

## Veille Internet sur les phtalates du 18/12/2011 au 17/01/2012

### Faits marquants :

#### ARTICLES EN ANGLAIS

- |                               |   |      |
|-------------------------------|---|------|
| ● Plasticstoday.com           | <p><b>- It's an uphill fight to replace PVC in medical tubing</b></p> <p><i>Teknor Apex, l'un des plus grands formulateurs de PVC flexible au monde, est en train de développer activement des alternatives au PVC pour les applications médicales. La tâche est ardue en raison du faible coût des composants du PVC, des grandes infrastructures en place pour la fabrication des matériaux et du processus d'examen réglementaire requis. Toutefois, Teknor a officiellement présenté la série d'élastomères "Medalist MD-500" en remplacement du PVC dans les tubulures médicales l'année dernière.</i></p> | p2-3 |
| ● Environmentalhealthnews.org | <p><b>- Plastizer increases miscarriage risk.</b></p> <p><i>Des scientifiques danois ont trouvé que les femmes exposées à des niveaux relativement courants de phtalate (DEHP) sont davantage susceptibles de faire une fausse couche précoce que les femmes avec une exposition plus faible.</i></p>   | p4-5 |
| ● Chemicalwatch.com           | <p><b>- Sweden finds high levels of phthalates in toys</b></p> <p><i>L'Agence suédoise de produits chimiques (Kemi) a publié un rapport sur les jouets pour enfants qui contiennent des quantités illégales de phtalates après qu'elle a testé 28 produits. Certains jouets dépassent très largement la limite de 0,1% autorisée.</i></p>   | p6   |



# It's an uphill fight to replace PVC in medical tubing

By Doug Smock

Published: January 11th, 2012

Teknor Apex, one of the world's largest compounders of flexible PVC, is actively developing a PVC-free alternative for medical applications and already reports a handful of commercial applications in smaller sizes.

Replacing PVC in medical applications is a daunting task because of the low cost of PVC compounds, the large infrastructure in place for manufacturing the material, and the regulatory review process required.



Some would say it's also hard to match PVC's performance record.

"PVC has been the material of choice for flexible medical tubing and respiratory masks for more than 30 years because of its balance of cost and functional properties," Elliott Pritikin, senior medical market manager at [Teknor Apex Co.](#) (Pawtucket, RI) told [PlasticsToday.com](#) in an interview.

To be sure, PVC remains strongly entrenched in medical applications.

*A highly flexible elastomeric option is available as a PVC replacement in medical tubing.*

But the drumbeat of negative publicity about PVC is ongoing and has led to increased efforts by some design engineers in the medical device community to explore alternatives. The

Medical Device Directive in Europe requiring special labeling for all devices containing phthalate plasticizers coupled with a ban on children's products made using certain phthalates by the US Consumer Products Safety Commission has contributed to a bigger push in the medical design community.

Teknor Apex formally introduced Medalist MD-500 Series elastomers as a PVC replacement in medical tubing at MD&M West last year.

Pritikin says the Medalist compounds exhibit comparable crystal clarity and mechanical properties to PVC; provide similar clamp resilience and resistance to kinking and necking; have a similar "feel"; and are substantially more flexible and significantly less dense than PVC. At the same time they undergo minimal color shift upon heat aging after exposure to gamma irradiation, the most severe type of sterilization. A typical compound in the series, Medalist MD-575, actually exhibits 70% less heat-aged color shift than a gamma-stabilized PVC compound of comparable hardness, according to Teknor Apex.

## Kune tests line speed

In a demonstration with American Kuhne, tubing made from the elastomeric compounds ran at speeds up to 830 ft/min while running Teknor's Medalist medical elastomer. At 600 ft/min line speed, tight tolerances of +/- 0.0004" on the OD and +/- 0.0001" on the wall thickness were held.

Pritikin says that the chemistries in the specific Medalist series are proprietary, but are drawn from the company's portfolio of polyolefin, styrenic, and vulcanizate materials.

The big job for Teknor Apex now is working with the entire supply chain to develop potential net cost savings for a total systems approach given the cost pressures in the medical market now and the significant cost discrepancy between PVC and TPE on a per pound basis. Elastomers can easily cost much more than 50% per pound than PVC. They have a 30 to 40% lower specific gravity, but that doesn't make up the difference in materials' cost. Plus there is the substantial cost to qualify the new materials. The improvement in flexibility can be a significant advantage in some applications.

In an important breakthrough, Teknor Apex has developed patent-pending adhesive systems to bond specific grades of its new Medalist medical series.

According to Teknor Apex testing, the new systems enable common-size TPE infusion tubing to achieve bonds exhibiting a retention force significantly greater than the minimum required by device manufacturers, with 99.7% confidence that failures will not occur below the threshold of 35.6 Newton force (8.0 lbf).

"Commercially available adhesive and solvent systems used with PVC tubing either do not enable most TPE tubing to achieve this bonding strength or do not permit sufficient work time for ease of assembly," says Pritikin. "Teknor Apex has overcome these limitations for TPE tubing in the 65 to 85 Shore A range with development of two patent-pending adhesive systems and one patent-pending solvent bonding system."

One of the systems uses commonly available solvents and may eliminate need for multilayer extrusion, a significant cost savings.

Teknor Apex feels that the breakthroughs in bonding technology remove remaining barriers to use of Medalist MD-500 Series elastomers in medical tubing.

Samples of tubing of the material will be part of the Teknor Apex exhibit in booth 58038 at [NPE 2012](#) being held April 1-5 in Orlando, FL.

For the record, Pritikin says the concerns raised about PVC are "undue" and that Teknor Apex "has a great deal of confidence in the long-term sustainability of PVC. We wanted to offer the market an alternative where it's desired." The following table was provided by Teknor Apex:

[Retour au début](#)



## Plastizer increases miscarriage risk.

Jan 12, 2012

Toft, G, BAG Jönsson, CH Lindh, TK Jensen, NH Hjollund, A Vested and JP Bonde. 2011. **Association between pregnancy loss and urinary phthalate levels around the time of conception.** [Environmental Health Perspectives](#) <http://dx.doi.org/10.1289/ehp.1103552>.

Synopsis by [Renee Gardner](#)

In the first study of its kind, scientists studied couples trying to conceive a child for the first time and found that women with greater exposure to a phthalate associated with plastics were more likely to experience a pregnancy loss.

Scientists in Denmark report that women exposed near the time of conception to relatively common levels of a particular phthalate are more likely to experience early pregnancy loss compared to women with lower exposures.

The phthalate associated with the losses is a breakdown product of a phthalate highly used in plastics. Only exposures around conception – and not in the prior month – were linked to the loss.

This is the first study to examine phthalate exposure and miscarriage in humans. It is unique because it measured exposures at a specific time after conception that is an important window for early pregnancy loss. The results are published in the journal *Environmental Health Perspectives*.

Rodent studies also report reproductive effects of phthalate exposure. Prior research shows phthalates can cause pregnancy loss and reduced litter size. The animals in these studies were exposed to phthalate levels about 100 times greater than those experienced by the general human population.

Adults are exposed to phthalates primarily through diet. Phthalates are used to make vinyl plastics softer and more flexible. Food packaging, medical tubing and children's toys can contain the chemicals. Other phthalates are also found in certain personal care products, such as fingernail polish, perfumes and cosmetics. Because of their wide use, exposure is ubiquitous and continuous.

About one-third of all pregnancies end before term. Many are lost during the first weeks of pregnancy before a woman may even know she is pregnant.

From 1992 to 1994, couples in Denmark trying to get pregnant for the first time participated in the study by donating daily urine samples. In 2009, researchers analyzed the samples for levels of a hormone called hCG (human chorionic gonadotropin), which is the same hormone that home pregnancy tests can detect. The scientists identified early pregnancy losses in the women by determining who had high levels followed by a decline of hCG in their urine. For pregnancies that were confirmed by a doctor, the women reported their pregnancy outcome after one year. Scientists also analyzed the urine samples taken shortly before ovulation for concentrations of several phthalates and the metabolites of these phthalates, which are excreted in the urine after the body has processed the chemical.

Of the 148 women followed, 48 had a pregnancy loss, of which 32 were early on and identified by fluctuating hCG hormone levels. The women in this study were exposed to phthalates at the same levels as women in other parts of the world, such as Germany and the United States.

The scientists found that the women with the highest levels of monoethylhexyl phthalate (MEHP) in their urine around the time of conception were more likely to experience a pregnancy loss compared to those with lower exposures. The associated risk was greatest when the scientists considered only early pregnancy losses occurring within the first six weeks of gestation.

High levels of MEHP indicate a greater exposure to the particular phthalate di-(2 ethylhexyl)phthalate (DEHP), which is a component in plastics.

The scientists only detected the association when they considered phthalate exposure during the month that conception occurred. Phthalate exposure from the previous month before pregnancy had no detectable effects in terms of pregnancy loss.

Since this study is the first of its kind in humans, further studies are necessary to confirm the relationship between phthalate exposure and pregnancy losses.

[Retour au début](#)



## Sweden finds high levels of phthalates in toys

16-Jan-2012

The Swedish Chemicals Agency (Kemi) has published details of children's toys containing illegal quantities of phthalates, following tests carried out on 28 products.

The agency found two children's dummies products containing levels of di(2-ethylhexyl) phthalate (DEHP) between 17% to 19%, far exceeding the permitted concentration of 0.1%. In addition, a Halloween mask was found to contain concentrations of both di-isononyl phthalate (DINP) and DEHP above allowed levels. Kemi has notified the product manufacturers of the results.

- [Kemi press release \(in Swedish\)](#)

[Retour au début](#)