



## THE DANGERS OF PVC AND PHTHALATES (DEHP) IN TUBING AND ASSEMBLIES

### EXPLORING ALTERNATIVES

10/30/2014

#### Abstract

A staple for medical device extrusion for decades, Polyvinyl Chloride (PVC) has been on the radar for several health organizations around the world and legislation continues to be passed concerning the use of PVC and related plasticizers. Global awareness of the dangers of PVC has led many to turn to production of products free of DEHP, a plasticizer that increases flexibility and transparency but which fails to eliminate the dangers all together. Manufacturers now have a viable alternative with additional benefits over traditional PVC tubing.

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## The Dangers of PVC and Phthalates (DEHP) in Tubing and Assemblies: Exploring Alternatives

A staple for medical device extrusion for decades, Polyvinyl Chloride (PVC) has been on the radar for several health organizations around the world and legislation continues to be passed concerning the use of PVC and related plasticizers. Global awareness of the dangers of PVC has led many to turn to production of products free of DEHP, a plasticizer that increases flexibility and transparency but which fails to eliminate the dangers all together. In the absence of a readily available substitute, what are the alternatives for medical device molders?

### Health Organizations and Industry movement away from PVC

As awareness has grown of the health risks posed by PVC, the medical industry has called for a move away from the use of current products and the manufacture of future ones. Over 100 healthcare institutions around the world are reducing or phasing out PVC and phthalates.<sup>1</sup> In addition, researchers at the **Harvard School of Public Health** have found that sick infants treated in neonatal intensive care units have high exposure levels to this reproductive toxicant.<sup>2</sup> Similarly, the **American Public Health Association** in November 2011 passed a resolution urging hospitals, schools and nursing homes to reduce the amount of PVC they use.<sup>3</sup> Even **Kaiser Permanente**, a major US healthcare provider, announced in the beginning of 2012 that it will no longer buy intravenous (IV) medical equipment made with PVC.<sup>4</sup>

### Plasticizers and Dioxins in PVC are Health and Environmental Risks

Dioxin (a carcinogen), ethylene dichloride and vinyl chloride are unavoidably created in production of PVC and are reported to cause severe health problems. Studies have shown that exposure to dioxins at high enough levels may cause a number of adverse health effects, including cancer.<sup>5</sup> The problem is that PVC is useless without the addition of a plethora of toxic chemical stabilizers - such as lead, cadmium and organotins - and phthalate plasticizers (DEHP).

The challenge is that plasticizers are necessary for the production of flexible PVC, of which over 85% are phthalates.<sup>6</sup> These leach, flake or outgas from PVC over time raising risks that include asthma, lead poisoning and cancer.<sup>7</sup> Exposure to DEHP has produced a range of adverse effects in laboratory animals, but of greatest concern are effects on the development of the male reproductive system and production of normal sperm in young animals.<sup>8</sup>

The seemingly simple solution would be to remove the toxic and/or carcinogenic materials, and some manufacturers have developed products that are **DEHP free (or Phthalate free)**. Unfortunately, this only eliminates the plasticizers used (phthalates) but **does not eliminate the dioxin, ethylene dichloride nor vinyl chloride** which are unavoidably created in the production of PVC. The only viable alternative is PVC FREE products, which eliminate all of these elements: phthalates, dioxin, ethylene dichloride and vinyl chloride.

## **Legislation and Regulatory Environment**

As the potential health risks have been revealed, the use of PVC has come under increased scrutiny and subsequent legislation in the U.S. and across the globe. In the U.S., since 1998, PVC has been banned in the manufacture of rattles, teething rings, pacifiers, and baby bottle nipples.<sup>9</sup> Similarly, New York City, Boston, Seattle, San Francisco, and Buffalo have passed PVC purchasing measures.<sup>10</sup>

On the international front, France passed legislation at the end of 2012 banning products containing DEHP (the plasticizer in PVC) starting in 2015.<sup>11</sup> Sweden first proposed restrictions on PVC use in 1995 and is working toward discontinuing all PVC uses.<sup>12</sup> Spain, over 60 cities have been declared PVC-free.<sup>13</sup> Germany has banned the disposal of PVC in landfills as of 2005, is minimizing the incineration of PVC, and is encouraging the phase out of PVC products that cannot easily be recycled. Since 1986, at least 274 communities in Germany have enacted restrictions against PVC.<sup>14</sup>

## **Challenges, Solutions and Alternatives to PVC**

Few would dispute the necessity of switching from PVC to more medically and environmentally safe alternatives, but the change is not without serious obstacles. First of all, the flexibility and transparency of PVC is difficult to duplicate. Secondly, there are significant costs associated with researching and replacing PVC products. There is an enormous capital outlay that is required to convert to materials that are completely PVC free.

The American Public Health Association in a Policy Statement from November, 2011 reports that viable alternatives to PVC tubing include polyurethane, silicone, and rubber. Similarly, IV bags can be manufactured from polyethylene, ethylene vinyl acetate, nylon, and a host of other plastics.<sup>15</sup>

Some plastics manufacturers have developed alternatives to PVC for everything from medical and beverage tubing to children's toys. The challenge is to eliminate the plasticizers, dioxins, and chloride while maintaining the clarity and flexibility in the material produced. In addition, converting to new, PVC FREE materials requires completely new manufacturing equipment that has never run PVC because of the permanent contamination that results from the production of PVC products.

Some manufacturers have risen to the occasion and have developed product lines that are PVC free and safe for medical applications. One alternative is thermoplastic elastomer (TPE), which has the added advantages of clarity, flexibility and high temperature.

The challenge with TPE is that adhesives commonly used to attach a fitting to the tubing are not effective because of the excellent chemical resistance of TPE. One solution is to combine a single barb fitting with TPE tubing, where both components are manufactured to similar tolerances. This has been proven to meet industry pull test standards in applications like gas sample lines, eliminating the need for adhesives all together. Polyurethane is another material that could be difficult to use with adhesives where barbed forums could be the solution.

New materials must be safe to use yet efficient to process. With the changing environment, selecting a molder with a deep knowledge of material alternatives and the technical prowess to engineer workable solutions becomes all the more critical.

#### Notes:

<sup>1,2, 12, 13, 14</sup> Center for Health, Environment & Justice PVC Factsheet - PVC Policies Across the World, <http://chej.org/wp-content/uploads/Documents/PVC/2009/Fact-Sheets/110909%20PVC%20Policies%20Across%20the%20World.pdf>

<sup>3,6, 15</sup> American Public Health Association Policy Statement: Reducing PVC in Facilities With Vulnerable Populations, November, 2011

<sup>4</sup> Smock, Doug. *Plastics Today*, Kaiser Permanente bans PVC tubing and bags, January 19th, 2012

<sup>5</sup> Schreiber, Judith. Affidavit before the Supreme Court of the State of New York in the matter of the Resilient Floor Covering Institute vs. New York State Department of Environmental Conservation, 2003

<sup>6</sup>American Public Health Association Policy Statement: Reducing PVC in Facilities with Vulnerable Populations, November, 2011

<sup>7</sup> Thornton, Joe, PhD. Environmental Impacts of Polyvinyl Chloride Building Materials, Healthy Building Network, Washington, DC 2002

<sup>8</sup> FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP, July 12, 2002

<sup>9, 10</sup> Center for Health, Environment & Justice PVC Factsheet - PVC Policies Across the World, <http://chej.org/wp-content/uploads/Documents/PVC/2009/Fact-Sheets/110909%20PVC%20Policies%20Across%20the%20World.pdf>

<sup>11</sup> Cioci, Grazia, Health Care Without Harm-Europe Press Release: France's Important Move Towards Phasing Out Phthalates in Medical Devices, 13 December 2012,