Phthalates and their Alternatives

Are Replacements an Improvement over Existing Products?

Better, Or Just Different? - As the world moves away from using phthalates because of their association with human health effects, making sure their replacement alternatives are actually an improvement is critical. Are they?

More than 25 phthalates are used in commercial applications, each one offering unique qualities to the plastic into which it is incorporated. Because of their widespread use in consumer products, phthalates are now found throughout our environment and in humans. For this reason, as well as studies linking phthalates to adverse health effects, countries on both sides of the Atlantic have banned some of them.

Background

Phthalates are the most commonly used plasticizers in the world, accounting for more than 80% of worldwide plasticizer production, according to plasticizers.org. The many different phthalates provide flexibility to PVC, as well as to other products, and can be found in almost anything, including toys, automobiles, food packaging, cleaning materials, cosmetics, building materials, medical devices, clothing and household furnishings.

Eight common phthalates are dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), di-isononyl phthalate (DINP) and 1,2-diisodecyl ester (DIDP).
Sources and information regarding alternatives to phthalate plasticizers are less available than for phthalates themselves, but more than a dozen are mentioned in various reports, industry literature and articles. Common alternatives include Hexamoll DINCH (DINCH), acetyl tributyl citrate (ATBC), dioctyl terephthalate (DOTP), 2,2,4-trimethyl 1,3-pentanediol diisobutyrate (TXIB), trioctyl trimellitate (TOTM) and di-(2-ethylhexyl) adipate (DEHA).

Phthalates **do not form covalent bonds** with the products in which they are used, and, therefore, have the potential to leach, resulting in **possible human exposure**.

Since phthalates are ubiquitous in consumer products, and many infant and children products have traditionally been made of flexible PVC, which can contain up to **60% plasticizers by weight**, the potential of leaching phthalates has alarmed the public and the media. As a result, scientists have focused on whether these chemicals pose adverse health risks in humans.

Studies have shown that **certain phthalates** have the potential to be **endocrine disruptors**. For example, an in utero study of pregnant rats exposed to di-n-hexyl phthalate (DNHP) resulted in permanent and dose-related variations in male rat reproductive development (Saillenfait et al. 2009). It is important to note that these adverse effects were observed at particularly high doses - more than 100 times the doses to which a child or pregnant mother might ever be exposed. While most studies exploring the **potential endocrine-disrupting effects** of selected phthalates have been performed on animals, few studies have examined the effects of phthalates **on human reproductive development**. Although certain studies have linked selected phthalates to adverse human reproductive effects, the Phthalate Information Center reports that there is no reliable evidence that phthalates have caused human health problems from their intended use.

**Legislation And Bans**

Regardless of the inconsistent scientific findings, in 1999, mounting concern and uncertainty over the potential health effects of selected phthalates, specifically related to children, prompted **the European Union to ban the use of six phthalates** in the production of children's toys: DINP, DEHP, DBP, BBP, DIDP and DnOP.

The U.S. followed suit in 2008 by passing **the Consumer Products Safety Improvement Act** banning the same six phthalates in children's toys. With
pressure mounting from legislation, public interest groups, and the media, companies began substituting alternative chemicals for phthalates in their products. Today, non-phthalate plasticizers are growing three times faster than the rest of the plasticizer market, and represent more than 10% of the entire global market.

European authorities have further classified phthalates with three to six carbons in their backbone as Category 1B Reproductive Agents. For this reason, and based on the precautionary principle, these particular phthalates may not be used in toys, child care items or cosmetics. These same phthalates, which include DBP, BBP, DIBP and DEHP, are recognized as "substances of very high concern" (SVHC) under REACH, and are subject to authorization. But are the alternatives to phthalates any better?

Given the history of phthalates, it would be expected that scientists and the public alike would have given a great deal of scrutiny to these alternatives. But what do we know about these alternatives and how they compare with the phthalates they are replacing?

To help answer this question, based on data collected on both phthalates and their alternatives, we compared various toxicological end points and the associated risks of the six banned phthalates and six commonly used alternative chemicals (DINCH, ATBC, DOTP, TXIB, TOTM, DEHA). Given that these alternatives have been used more frequently, it is surprising how little attention has been paid to comparing the toxicological and risk-based properties of these two groups of chemicals.

Phthalates are commonly termed "toxic." As all toxicologists know, however, the dose makes the poison; that is, all compounds, including water, are inherently toxic, but the amount that people are exposed to is what matters. A direct measure of acute oral toxicity is called the median lethal dose, LD$_{50}$. In basic terms, LD$_{50}$ is the dose that causes half the animals in a toxicological study to die. Figure 1 shows the LD$_{50}$ of phthalates and the alternatives generally lie somewhere between that of sugar and salt. The bigger the bar, the less toxic it is. All of the phthalates and the alternatives are above the levels considered to be acutely toxic.

Historically, the main health concern associated with phthalate exposure has been the link to developmental or endocrine-system effects. Figure 2 compares the Developmental Toxicity No Observed Adverse Effect Levels (NOAEL) for the banned phthalates and the common alternatives. The NOAEL, in this case, is the dose at which no adverse health effects were observed in toxicological studies.
using rats. Once again, the bigger the bar, the less "toxic" it is. With the exception of DEHP, which is by far the most potent developmental toxin in this group, there is limited differentiation between the banned phthalates and the various alternatives.

More points of comparison, including the ability of these substances to bio-accumulate and their carcinogenicity rankings, are available. The results are similar to the above examples.

Conclusions

First, any plasticizer, whether a phthalate or an alternative, should be examined for its own properties. These substances should not be grouped based on whether or not they have "phthalate" in their name.

Second, before substituting a phthalate with an alternative, sufficient data should be acquired to prove the alternative is actually an improvement over the existing product. We evaluated a number of toxicological end points in our study (too many to discuss here), but consistently found that data were lacking for many of the phthalates and alternatives. Without data, "regrettable substitutions" are difficult to avoid. We also observed that the alternatives to phthalates were not that much, if at all, better than the phthalates they were replacing in terms of the toxicological end points evaluated.

Lastly, based on the parameters evaluated, the phthalates were not nearly as "toxic" as might be expected of a banned chemical. We did not find the various phthalates to be risky at existing exposure levels.

Autor(en)


Kontaktieren

CARDNO Chemrisk
101 Second Str., Suite 700
San Francisco, CA 94105
USA
Telefon: +1/415/896-2400
Telefax: +1/415/8962444