyolefin laminate
Medications	Polyolefin, Polyolefin laminated PVC

The primary products derived from whole blood are red blood cells, plasma, and platelets. Whole blood, the unseparated blood that comes from a donor, is typically stored in DEHP/PVC bags. Using a centrifuge, whole blood is separated into platelet-rich plasma and red blood cells.

Figure 7.4.2 E shows an example of an IV bag made from a polyolefin sheet material that is commercially available. When evaluating alternative materials for sheeting in the medical device industry, the ability of the sheet or film to provide a barrier to gas exchanges between the stored solution and the surrounding environment is important. Specifically, for the storage of sensitive solutions such as blood and platelets, minimizing the gas exchange of carbon dioxide and oxygen will result in a longer shelf life for the solution. Shelf-life is a critical factor driving material selection for packaging blood products because a container with a longer shelf-life reduces product losses. Other performance criteria discussed in Section 7.4 (with the obvious exception of PVC compatibility) also apply when evaluating material alternatives.

Figure 7.4.2 E: Typical Polyolefin Intravenous Bag

(Cryovac Medical, Sealed Air Corporation)

Ethylene Vinyl Acetate (EVA)

EVA is a copolymer blend of vinyl acetate, ethylene, and ethyl acetate and may contain other compounds in trace amounts. EVA has been used for medical sheet (or film) applications for parenteral and enteral solutions for many years. Empty EVA bags are also used for custom mixing of drugs by pharmacies, and because bags for these uses do not need to be steam sterilized, the temperature resistance capabilities of flexible PVC are not required.

The EHS characteristics of EVA are summarized in Table 7.4.2 E.

Table 7.4.2 E: Ethylene Vinyl Acetate Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of EVA
Raw Materials	• Co-polymer of ethylene and vinyl acetate	• Non-chlorine
Use		• Does not leach plasticizer (none present)
End of Life	• Recycling infrastructure for EVA is largely non-existent	• No potential chlorine derivatives from combustion • Recyclable

EVA bags can be sterilized by gamma radiation or ethylene oxide (EO) without negative impact on their physical properties; because the melt temperature is below 121°C EVA cannot be autoclaved (steam sterilized) and is therefore not appropriate for use in IV solution storage. Flexible films made with EVA exhibit excellent clarity and, because they are manufactured without plasticizer, they are well suited for packaging and administration of lipophilic fluids. EVA films are also promoted as combining toughness and low-temperature sealability with impact and puncture resistance (Ellay 1997). The water vapor transmission rate from EVA film is less than that of PVC film; however, its gas exchange rate is approximately twice that of PVC film (Lipsitt 1997). EVA is thus more suited for parenteral and enteral solution and drug storage rather than blood and platelet storage.

As with PVC, EVA bags can be manufactured using radio-frequency sealing equipment that provides a highly reliable seal.

Based on our review, EVA is expected to be currently only slightly more expensive than PVC for these applications. Because the density of EVA is less than that of PVC, film manufactured using EVA can be of a smaller gauge than similar PVC film. This can lead to a cost reduction, making EVA overall a cost-competitive alternative to PVC.

Polyolefins - Polyethylene (PE) and Polypropylene (PP)

The polyelefins PE and PP are widely used compounds that are valued for their flexibility, transparency and toughness. PE is manufactured in high density and low density forms (HDPE and LDPE). PE and PP are stable and inert polymers that exhibit very high resistance to chemical attack. PE resins, for example, are almost insoluble at room temperature in all organic solvents although some absorption, softening or embrittlement may occur. LDPE is more readily impacted by exposure to chemicals than HDPE. Some chemicals such as detergents and silicone oil will cause the phenomenon known as environmental stress cracking. PE and PP are very resistant to water and water vapor, which is an advantage when storing aqueous solutions which normally require an extra overwrap layer on top of PVC.

The EHS characteristics of polyolefins are summarized in Table 7.4.2 F.

Table 7.4.2 F: Polyolefin Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Polyolefins
Raw Materials	• Petroleum based thermoplastic	• Does not require additives to achieve desired flexibility • No chlorine
Use		• Does not leach plasticizer (none used)
End of Life		• No chlorine-related combustion products of concern • Recyclable

All oils attack polyolefins to some extent. Mineral oils will dissolve the polymer at elevated temperatures and at lower temperatures they can be absorbed causing swelling, discoloration and in the extreme, disintegration. Vegetable and animal oils do not have such a pronounced effect but some may cause environmental stress cracking to occur. The influence of oily substances on the structural integrity of polyolefins can be an issue when considering the use of these polymers in medical devices as the stored solutions are often oily or lipophilic in nature.

Metallocene polyethylene (mPE) is a modification of the PE copolymer resin that uses a metallocene catalyst to control the molecular architecture of the PE resin, allowing for very low densities and narrow molecular-weight distributions. Metallocene-catalyzed PE copolymer resins (mPE) are made with specific gravities in the range of 0.86 – 0.92. mPE has greater strength and toughness, better heat-sealing properties, greater clarity and low catalyst residues compared with conventional PE (Eastman 2006). Use of mPE allows for the storage and transportation of human plasma, bone marrow, and other biologically active materials that require extremely low temperatures, from -78° to -195°C, whereas PVC is very brittle at these very low temperatures (Esposito 1997).

The toughness of mPE resins can allow for thinner, lighter-weight films, and the lower density of the mPE films results in a higher yield than is possible with PVC, producing more film area per pound (Lipsitt 1997). This can result in a lower cost device than with PVC. mPE is an emerging material alternative for the medical device market.

PE can be made biodegradable by creating weak links in the polymer chain so that bacteria and other microorganisms can break it down.

Unlike with PVC and EVA, sealing of PE medical bag devices requires additional operating control if the radio-frequency technique is desired. This is somewhat alleviated when mPE is used.

Like PE, PPs attributes include softness, flexibility, good low temperature toughness and melt point above 121°C. A commodity production plastic, PP is relatively cost effective. Additionally, with a 30% lower density than PVC, less material is needed to provide the same level of performance; creating opportunities for down gauging products. A drawback is that PP does not radio-frequency weld (Leaversuch 1999).

PP is too brittle and stiff for sole use in medical sheet devices. All PP medical sheeting require the addition of other materials to enhance its flexibility and durability. PP IV bags, for example, made by BBraun, Hospira (formerly Abbott) and Cryovac, have all developed products that include polyethylene and/or copolyester resins. The multilayer product provides toughness, clarity and flexibility (Polin 2002).

Because the barrier properties of the multilayer PP sheet devices are significantly greater, at least one supplier (Hospira) has chosen to forego the overwrap used with other IV bag products, resulting in 40-60% less waste according to Hospira (Modern Plastics 2006).

Glass

Prior to the extensive use of plastics, glass bottles were used to store medical solutions. This can still be done. Glass bottles have certain EHS advantages over other materials, which are summarized in Table 7.4.2 G.

Table 7.4.2 G: Glass Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Glass
Raw Materials	• Silicone sand	• No chlorine present
Use	• Potential for breakage leading to worker injury	• The most inert material available on the market today for health care
End of Life		• No chlorine-related combustion products of concern • Recyclable

Glass has a major advantage in that it has excellent clarity and is virtually impermeable. Relative impermeability of glass bottles make them potentially well suited for storage of blood and platelets. However, glass bottles require special handling and storage as they are prone to breakage. Currently, glass bottles are more commonly used in the storage of small volumes of medical; they can, however, also be used to store IV solutions.

Because they are flexible and collapsible plastic containers do not need air to replace fluid flowing from the container. Being rigid, glass bottles require air vents. The incorporation of appurtenances such as vents, as well as the overall processing techniques associated with specialty glass bottle manufacture, result in higher manufacture costs than for PVC bags. As a result, glass bottles are more expensive than DEHP/PVC.

Tubing Devices

Medical tubing devices must be formed in a variety of configurations to accommodate differing medical needs. Important specifications for medical tubing include not only OD and ID, but also wall thickness. To produce medical tubing with extremely thin walls, manufacturers force material to flow through the small orifices of processing equipment. Some medical tubing includes reinforcements made from many layers of different materials.

The materials used in flexible medical tubing have to satisfy a wide range of performance and processing criteria. They must be flexible, durable and strong with a low coefficient of friction to withstand fluid flow pressures and to facilitate flow. They must be highly resistant to chemicals and to temperature variations, not only to satisfy end-use requirements, but also to tolerate the conditions encountered in various sterilization methods. They must be biocompatible and inert in contact with blood, tissue and other body fluids/matter. Transparency is at times convenient and at other times vital in order to monitor visually or electronically the flow of contents through the tube. And in the final analysis all these properties must be delivered cost-effectively in standard extrusion or co-extrusion processing equipment.

Olefins are suitable for tubing applications. The discussion of their technical, EH&S and economic considerations are presented above and do not differ significantly for tubing applications. In addition, silicone and thermoplastic polyurethane (TPU) are assessed for medical tubing alternative materials.

It is recognized that leaching of DEHP from tubing, including nasogastric tubes is of particular concern even for short time periods, less than 24 hours (Federation of Swedish County Councils 2000). Tubes used for longer than a few days are typically made from silicone or TPU. The decision of how long to leave a tube in place is a clinical decision. A benefit of short-term duration is potentially lower rates of infection (Tcholakian and Raad 2001). A benefit of longer-term duration, for example, with nasogastric tubes used in enteral feeding is reducing the frequency of inserting the tube through the nasal cavity, which causes patient discomfort (Penrod et al. 1999).

Silicone

Silicone is a synthetic rubber that exhibits certain EHS characteristics summarized in Table 7.4.2 H.

Table 7.4.2 H: Silicone Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Silicone
Raw Materials		• No chlorine
Use		• Does not leach plasticizers (none used)
End of Life	• Difficult to recycle	• No potential chlorine derivatives from combustion

Silicone tubing has demonstrated superior performance properties that make it well suited for medical device applications. Silicone is naturally translucent (though not entirely clear), odorless and tasteless. Silicone is biologically inert and its inherent lubricity and flexibility eases medical procedures.

Conventional silicone elastomers can have fairly high ultimate elongations, but only low-to-moderate tensile strengths. Consequently, the toughness of most biomedical silicone elastomers is not particularly high. One of the least attractive properties of conventional silicone elastomers in device manufacturing is that the materials require covalent cross-linking to develop useful properties. Fabrication of device components must include, or be followed by, cross-linking to form chemical bonds among adjacent polymer chains. Cross-linking of extrudable and moldable silicone stock is usually done via peroxide-generated free radicals adding to vinyl groups incorporated along the polymer backbone, or, increasingly, by the platinum-catalyzed addition of silane.

Regardless of how the cross-linking is accomplished, the resulting thermoset silicone cannot be redissolved or remelted. This reduces the number of post-fabrication operations that can be used in device manufacturing with these silicones. For instance, thermal forming, tipping, and tapering; radio-frequency welding; heat sealing; and solvent bonding are all useful post-fabrication methods that are essentially unavailable when building devices from conventional silicone (Ward 2000).

Cost information for silicone tubing was obtained from one industry source at a range of $90 - $110/100 linear feet of tubing. This is a snap-shot cost estimate that can be compared to the same source's estimate of cost for PVC tubing at $40 - $45/100 linear feet of tubing for similar gauge. The cost per linear foot provides a very rough gauge of the cost per treatment because silicone products are used for longer term applications than DEHP/PVC. For example, the cost of providing 30 days of feeding through a nasogastric tube will depend on the number of tubes used. Since DEHP/PVC, with its shorter use life, will require more tubes (than silicone), the comparative cost of silicone relative to DEHP/PVC for functional unit will decline relative to the comparative per pound price. No studies were located detailing the cost differences per treatment period.

Tubing that remains in the body for days as part of the medical procedure is usually made from silicone or TPU because these materials do not turn brittle over time, as does PVC tubing (a characteristic that may be associated with migration and loss of plasticizer from the polymer matrix into the body). However, studies indicate that infection can be associated with the use of silicone tubing in uses such as parenteral feeding, and that the infection can begin almost immediately (Tcholakian and Raad 2001). Silicone can however withstand repeated sterilization. One study evaluated the level of residual EO present in three medical grade tubing materials (PVC, silicone and TPU) after sterilization. The absorption and desorption of EO from PVC and TPU tubing were similar. In contrast, silicone tubing absorbed 85% less EO. The time required for desorption of residual ethylene oxide was 2 hours for silicone tubing and 7 to 8 hours for PVC and TPU tubing (McGunnigle et al. 1975).

Thermoplastic Polyurethane (TPU)

In contrast to cross-linked silicone, many polyurethane elastomers are thermoplastic in nature. Specifically, TPU elastomers can be processed by methods that involve melting or dissolving the polymer to reshape it. The molecular structure of a typical biomedical TPU consists of alternating high-melting "hard" urethane segments and liquid-like "soft" segments.

Cost information for TPU tubing was obtained from one industry source at a range of $110 – 120 / 100 ft of tubing. This is a snap-shot cost estimate that can be compared to the same source's estimate of cost for PVC tubing at $40 - $45/100 ft of tubing. The cost per linear foot provides a very rough gauge of the cost per treatment because TPU products, like silicone, are used for longer term applications than DEHP/PVC. Since DEHP/PVC, with its shorter use life, will require more tubes (than TPU), the comparative cost of TPU for functional unit will decline relative to the comparative per pound price. No studies were located detailing the cost differences per treatment period.

TPU is formed by reacting an alcohol containing more than two reactive hydroxyl groups per molecule with a diisocyanate or a polymeric isocyanate in the presence of suitable catalysts and additives. The primary diisocyanates used in the manufacture of TPU are methylene diphenylene diisocyanate (MDI) and toluene diisocyanate (TDI).

Both MDI and TDI are regulated based on their environmental and human health impacts and are listed on the Massachusetts Science Advisory Board's list of more hazardous chemicals. The production of TPU has been linked to numerous occupational health problems including heart disease, asthma, and reduced sperm quality. In addition, incineration of TPU releases numerous hazardous chemicals including isocyanates and hydrogen cyanide. Polyurethanes are also potentially more hazardous in the work environment than PVC (Tickner 2000).

The EHS considerations associated with TPU are summarized in Table 7.4.2 I.

Table 7.4.2 I: Thermoplastic Polyurethane Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of TPU
Raw Materials	• MDI and TDI used in manufacture or TPU – associated occupational exposure hazards	• No chlorine in final product
Use		• Does not leach plasticizer (none used)

Table 7.4.2 I: Thermoplastic Polyurethane Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of TPU
End of Life		• Can be mechanically or chemically recycled • No potential chlorine derivatives from combustion

Conventional TPU generally has excellent physical properties, combining high elongation and high tensile strength to form tough elastomers. Whereas natural rubber latex may have an initial modulus of a few hundred pounds per square inch (psi), an 80A aromatic TPU might have a modulus of >2000 psi, making it considerably less compliant. Aromatic polyether TPU, on the other hand, can have excellent flex life, a tensile strength of >5000 psi (34 MPa), and ultimate elongations of >700% (Ward 2000).

Summary of Material Alternatives Assessed for Medical Devices

Based on the discussion presented above, the following table summarizes the key assessment criteria for sheet and tubing medical devices as compared to DEHP plasticized PVC.

Table 7.4.2 J: Materials Alternatives Assessment Summary for Medical Devices

Key Assessment Criteria		DEHP/PVC Reference	Comparison of Materials to DEHP/PVC				
			EVA	Polyolefin	Glass	Silicone	TPU
Performance	Elastic Recovery	**Excellent**	?	=	-	=	-
	Cold Flexibility	**Good**	?	?	-	+	=
	Sterilizability (Radiation, Ethylene Oxide, Steam)	**Good** (R, EO, S)	= (R, EO) - (S)	= (R, EO) - (S)	=	=	=
	Gas Permeability	**130** cm^3-mm/m^2/day	-	-	=	?	?
	Manufacturability	**Good**	-	=	+	-	-
Cost	Raw material cost (Sheet)	**~$25**/$ft^2$	=	=	-	NA	NA
	Raw material cost (Tubing)	**~$45**/100ft	NA	=	NA	-	-
	Relative Use Cost (Tubing)[36]	**~$45**/100ft	NA	=	NA	?	?

[36] This cost factor assumes the relative use life of tubing, with DEHP/PVC and polyolefin assumed to be limited to short term use in applications such as enteral feeding (requiring multiple insertions of new tubing), and silicone and TPU assumed to be appropriate for longer term use of a single tubing set in similar applications. The ? for silicone and TPU indicates that the actual use cost relative to DEHP/PVC is not known, and is related to the number of new tubing sets required per procedure.

Key Assessment Criteria		DEHP/PVC Reference	Comparison of Materials to DEHP/PVC				
			EVA	Polyolefin	Glass	Silicone	TPU
Environmental Criteria	Derived from Sustainable Material	**No**	=	=	+	=	=
	Recyclable[37]	**Possible**	-	=	+	-	=
	End of Life	**Potential Hazardous Byproduct Generation** (Incineration)	+	+	+	+	+
Human Health	Human Exposure to Chemicals During Use	**Leaching of plasticizer**	+	+	+	+	+

Comparison Key + Better = Similar - Worse ? Unknown **NA** not applicable/not assessed

7.4.3 Alternatives Assessment for Wall Coverings

DEHP/PVC wall coverings are used in both commercial and residential settings for decorative as well as protective purposes. Vinyl wall coverings are popular because they are available in a wide array of different patterns and colors and are both durable and scrubbable. DEHP is not the only plasticizer used in vinyl wall covering applications. Most vinyl wall covering products sold in the European Union do not contain DEHP. Because of market drivers, nearly all vinyl wall covering sold in the United States today is made in China and Southeast Asia. According to industry sources, the majority of US vinyl wall covering imports use DEHP (Eastman 2006). Commercial wall coverings are available in 54 in. widths in 30 or 50-yard roll lengths and residential are made into 20.5 in. to 28 in. widths (VBD 2006).

Composition

The exact formulation of most vinyl wall coverings varies among manufacturers, who keep their chemical compositions proprietary. Additives typically used in most products include:

1. Plasticizers to improve low temperature product flexibility, and stain and abrasion resistance, and can impact fire retardancy.
2. Stabilizers to prevent the vinyl from degrading during high temperature processing and prevent discoloration of the finished product.
3. Other additives including pigments, fungicides, flame-retardants or smoke suppressors (VBD 2006).

[37] For medical devices that are considered a biohazard recycling is only appropriate when specially managed (*e.g.,* steam sterilized prior to recycle), which may limit the opportunity for recycling as a management method.

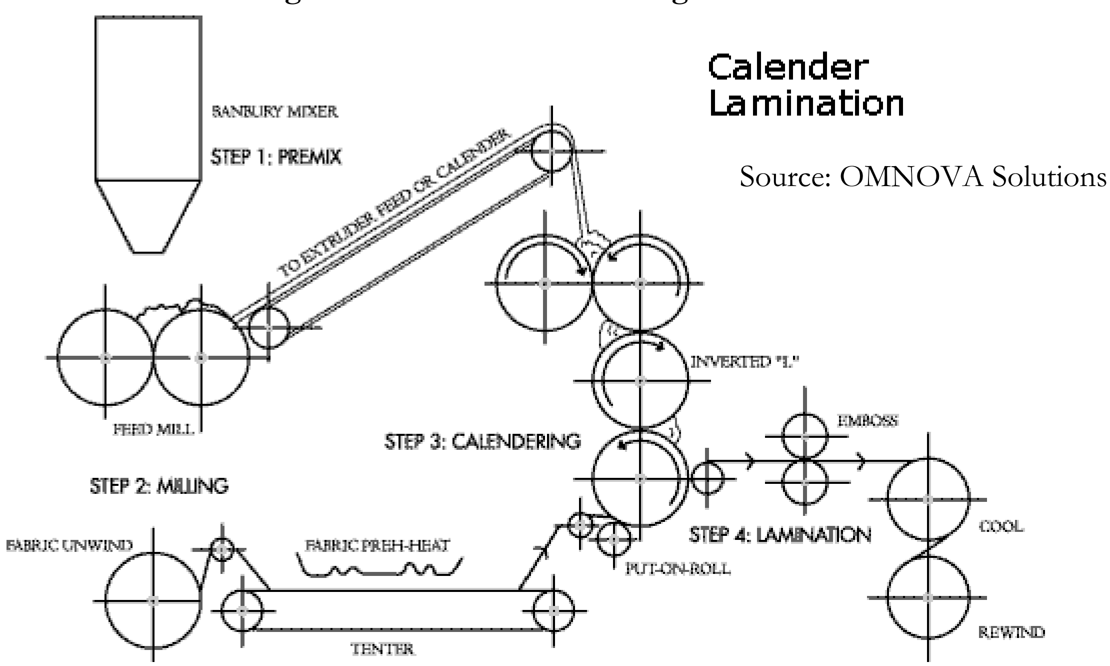
Vinyl Wall Covering Production

The production of vinyl wall coverings includes mixing and calendaring, printing, embossing and texturing and finishing. A process called "calendaring" is often the initial stage of vinyl wall covering production (see Figure 7.4.3 A) Calendaring begins by mixing and heating several ingredients (including PVC, stabilizers and plasticizers) to a uniform consistency. The compound is heated and "squeezed" through a series of hot metal rollers that flatten the vinyl compound into a sheet of vinyl film. The process is repeated until the film reaches a specific uniform thickness. During the final stage of the calendaring process, a fabric backing can be added to the film using a mixture of heat and pressure. Wall coverings can also be produced using a pre-mixed liquid vinyl called plastisol and a manufacturing technique similar to the calendaring process.

Finishing operations such as printing, embossing, and texturizing follow the calendaring or plastisols production process. During this stage of the manufacturing process, large, specialized printing presses apply one or more stages of ink to the vinyl surface to create specific wall covering colors and patterns. A surface texture can also be applied to the wall covering using embossing rollers.

The final stage of production includes applying a finish or top coating to the surface of the wall covering. These coatings include a basic clear vinyl coating or a clear film laminate to provide additional surface protection, durability and cleanability (OMNOVA Solutions 2006).

Figure 7.4.3 A: The Calendering Process



Installation/Cleaning/Maintenance

Surface preparation, such as making sure that the wall surface is clean, dry, structurally sound and free of grease, mildew or other stains, ensures that the wall covering permanently adheres to wall surfaces. Selecting the correct adhesive and surface treatment is also essential when installing vinyl wall covering. Many manufacturers recommend professional installation to ensure long life.

Manufacturers recommend cleaning with a mild detergent to remove accumulated dirt, grease and most stains without damaging the vinyl wall coverings. Stains should be removed as soon as possible. Ordinary dirt spots can be removed with a mild soap and warm water. Rinse thoroughly with clean water. For more difficult stains that are only surface deep, manufacturers recommend a stronger detergent.

Financial

Typically, the installation cost for vinyl wall covering, including equipment and labor, ranges between $7.00 to $10.00 per linear yard, depending on the thickness and pattern. Uninstalled retail vinyl wall covering costs range anywhere between $3.00 and $5.00 per linear yard for low end product up to between $14.00 and$22.00 per linear yard for high end product. Higher quality vinyl wall covering is thicker and is expected to last for more than 25 years (Vinyl Institute 2006).

Environmental and Human Health Issues

The principal environmental and human health issues associated with DEHP/PVC wall covering are similar to those of DEHP/PVC flooring. Table 7.4.1B outlines these issues in detail, examining PVC intermediates manufacturing, human health impacts of DEHP, and the potential for chlorine related emissions from uncontrolled or poorly controlled PVC incineration[38]. Other impacts include energy use impacts from manufacturing and transport and a lack of end-of-life recycling and recovery options.

Specific Plasticizer Alternatives for Wall Coverings

In the initial prioritization DEHA and DINP were found to be feasible alternatives. Wall covering manufacturers have suggested that DINP may be acceptable as a 'drop in' replacement which off-sets its higher raw material cost (Carnegie 2006).

Di Ethylhexyl Adipate (DEHA)

DEHA is an adipate plasticizer whose specific chemical structure is shown in Figure 7.4.1F. Adipates have a different chemical structure from phthalates, with the synthesis of the first based on adipic acid as opposed to the synthesis of the second, which is based on phthalic anhydride. The adipates are classified as low temperature plasticizers and are all relatively sensitive to water (*DEPA 2001*). The volatility of DEHA is lower than DEHP, with a vapor pressure of 8.5 x10^{-7} mmHg (refer to Appendix C for data). DEHA is also less compatible with PVC (than DEHP), which can lead to exudation (*i.e.,* plasticizer migrating to the surface), causing an undesirable appearance on the surface of the PVC. DEHA is known to be slightly more difficult to process compared to DEHP.

The Danish EPA conducted a review of toxicological data associated with a number of plasticizers, including DEHA. A NOAEL of 610 mg/kg bw/day has been reported (DEPA 2001), which is orders of magnitude higher (*i.e.,* indicating lower toxicity) than the NOAEL for DEHP. The Chronic Health Advisory Panel for the US Consumer Product Safety Commission quotes a study that indicates a fetotoxicity issue associated with oral exposure to DEHA (CHAP 2001).

Diisononyl Phthalate (DINP)

DINP is a phthalate ester plasticizer made from C9 alcohols as opposed to C8 alcohols used in the manufacture of DEHP. The chemical structure of DINP is depicted in Figure 7.4.1B. The plasticizing efficiency of DINP is somewhat lower than DEHP and therefore more plasticizer is required to gain the same softness. Because the molecular weight of DINP (418) is greater than DEHP (390), DINP has better high temperature performance and extraction resistance. Compared

[38] For a more detailed outline of DEHP/PVC environment and human health issues, readers are encouraged to review the US Green Building Council website on PVC: http://www.usgbc.org/DisplayPage.aspx?CMSPageID=153).

with DEHP, DINP processing emits noticeably lower levels of plasticizer mist from process equipment. As a result, there is less plasticizer lost to the air and more retained in the product, therefore overall cost savings.

DINP is a "drop in replacement" for DEHP. To process well, plasticizers must be absorbed into the PVC resin particles during this blending process (DEPA 2003). Known as processability, PVC resin, plasticizer(s), stabilizers and lubricants should blend together readily in a high-speed mixer or a ribbon blender. DINP's processability is similar to DEHP's.

Exposure to DINP during processing or use of wall coverings is expected to be minimal due to the lower emissions relative to DEHP. During use there is little likelihood that DINP will migrate out of the polymer matrix and be exposed to humans. In the event that humans do become exposed to DINP from this use however, there may be associated health effects.

According to the Chronic Health Advisory Panel, exposure to DINP results in potential acute toxic effects (CHAP 2001). The NOAEL for systemic toxic effects induced in laboratory animals by exposure to DINP is estimated to be between 15 mg kg/d and 88 mg/kg bodyweight/d. To put this into context, a study by the Consumer Council Austrian Standards Institute (Fiala n.d.) used the lowest NOAELs for DINP and DEHP to determine a total daily intake level for these plasticizers (this study focused on the use of DINP and DEHP in children's toys that would be mouthed, using a safety factor of 100) of 15.0 μg/kg bodyweight /d for DINP and 37 μg/kg bodyweight /d for DEHP.

According to its review of relevant studies, the CHAP concludes that DINP is clearly carcinogenic to rodents, inducing hepatocellular carcinoma in rats and mice of both sexes, renal tubular carcinoma in male rats, and mononuclear cell leukemia in male and female rats. The studies they reviewed also suggest possible carcinogenicity in the testis, uterus, and pancreas (CHAP 2001). DINP has not been listed as an EPA or IARC possible human carcinogen.

Summary of Plasticizer Alternatives for DEHP

The primary plasticizer alternatives for DEHP vinyl wall covering include a phthalate plasticizer, DINP and an adipate plasticizer, DEHA. While DINP had a higher cost premium than desired, information from plasticizer as well as wall covering manufacturers indicated that DINP should be further examined. DEHA met all of our preferred attributes including cost, performance and environmental health and safety. The two plasticizers were compared to DEHP for all criteria; the results are shown in Table 7.4.3 A.

Table 7.4.3 A: Summary of Plasticizer Alternatives Assessment for Wall Covering

Assessment Criteria		DEHP (Reference)	Comparison Relative to DEHP	
			DEHA	DINP
Technical/ Performance Criteria	Volatility	**1.4 x 10-6 mm Hg**	+	=
	Compounding	**Good**	=	=
	Tensile Elongation (life of product)	**MW 390**	=	=
	PVC Compatibility	**Good**	-	=
	Emissions • Manufacture • Use	**Acceptable (M, U)**	-	=
Cost	Cost /lb applied	**$0.70** (March 2006)	=	=
Environmental Criteria	Persistence	**Sediment (140 days)**	+	=
	Bioaccumulation	**BCF = 320**	+ (BCF = 61)	+ (BCF = 3.2)
	Aquatic (Fish) Toxicity	**>0.0025 mg/L**	+ (>100 mg/L)	= (>0.14 mg/L)
Human Health Criteria	Carcinogen	**EPA B2, IARC 3**	?	= (indicated in rodents – *CHAP 2001*)
	Reproductive Toxicity	**Yes (Prop 65, EU; NOAEL = 3.7 – 100 mg/kg bw/d)**	= (potential fetotoxicity, NOAEL = 610)	+
	LD50	**34 g/kg**	- (5.6 g/kg)	?
	Irritation	**Yes** (Dermal, Ocular, Respiratory)	+ (D) = (O,R)	+

Comparison Key + Better = Similar - Worse ? Unknown

Material Alternatives Analysis

This section analyzes three priority alternative materials: Glass Woven Textiles, Cellulose/ Polyester Blends, and Wood Fiber/Polyester Blends.

Wall Covering Material Alternative #1: Glass Woven Textiles

Glass woven textile wall coverings are manufactured in the U.S. by Johns Manville (JM) and known by the trade name Textra™. The wall coverings include recycled glass and gypsum. Glass textile wall coverings have been used in Europe for more than 60 years and are mandatory for government and health care facilities in Germany (Glass Textile North America (GTNA) 2005). These wall coverings can be painted and re-painted up to 8 times to change the decor. JM offers more than 20 patterns and estimates a product lifetime of more than 30 years. Both scrubbable and durable, these wall coverings are breathable, reducing the chance of mold and/or mildew.

Construction

According to the manufacturer, the composition of this material is as described in Table 7.4.3 B.

Table 7.4.3 B: Composition of Glass Woven Textiles

Wt. %	Material	Origin/Precursor Materials
>60%	Continuous filament glass fibers	Sand
<40%	Binder	Starch, cellulose derivative and polymer

Installation/Cleaning/Maintenance

Regular maintenance of the woven textile wall covering includes dusting with a dry mop. If there are marks on the wall, they can be scrubbed with a wet cloth. Remove, patch and paint damaged sections. The wall covering can also be repainted to clean it up or change the look of a room. Detailed installation instructions are available at www.jm.com.

Financial

Installation equipment and labor cost for Textra™ wall covering ranges from $7 to $10 per linear yard, depending on the contractor and equipment costs. Textra™ glass woven textile wall coverings cost between $13.00 and $15.00 per linear yard depending on the pattern. The total costs for Textra™ wall coverings are between $20 and $35 per linear yard when professionally installed.

Environmental and Human Health Issues

Textra™ wall covering products meet State of Washington and USEPA indoor air pollution criteria for particles, VOCs and formaldehyde. Glass woven textiles are made from natural ingredients; sand to make the glass and some potato based starch to increase stiffness and make it easier to hang. The glass manufacturing process is very energy intensive. Very high temperatures are required to melt sand and make glass. The fuel burned to reach the high temperatures produces NO_x, an ozone precursor, and CO_2, a greenhouse gas. A water-based latex adhesive is recommended for installation. There are VOC emissions upon installation and when the product is painted. Low VOC paint is widely available and can be used to reduce these emissions. At the end of life, glass woven textile wall coverings are most commonly left in place to strengthen the wall. When left in place, there is no need to dispose of the old product until the building is dismantled.

Table 7.4.3 C: Glass Woven Textiles Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Glass Woven Textiles
Raw Materials	• Natural ingredients sustainable • Minimal recycled content; only includes 5% postindustrial glass from manufacturing process	• Derived from natural ingredients (sand and potato based starch)
Manufacture	• Energy use and associated greenhouse gas, particulate and other related emissions • NOx generation during the manufacturing process	
Installation	• Surface topcoat of paint primer usually applied • If painted after installation, high VOC paints will cause emissions	• Latex based (VOC free) clear adhesive recommended for installation • Can use low VOC paint and primer on wall covering
Use and Maintenance	• Re-painting recommended to remove stubborn stains • Patch damaged sections, or change décor • VOC emissions can result	• Dusting with a dry mop for regular cleaning
End of Life	• Not recyclable or compostable • If removed, product is landfilled	• Leaving the product in place to strengthen the wall at the end of life • Re-covering with new wall covering is common • No chlorine products generated if incinerated

Wall Covering Material Alternative #2 – Wood Fiber/Polyester

Wood Fiber and polyester wall covering, specifically the Allegory™ series from Innovations in Wall Coverings (IWC), is made of 50% virgin spun-woven polyester and 50% wood fiber and comes in 34 different colors. Washable, scrubbable and stain resistant, the wall covering breathes and therefore reduces mold and mildew formation. It does not require backing and adheres directly to wall surfaces.

Installation/Cleaning/Maintenance

Professional installers report that Allegory™ wall coverings hang easier than standard vinyl wall coverings because it is lighter and easier to maneuver. Manufacturers of the wood fiber /polyester wall covering recommend using a qualified installer to apply the wall covering. While the use of a clear strippable adhesive is recommended, they do not recommend any specific brand.

To remove dirt and smudges, a mild soap and warm water solution followed by a rinse with clean clear water and a soft cloth is recommended. Only soft bristle brushes are advised. Damp spots and stains should be treated promptly to ease clean-up. Blotting with an absorbent cloth or polyester sponge is recommended.

Financial

Installation cost, including equipment and labor for wood fiber/ polyester wall covering ranges from $7 to $10 per linear yard, depending on the contractor and equipment costs. Allegory™ wood fiber/polyester wall covering costs $14.95 per linear yard (as of 3/06) and is backed by a one year warranty.

Environmental and Human Health Issues

Allegory™ is made using wood pulp from managed forests. The forests are certified using the European Sustainable Forestry Initiative (SFI). SFI was developed in 1995, and is described as "raising the floor of minimum standards of forest management and aims to improve the image of US forest products industry (Canadian Environmental Network 2006)." Allegory™ is heavy-metal free and contains water soluble inks. Allegory™ contains no recycled content. IWC claims the Allegory™ product can be recycled, although this may be difficult given the mixed plastic-wood fiber material. Furthermore, no formal take-back program has been established.

Table 7.4.3 D: Wood Fiber/Polyester Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Wood Fiber/Polyester Wall Covering
Raw Materials	• Mix of wood pulp and spun woven polyester. Does not contain recycled content.	Wood pulp from managed SFI forests.
Manufacture	• Energy use and associated greenhouse gas, particulate and other related emissions. VOC generation during the manufacturing process.	
Installation	• Off-gassing of adhesives	
Use and Maintenance	• Cleaning, VOC off gassing potential depending on product used.	Can be cleaned with a mild detergent
End of Life	• No take-back program • Recycling may be difficult due to mixed plastic-wood fiber material.	• Product is recyclable • No chlorine products generated if incinerated

Wall Covering Material Alternative #3 - Cellulose/ Polyester Blend

Cellulose/polyester blend wall coverings are sold under a few brand names (Enspire™ and EnVision™) and are expected to last between 10 and 15 years. These non-woven blends are breathable, reducing the risk of mold and mildew growth. The wall coverings are scrubbable and available in over 40 colors and patterns colors and patterns.

Table 7.4.3 E: Cellulose/Polyester Wall Coverings

Manufacturer	Trade Name	Construction
MDC Wallcoverings	Enspire™	Polyester/cellulose
NaturDecor & Supply	EnVision™	Nonwoven polyester-cellulose blend
Seabrook Contract	Nonwoven Wall Materials	70% polyester 30% cellulose

Installation/Cleaning/Maintenance

The manufacturers of these wall coverings recommend professional installation. The wall surface must be cleaned and dried before installation. Detailed installation instructions are available at www.mdcwallcovering.com.

For maintenance purposes, stains should be removed immediately with a clean sponge or cloth. The material can be rinsed with water if necessary. For cleaning, use a soft detergent (e.g. dishwashing detergent) if necessary and then rinse with water. Hard rubbing and excess water should be avoided.

Financial

Installation costs for cellulose and polyester wall covering range from $7 to $10 per linear yard, depending on the contractor and equipment costs. Enspire™ wall covering costs between $18 and $22 per linear yard depending on the pattern.

Environmental and Human Health Issues

The Enspire™ collection by MDC Wallcoverings can be returned using the Ecologic Reclamation Program run by the manufacturer. This program, which claims to be the first of its kind in the wall covering industry, has succeeded in finding a variety of secondary uses for old wall covering. It provides the opportunity to specify environmentally friendly materials that would otherwise end up in landfills. There are specific requirements for the reclamation program that can be found on MDC Wallcoverings web site; www.mdcwallcoverings.com.

Enspire™ is PVC- and chorine-free, and the cellulose is from totally chlorine free (TCF)-pulp. The wall covering is made using water-based inks that contain no heavy metals and are formaldehyde free. Polyester is defined as a "long-chain polymers chemically composed of at least 85% by weight of an ester and a di-hydric alcohol and a terephthalic alcohol." Two types of polyester are commercially manufactured today are polyethelene terphthalate (PET) and poly-1,4 cyclohexylene dimethylene (SwicoFIL AG Textiles 2006).

An important additional consideration associated with these cellulose/polyester blends is the use of Teflon® coatings. These coatings are routinely applied to provide improved stain resistance and washability. However the use of Teflon® indicates a potential occupational exposure issue associated with the perfluorinated compounds from which Teflon® is manufactured. An assessment of the impact of this potential is beyond the scope of this study, but it should be noted.

Table 7.4.3 F: Cellulose/ Polyester Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Cellulose/ Polyester Wall Covering
Raw Materials	• Mix of polyester and cellulose. Sustainability of natural ingredients (e.g. cellulose) not assured. No recycled content	
Manufacture	• Energy use and associated greenhouse gas, particulate and other related emissions • VOC generation during the manufacturing process. • Surface topcoat of Teflon® often applied	
Installation	• Some adhesive offgas VOCs	• Can use "natural" adhesives based on wheat and corn starch polymers
Use and Maintenance	• Cleaning VOC off gassing potential	• Can be cleaned with a mild detergent
End of Life	• Not recyclable • Secondary Uses?	• Ecologic reclamation program run by MDC wall coverings will take back the old product • No chlorine products generated if incinerated

Wall Covering Material Alternative #4 – Wood Pulp/Recycled Paper

The wood pulp/recycled paper wall covering the Institute studied is sold by Designtex under the brand name Duraprene™. Duraprene™ is composed of wood pulp from sustainable managed forests and recycled paper and board[39]. Designtex manufactures the wall covering using wood pulp mixed with latex and sealed with a water-based polyurethane coating, providing a scrubbable and durable surface. The 20 colors used in the 11 current patterns are absorbed by the paper so they will not lift off with cleaning. Table 7.4.3 G details the construction of Duraprene™ wood pulp/recycled paper wall covering.

Table 7.4.3 G: Wood Pulp/ Recycled Paper Wall Covering

Manufacturer	Trade Name	Construction
Designtex	Duraprene™	• 50% wood pulp (cellulose) • 40% post-industrial waste • 10% post consumer recycled waste • Sealed with water-based polyurethane coating

Installation/Cleaning/Maintenance

The manufacturer recommends checking for moisture problems before installing any wall covering. Moisture could have an effect on mold and mildew growth after wall covering installation. Before beginning installation, make sure that the surface is clean, smooth, dry and structurally intact. A clay-based or "clear" vinyl adhesive and primer by the same manufacturer is recommended[40].

The manufacturer recommends routine maintenance including regular vacuuming and promptly treating spots and stains. Excessive rubbing and brushing can cause fuzzing and should be avoided (Designtex 2006).

Financial

Installation cost for the Duraprene™ wall covering range from $7 to $10 per yard, depending on the contractor and equipment costs. Duraprene™ wall covering costs between $18 and $20 per yard depending on the pattern.

Environmental and Human Health Issues

Duraprene™ uses recycled office paper and salvage from carton manufacturing and wood pulp. Duraprene™'s recycled content is reported to be 6% post-consumer and 28% total recycled composition.

Table 7.4.3 H: Wood Pulp/Recycled Paper Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Wood Pulp /Recycled Paper Wall Covering
Raw Materials	Sustainability of natural ingredients not assured	• Contains post-consumer recycled materials. • Up to 28% recycled composition
Manufacture	Wood pulp mixed with latex	• No Teflon® topcoat applied
Installation		• Sealed with water-based polyurethane

[39] Despite several calls to the manufacturer, we were unable to find out the specific forest certification scheme used.
[40] Detailed installation instruction can be found at: www.dtex.com/files/durapreneHanging.pdf.

Table 7.4.3 H: Wood Pulp/Recycled Paper Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Wood Pulp /Recycled Paper Wall Covering
Use and Maintenance	Avoid excessive rubbing and brushing can cause fuzzing	• Can be cleaned with a mild detergent
End of Life	Compostable but no infrastructure	• Biodegradable raw materials • Compostable but no infrastructure • No chlorine products generated if incinerated

Wall Covering Material Alternative #5 – BioFibers

BioFiber or natural textile wall coverings are made from a variety of natural materials from cotton and linen to wood pulp and viscose. They are usually laminated to a backing to make the product more stable and to prevent the adhesive from coming through to the surface. These backings are usually paper or acrylic. Natural textiles can be finely designed or coarse in texture depending on the desired look.

Construction

MDC Wallcoverings Naturals line includes wall coverings made from a variety of different natural materials including cotton, viscose, wood pulp, sisal, and linen. Viscose is a natural polymer made from wood pulp, also known as rayon. Sisal is a natural fiber extracted from the long leaves of sisal plants. The specific products available in the line are outlined in Table 7.4.3 I below. These are paper backed, Teflon® treated products. The Teflon® treatment ensures durability and makes the product suitable for commercial applications.

Table 7.4.3 I: MDC Wallcoverings Natural Line of BioFibers

Product Name	Type	Cotton	Viscose	Wood-pulp	Linen	Sisal	Polyester	Poly-propylene
Belize and Bargello	Textile	40%	60%					
Carina	Textile	10%	75%				15%	
Casablanca	Textile	50%	50%					
Leoni/Cavalli	Textile	20%	40%				20%	20%
L – Torrens	Textile	40%	30%		30%			
L – Logan, Devonport and Camberra and L Naturals IV - Hobart	Textile				100%			
L – Brisbane	Textile	20%			80%			
L- Lismore	Textile	95%					5%	
L – Wales	Textile	35%			65%			
L Naturals III - Hirano and Emilla	Textile	20%			80%			
L Naturals III - Callisto	Textile	40%			60%			
Loft and Papasan	Suede						100%	
Sohi	Textile	40%	40%				20%	
Theda	Textile	20%	50%				30%	
Filament	non-woven			30%			70%	
Gossamer	non-woven			40%		10%	50%	
Labyrinth	non-woven						100%	

Installation/Cleaning/Maintenance

The manufacturer recommends professional installation of the Naturals Wallcovering line. Specific installation instructions including surface preparation, adhesive application, and material hanging can be found on the MDC Wallcoverings website www.mdcwall.com.

For general maintenance, light brushing or occasional vacuuming is recommended. Stains should be treated immediately usually with a moist cloth. Tougher stains should be treated with a weak detergent solution.

Financial

Cost information for these products was not available at the time of this report preparation.

Environmental and Human Health Issues

BioFiber wall covering products are made from natural fibers and are paper backed, making them both renewable (less than 10 years) and recyclable. They also release minimal indoor air pollutants such as VOCs. An important additional consideration associated with many of these biofiber blends is the use of Teflon® coatings. These coatings are routinely applied to provide improved stain resistance and washability. However the use of Teflon® indicates a potential occupational exposure issue associated with the perfluorinated compounds from which Teflon® is manufactured. An assessment of the impact of this potential is beyond the scope of this study, but it should be noted.

Viscose (rayon) was the first manufactured fiber, but unlike most man-made fibers, it is not synthetic. It is made from wood pulp and as a result, its properties are more like natural cellulosic fibers (e.g. cotton or linen) than the thermoplastic, petroleum-based synthetic fibers (e.g. nylon or polypropylene). Viscose is made using two different chemical and manufacturing techniques to develop two types of rayon, viscose rayon and cuprammonium[41].

The polyester manufacturing process is described in the Alternative #3 - Cellulose/ Polyester section. Linen (also known as flax) fiber comes from the stalk of a *Linum usitatissimum* plant. France is the world's top flax producer. 70% of linen is composed of cellulose.

Table 7.4.3 J: BioFiber Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Natural Wall Coverings
Raw Materials	• Sustainability of natural ingredients not assured • Does not contain recycled content. • Manufactured in Europe (linen) • Conventional cotton known to be herbicide and pesticide intensive	• Derived from natural ingredients
Manufacture	• Processing (viscose and polyester) requires high water and energy use resulting in air emissions and water pollution • Surface topcoat of Teflon® applied	
Installation	• Premixed vinyl clear adhesive could off gas VOCs	• Can use adhesive based on natural polymers (e.g. wheat, and corn starch)
Use and Maintenance		• Can be cleaned with water or a mild detergent

[41] http://www.swicofil.com/products/200viscose.html

Table 7.4.3 J: BioFiber Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Natural Wall Coverings
End of Life		• Paper backed, makes them renewable and recyclable • No chlorine products generated if incinerated

Wall Covering Material Alternative #6 - Polyolefin

Polyolefin/ synthetic textile wall coverings are woven and non-woven looking wall coverings that were developed to give the appearance of a natural textile while adding better stain resistance and durability. These products generally have an acrylic or paper backing. Many of these products are made of polyolefin yarns, which are olefin fibers made from polymers or copolymers of propylene.

Construction

MDC Wallcoverings has a line of polyolefin wall coverings. There are 18 different colors/patterns available. This line is made of woven polyolefins that are known to be good for high traffic areas. This is due to their stain and abrasion resistance. These wall coverings have a Teflon® treated finish, which enhanced their durability. In this collection, the fibers are solution dyed which means that the color pigment is mixed into the spinning solution before extrusion. As a result the color becomes an integral part of the yarn and does not rub off or fade when vacuumed or cleaned.

Table 7.4.3 K: MDC Polyolefin Wallcoverings

Type	Backing	Finish
100% Olefin	Acrylic	Teflon® Treated
50% Olefin 50% Polyester	Acrylic	Teflon® Treated
85% Olefin, 15% Polyester	Acrylic	Teflon® Treated

Installation/Cleaning/Maintenance

The manufacturer recommends professional installation of the Polyolefin Wallcovering line. Specific installation instructions including surface preparation, adhesive application, and material hanging can be found on the MDC Wallcoverings website www.mdcwall.com.

Regular maintenance of the polyolefin wall coverings includes vacuuming and dusting with a dry cloth. Since the yarns in the polyolefin wall coverings do not absorb water, stains will remain on the surface where they can be removed with a clean, dry cloth.

Financial

Installation cost for the polyolefin wall covering ranges from $7 to $10 per yard, depending on the contractor and equipment costs. MDC Polyolefin wall covering costs between $18 and $22 per yard depending on the pattern.

Environmental and Human Health Issues

Polyolefin wall coverings are made from petroleum-based ingredients. Polyolefin wall coverings are often treated with a Teflon® finish to increase both the durability and scrubbability. The use of Teflon® indicates a potential occupational exposure issue associated with the perfluorinated compounds from which Teflon® is manufactured. An assessment of the impact of this potential is beyond the scope of this study, but it should be noted.

It is recommended that these wall coverings be installed using a premixed, heavy-duty vinyl adhesive. These adhesives are made using either natural polymers (wheat and corn starch) or synthetic polymers. Although polyolefins can be recycled there is no known take-back or recycling programs in place.

Table 7.4.3 L: Polyolefin Considerations

Life Cycle Phase	Environment and Human Health Issues	Positive Aspects of Polyolefin
Raw Materials	• Derived from petroleum based ingredients • No recycled content	
Manufacture	• Energy use and associated greenhouse gas, particulate and other related emissions. • Air pollutants generated during the manufacturing process. • Teflon® treated finish	
Installation	• Premixed, heavy-duty vinyl adhesive could off gas VOCs	• Can use a vinyl adhesive made from natural polymers
Use and Maintenance		• Can be cleaned with water or a mild detergent
End of Life	• Recycling or take back program not in place.	• Can be recycled • No chlorine products generated if incinerated

Wall Covering Materials Alternatives Summary

TURI analyzed six wall covering alternatives to DEHP-PVC. The alternatives include both natural fibers and other petrochemical derived polymers and come in a wide range of colors and patterns. Most of the alternatives are comparable in price to high-end PVC wall covering products, but are much more expensive than low-end vinyl. Table 7.4.3 M below summarizes the cost, choice, maintenance and environmental health and safety aspects of these alternatives.

Table 7.4.3 M: Materials Alternatives Assessment Summary for Wall Covering

Assessment Criteria		**DEHP/PVC Reference**	Comparison of Materials to DEHP/PVC					
			Glass Textile	Wood Fiber/ Polyester	Cellulose/ Polyester	Wood Pulp/ Recycled Paper	BioFibers	Polyolefin
Performance	Color/Pattern Choices	**Unlimited**	-	=	=	-	-	-
	Ease of Maintenance	**Easy**	=	=	=	=	=	=
Cost	Cost per yard (material only)	**$3 – $22/yd** (depends on quality)	=	=	=	=	?	=
Environmental Criteria	Derived from Sustainable Material	**No**	+	+	+	+	+	=
	Recyclable	**No**	=	=	+	?	+	+
	Compostable	**No**	=	?	?	+	?	=
	Teflon® Coated	**Possible**	+	+	=	+	-	-
Human Health	Exposure to Emissions During: • Manufacture • Installation • Use	**VOC emissions (M, I, U)**	= (U)	?	?	?	?	=

Comparison Key + Better = Similar - Worse ? Unknown

7.5. Summary and Conclusions

Di (2-ethylhexyl) phthalate (DEHP) is globally the most commonly used PVC plasticizer, used to impart flexibility into this otherwise rigid polymer. As a plasticizer for PVC, DEHP offers excellent compatibility and performance properties at a low cost. DEHP is found in a wide variety of flexible plastic products, and can be found in amounts ranging from less than 20% to more than 50% by weight.

DEHP is not chemically bound into the polymer matrix and therefore can migrate out of the polymer. It is lipophilic, so that in the presence of fatty solutions it will be more likely to migrate out of the polymer. DEHP has been shown to be a reproductive toxin to male rodents, and the CERHR has expressed "serious concern" about the potential exposure to human neonates. In addition, while it has a relatively low vapor pressure, the potential for worker and public exposure to DEHP that does volatilize into the air is a concern to public health advocates. Finally, it has been shown to be present in indoor air dust particles, especially in homes where PVC surfaces are prevalent. Although the scientific evidence of a direct link between adverse health effects and exposure to DEHP in air, dust or in solutions to which humans are exposed (*e.g.,* solutions injected into the body during medical procedures) has not been shown to be incontrovertible, both the public and the federal agencies charged with protecting public health express concern that health effects do exist.

The Institute looked at plasticizer and material alternatives to DEHP and DEHP/PVC blends used in resilient flooring, medical devices for neonatal care, and wall coverings. These uses were chosen because of their prevalence of manufacture and use in Massachusetts, as well as their potential to expose workers and the public to DEHP and its metabolites.

Resilient Flooring

Resilient flooring is used in residential, commercial and industrial settings. Many of these applications use DEHP/PVC blends. In fact, the largest user of DEHP in the Commonwealth manufactures resilient flooring for industrial applications.

The Institute identified and assessed four plasticizer alternatives and three material alternatives to DEHP/PVC. Each of the plasticizer alternatives assessed (DEHA, DINP, DGD and DEHT) exhibit equal or better EH&S profiles compared to DEHP. They also exhibit comparable costs and performance characteristics, though industry feels that cost is a limiting factor in the lower end industrial and commercial resilient flooring markets. In addition, it is likely that some processing modifications would be required in order to switch to an alternative plasticizer. This could present an initial capital cost to industry.

Of the three materials assessed as alternatives to DEHP/PVC, cork and linoleum appear to have equal or better EH&S, performance and cost profiles. Emerging recycling and infrastructure opportunities will improve this assessment for linoleum.

Medical Devices for Neonatal Care

DEHP is used in many different medical devices. The primary groups of medical devices are sheet (*e.g.,* IV and blood storage bags) and tubing devices. Based on the serious concern expressed by the CERHR for neonate exposure to DEHP via medical procedures, as well as the continuing debate over the actual exposure to DEHP and the associated health impact from these devices, the Institute limited its assessment to sheet and tubing devices used for neonatal care. The medical procedure that appears to present the highest potential for exposure to DEHP is extracorporeal membrane oxygenation, a procedure that is used only in neonatal care situations.

Sheet devices are used to store the following solutions: blood products (red blood cells, platelets and fresh frozen plasma), nutritional solutions (total parenteral nutrition and enteral solutions), intravenous solutions and drugs. The choice of plasticizer or material for a specific sheet device is highly dependant on the medical solution stored. Therefore no single alternative can be promoted for all potential uses. For red blood cell storage DEHP/PVC continues to be the material of choice, though BTHC/PVC has been FDA-approved for use in red blood cell storage. However BTHC is less amendable to steam sterilization than is DEHP and is significantly more expensive than DEHP. There is a continuing need for research to identify other plasticizer and material alternatives for this use.

TOTM, DEHA, BTHC and DINCH all appear to be potentially appropriate alternatives to DEHP for other medical solution storage options, though DINCH has not yet received FDA approval for use in medical products in the US. More research is required to determine the migration potential of these plasticizers into various solutions, and to assess the potential toxicology associated with exposure to these plasticizers and their metabolites in neonates. Modifications in processing requirements are likely to be associated with a switch to any of these alternative plasticizers. In addition, the cost of TOTM, BTHC and DINCH are relatively higher than DEHP

For tubing devices, DINP and DEHA were assessed as alternative plasticizers. Both are comparable in cost, with some processing and EHS issues that require further study before determining a preferred alternative to DEHP.

Several alternative materials were assessed for both sheet (EVA, polyolefins and glass) and tubing (polyolefins, silicone and TPU) applications. Products utilizing the alternative materials, either singly or in multi-layer laminates, are currently commercially available for sheet and tubing device applications with the notable exception of red blood cell storage. Many manufacturers are currently offering non-DEHP and/or non-PVC alternatives for both sheet and tubing uses.

Wall Coverings

Despite the relatively low vapor pressure of DEHP, public health advocates express concern that DEHP will volatilize into the air and/or be present in dust associated with DEHP/PVC (vinyl) wall coverings. The Institute assessed two plasticizer alternatives to DEHP: DEHA and DINP. Both DEHA and DINP appear to be technically feasible alternatives to DEHP in wall covering applications, exhibiting comparable EH&S, performance and cost profiles.

Numerous alternative materials were assessed, including woven glass textiles, a wood fiber/polyester blend, cellulose polyester blends, a wood pulp/recycled paper blend, biofiber products, and polyolefin/synthetic textiles. Each appears to present a feasible alternative to DEHP/PVC for wall covering applications.

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