Getting Smart Around Phthalates and PVC

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Flexible Vinyl Alliance

www.flexvinylalliance.com

What is "vinyl" or "PVC?"

PVC is shorthand for polyvinyl chloride, or simply, "vinyl." Vinyl is a widely used plastic material. It is composed of two simple building blocks: chlorine, based on common sea salt, and ethylene, derived from natural gas liquids. By employing further chemistry, vinyl can be made flexible or rigid; clear or colorful; thick or thin – making it an extremely versatile plastic material.

Why are vinyl products important?

Rigid vinyl is employed primarily in large and small diameter pipes, residential siding, window frames, and heavy industrial applications. 75 percent of vinyl resin is employed in vinyl-based products that are rigid, i.e., non-flexible.

On the other hand, flexible vinyl is used in hundreds of other unique applications. These include computer and phone charging cords, automotive seats and dashboards, fabrics and upholstery, hazard suits for hospital workers, blood bags, roofing, flooring and wall coverings for homes, hospitals and businesses of all types, as well as traffic cones, banners and signs, food packaging, and pharmaceutical safety seals.

Obviously, vinyl serves multiple markets but in each case delivers performance through stringent, exacting manufacturing processes, tied to chemistry, formulation, compounding, conversion, packaging, delivery and life-enhancing and life-saving deployment.

Hundreds of products in all these "flexible PVC" categories employ "plasticizers" – in many cases "phthalates" to enhance their performance and durability as engineered products and to provide the product the performance requirements needed for the specific, custom function.

What are phthalates?

Phthalates (THAL-ates) are a family of compounds, some of which are primarily used to soften or "plasticize" vinyl. Phthalates are held in the structure of vinyl products. The bond strength is measurable. Various chemical-physical attractive forces hold the phthalate within the vinyl matrix, so that migration occurs at a very low rate under extreme conditions or if at all during normal use.

Therefore, retention in the polymer matrix is one of the main factors in considering which phthalate ester to use. Together with their low vapor pressure, phthalates are beneficial to long service life to keep products flexible, and in service for years and decades.

Reference: Phthalate Esters (The Handbook of Environmental Chemistry) (v. 3) 2003 Edition.

Are phthalates safe?

Phthalates have been safely used in consumer and commercial products for more than 50 years to enhance durability, flexibility, and performance. Phthalates are some of the most tested substances in commerce. Phthalate use is regulated, but not all phthalates are regulated in the same manner across the globe. Rigorous risk assessments by multiple government agencies in the United States, Europe, Canada and Australia have concluded that many phthalates present a low-risk for their current intended uses. In spite of this, phthalates continue to be called out in speculative health studies that do not meet typical "peer-reviewed" scientific standards, which are fueling safety misperceptions. Phthalates are not alone in this regard – consider the decades-long safety debates around coffee, sweeteners, vaccines, power lines and cell phones.

Assessing safety "Studies": Some are science, many are observational exercises

Sensationalist science more often than not drives misperceptions around chemicals. The most frequently cited studies attacking phthalates don't account for cause and effect, real risk or exposure. The "trustworthiness" of any given study, whether it be around phthalates or any other plastic additive is steeped in an accepted "hierarchy" of legitimate scientific studies. They are:

1. An observational study which may be interesting but is not trustworthy;

2. An epidemiological study: trustworthy if large and well done;

3. A meta-analysis study or review study: trustworthy;

4. A randomized controlled trial: the gold standard.

Source: Wrong: Why Experts Keep Failing Us – and How to Know When Not to Trust Them: David H. Freedman 2010: Little, Brown, and Company.

Unfortunately, the breathless reports often seen in the "health" sections of newspapers, television news and countless websites are often based on "studies"

that fall into Category 1 as "observational." Thus, it is incumbent on the news reporter, and the consumer, to assess if the study is legitimate, according to the above categorizations. The question is easily asked by any investigator or journalist if only they would take the time.

In this vein, several scientists over the years have attempted to define reproductive and developmental effects in humans from phthalate exposure in laboratory animals. Despite the publicity often surrounding such studies, none prove a direct link between phthalates and the human health effects often claimed, or the causation agents that are purported to elicit such "health effect(s)."

Moreover, much reported research is often not able to be reproduced by other scientists. If reproducibility efforts are made, and the study is proven flawed, the challenge often goes unreported. So, the consumer, many times a concerned parent, is essentially left both nervous and ill-informed. For an accurate, if irreverent, assessment of "bad science" see HBO's John Oliver's take on the issue here: https://www.statnews.com/2016/05/09/john-oliver-bad-science/.

Why are "non-scientific" studies so often featured in the media?

This largely is due to the fact that certain groups rely on scare tactics to fund their anti-chemical advocacy efforts, and because for-profit media outlets need "eyeballs." Case in point is the *New York Times* (NYT) story www.nytimes.com/2017/07/12/well/eat/the-chemicals-in-your-mac-and-cheese.html around macaroni and cheese products: although the report relegated Easy Mac to the hazard bin, the study was neither accepted for publication in a peer-reviewed journal nor adequate enough to convince participating researchers to lend their names to the data. It was, however, paid for by self-interested "watchdog" groups such as We Act for Environmental Justice, Center for Science in the Public Interest, and Center for Food Safety. The story was the "most clicked" story that day on the NYT digital site.

In fact, U.S. Food and Drug Administration researchers, in an analytical report on the types of plasticizers used in common food-contact materials (March 2018), noted that: "There have been no studies to date which show any connection between human dietary exposure to phthalates and adverse health effects."

Source: Investigation of the primary plasticizers present in polyvinyl chloride (PVC) products currently authorized as food contact materials. Article in "Food Additives and Contaminants" Part A: March 2018.

There is "Good Science" being reported: Using MMR Vaccine studies as a benchmark

For an example of "sound science" note the methodologies surrounding the safety of the MMR vaccine. In the latest study, researchers analyzed data collected from all children born in Denmark to Danish-born mothers between 1999 and 2010. 657,461 children were included in an analysis over the course of a decade, concluding there was no overall risk for development disorder among

those who received the MMR vaccine when compared with those who had not gotten the vaccine, the researchers found. This was a long-term randomized control trial – the gold standard. When determining study validity, this Danish study stands out as exemplary.

Source: https://annals.org/aim/fullarticle/2727726/measles-mumps-rubella-vaccination-autism-nationwide-cohort-study.

The Last Word

Science is already under threat of losing sway in the public eye. Advocacy groups fear-conditioning us through the promotion of unsound science, amplified by media outlets, is doing no favors to the consumer, especially parents.

In general, it is critical that good product development and manufacturing practices are employed to find the right chemistry for the right application. As new scientific experimentation is completed through reliable peer review processes, additional details continue to guide manufacturers on safe production and product use practices, including the use of phthalates.

Understanding the importance of detailed knowledge about these chemicals is paramount to their safe use, the consumer product's formulation, use, and disposal at the end-of-life, and identification of any potential exposure associated at each point in the product's life cycle. This is industry's abiding responsibility and it is taken seriously. We ask that science, good science, be a partner in this endeavor, as well as those who report on it.

For responsible information around PVC products:

- Chemical Fabrics and Film Association (CFFA): www.chemicalfabricsandfilm.com
- Communications Cable & Connectivity Association (CCCA): www.cccassoc.org
- Flexible Vinyl Alliance (FVA): www.flexvinylalliance.com
- Plastics Industry Trade Association, The Vinyl Products Division: www.plasticsindustry.org
- Resilient Floor Covering Institute (RFCI): www.rfci.com
- Vinyl Institute (VI): www.vinylinfo.org
- Vinyl Verified: www.vinylverified.com