

essential₂know

about Phthalates

Phthalate Esters Panel



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PHTHALATES — THE BASICS

What are phthalates?

Phthalates are a family of compounds made from alcohols and phthalic anhydride. They are oily, colorless, odorless liquids that do not evaporate readily.

Used primarily in vinyl, they are an important part of our everyday lives.

Most phthalates are used to make vinyl soft and flexible. From their use in medical devices to toys to cars to homes, flexible vinyl products help make our lives better and safer. And in hospitals and emergency rooms, they help save lives. They make our homes more decorative, easier to clean, more energy efficient and durable. Flexible vinyl products are high-performing and cost effective; their performance is difficult or impossible to match with competitive substitutes. They save money for consumers.

Some phthalates deliver unique benefits to the personal care products industry.

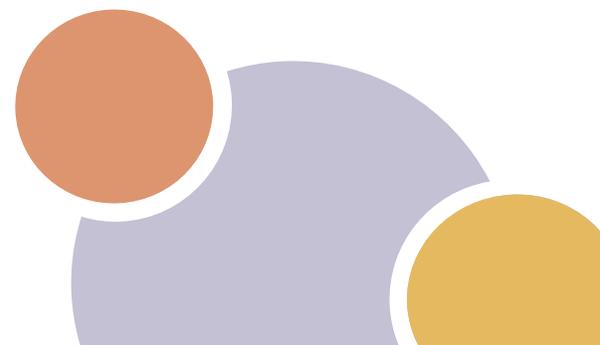
For more than fifty years, they have been a key ingredient in fragrances and in nail polish. One kind of phthalate fixes the fragrance in perfumes and other products to make it last longer. Another type is used in nail polish (as well as in tool handles and outdoor signs) to help prevent chipping and breaking.

Many independent reviews have declared them to be safe as used in toys and cosmetics.

Safety reviews by European and American scientific panels have specifically cleared phthalates for use in toys and in nail polish. The different reviews use phrases such as “safe as used,” or “no concern,” or “no

demonstrated health risk.” No governmental review has found any phthalate unsafe as used in products for the general public.

In more than fifty years of use, no reliable evidence has ever shown that any phthalate has ever caused harm to anyone.



DINP — VINYL TOYS AND HEALTH

DINP is the principal ingredient used in vinyl toys to make them soft, flexible, and affordable, as well as to increase their safety profile.

- DINP is the overwhelming choice of U.S. toy manufacturers to make vinyl toys soft because of its performance characteristics and its affordability.
- DINP has been used to make vinyl toys soft and flexible for decades.
- The U.S. Consumer Product Safety Commission has advised that “If DINP is to be replaced in children’s products... the potential risks of the substitutes must be considered. Weaker or more brittle plastics might break and result in a choking hazard. Other plasticizers might not be as well studied as DINP.”

Independent safety reviews of DINP have found it to be safe as used in vinyl toys.

- The U.S. Consumer Product Safety Commission spent four years studying DINP and conducted original research on the amount of time children hold toys in their mouths, and concluded that there is “no demonstrated health risk” from its use in toys and “no justification” for banning its use.
- A European Commission safety review, conducted under the direction of the European Chemicals Bureau, found that DINP’s use in consumer products, including toys, is “unlikely to pose a health risk to adults, infants, or newborns.”
- The National Toxicology Program, an arm of the U.S. National Institutes of Health, found “minimal concern” for the use of DINP in toys.
- Data from the Centers for Disease Control and Prevention show that average human exposure to DINP is far below safety levels set by the EPA.

No human health effect has ever been reliably linked to exposure from any phthalate, or any combination of phthalates.

- Average exposures of U.S. citizens to phthalates are well below government safety levels—even when exposures are added together.
 - No study claims to show a link between DINP and effects on humans.
 - Health effects seen in rodents are caused by doses of some phthalates that are far beyond what CDC data show people experience in daily life.
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PHTHALATES IN COSMETICS & PERSONAL CARE PRODUCTS

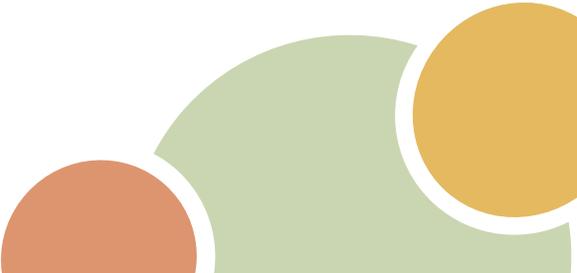
Phthalates deliver unique benefits to the personal care products industry. For more than fifty years, they have been a key ingredient in fragrances and in nail polish.

- The three phthalates used in personal care products (DBP, DMP, DEP) are “safe for use in cosmetic products in the present practices of use and concentration,” according to an FDA-sanctioned panel of university scientists, the Cosmetics Ingredient Review.
- Average human exposure to the phthalates used in personal care products is far below safety levels established by the Environmental Protection Agency, based on government biomonitoring data.
- DEP, DMP and DBP do not build up in the body. They break down rapidly and are cleared from the system within 24 hours. In the environment, they break down readily.

Major reviews have found DBP safe as used in nail polish.

- DBP has been used in nail polish for decades to help prevent chipping.
- An extensive safety review by a European Union scientific panel found “no concern for consumers using nail polish containing DBP.” The Cosmetics Ingredient Review found DBP “safe for use” in nail polish.
- Average human exposure to DBP is 300 times below the safety level set by the EPA, according to its 2006 draft calculation. That is three times more of a safety cushion than the original calculation.
- Exposure to DBP for women of childbearing age is the same as or below that for other age groups, according to CDC biomonitoring data. (Pressure-group statements to the contrary are wrong, based on an early CDC estimate of a very small number of subjects, which the CDC later corrected.)

U.S. and European experts chose not to conduct safety reviews on DEP; the evidence shows that it causes no health effects in rodents.

- DEP has been used for 40 years as a solvent to make fragrances in perfumes and personal care products last longer.
 - Consumer exposure to DEP is less than 1/100th of the safety level set by the EPA as shown by CDC data.
 - The CIR review of DEP found it “safe as used.”
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PHTHALATES IN MEDICAL DEVICES

The use of phthalates in medical devices revolutionized the storage and delivery of whole blood to patients and the military.

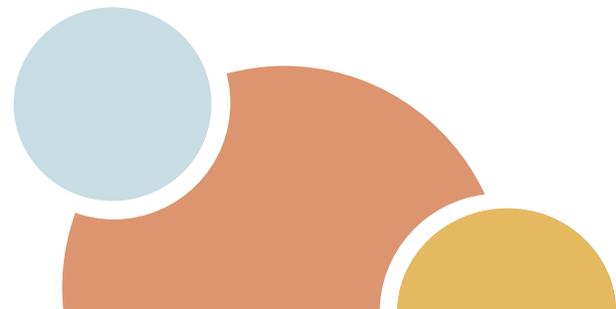
- Vinyl bags softened with a phthalate (DEHP) replaced glass bottles in the 1950s.
- Clear, strong, easily sterilized, shatter-resistant and flexible, vinyl blood bags remain the blood-storage device of choice for those who collect and deliver whole blood.
- Vinyl blood bags double the shelf life of whole blood from 21 to 42 days, greatly easing the pressure on blood supplies.

Vinyl tubing and other phthalate-softened vinyl medical devices are critically important tools for the medical profession, especially in crisis situations.

- Vinyl tubing softened with DEHP is the overwhelming choice for use with patients needing dialysis or receiving intravenous fluids, because it is strong, clear, does not kink, and returns to its original shape when stretched or pinched. Kinking can restrict or stop the flow of lifesaving blood, fluids, or medications.
- Vinyl tubing and medical devices are used to oxygenate the blood of critically ill newborns.

Vinyl tubing and other phthalate-softened vinyl medical devices are already well and appropriately regulated.

- The FDA regulates the use of these products, noting that they have been used for years in such cases “without apparent ill effect.”
- Exposure levels of DEHP can approach FDA safety levels when a critically ill neonate’s exposure to the equipment is prolonged, and the FDA has recommended “considering” alternative materials, but it has advised that “the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP.”
- These concerns are based on effects of high doses seen in rodents, not on any effects ever observed in humans.



PHTHALATES & YOUR HEALTH

There is no reliable evidence that any phthalate has ever caused any harm to anyone.

The cancer story:

In the 1980s, some phthalates were shown to cause liver cancer in rodents when administered at high doses over long periods of time.

Subsequent research showed that the cancer was caused by a biological process in rodents that does not occur in humans.

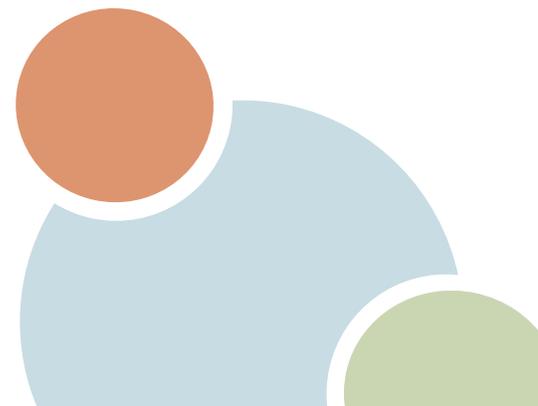
In 2000, the International Agency for Research on Cancer, an arm of the World Health Organization, declared DEHP to be “not classifiable” as a human carcinogen.

The reproductive effects story:

High doses of some phthalates have been shown to interfere with the development of the male reproductive system in rodents, an effect believed to be caused by suppression of testosterone production.

Some studies claim to show a link between phthalate exposure and reproductive effects in humans. Those most often cited were reviewed in 2006 by an independent government-sponsored panel and found to be “insufficient” for drawing any conclusions.

Some research suggests that reproductive effects seen in rodents are not relevant in humans, as is the case with cancer. Huge doses of a phthalate fed to male marmosets (a small monkey) as they matured resulted in no damage to their reproductive organs. Other studies show that marmosets (which are primates like humans) do not absorb phthalates as readily as rodents do, and break them down and excrete them more quickly. Research is continuing on this point.



Q & A

Q. What are phthalates?

- A. Phthalates are a large family of compounds used in a wide variety of everyday products. They are colorless, oily liquids with little or no odor and low volatility.

Q. What are they used for?

- A. The dozen or so phthalates in use today find thousands of applications. Their chief use is to make vinyl soft and flexible, without sacrificing its durability. They are used as softeners (or plasticizers) in toys, cars and products found in the home and in hospitals. For example, they are an important ingredient in vinyl medical devices used to help save lives. One member of the phthalate family is used in perfumes and other personal care products to make their fragrances last longer. Another type of phthalate is used in items such as tool handles and nail polish to help resist chipping.

Q. Are they safe?

- A. Regulatory agencies and independent authorities have found phthalates to be safe as used in vinyl products and personal care products. There is no reliable evidence that any phthalate has ever caused any harm to any human in their fifty-year history of use. Phthalates are one of the most thoroughly tested families of compounds in use today. An immense amount of information on their safety profiles is available to users.

Q. Who says so?

- A. The European Union has conducted extensive safety reviews of all the major phthalates, and has found they present no concern to the general public in their current uses. Its reviews specifically cover uses in nail polish and in toys.

The U.S. Consumer Product Safety Commission has found that the principal phthalate used in toys presents “no demonstrated health risk” to children.

The U.S. Centers for Disease Control and Prevention (CDC) has tested thousands of Americans for evidence of exposure to phthalates (as well as to more than one hundred other chemicals and elements). CDC data show that average human exposure is far below levels set by the U.S. Environmental Protection Agency as protective of human health.

Q. Why have phthalates been banned from personal care products in Europe?

- A. Not because any human health effects have been found. The European Cosmetics Directive says that any substance known or strongly suspected to have certain health effects in laboratory animals—even if this occurs only at extremely high doses—is assumed to present similar risks to humans, and

may not be used in cosmetics. The directive is not based on any evidence that there is any actual risk to humans. In fact, an EU safety review states that there is “no concern for consumers” who use nail polish containing the phthalate DBP.

Q. Why have some phthalates been banned from use in toys in the EU?

- A. The European legislature voted to pass that ban, even though the draft conclusion of an exhaustive safety review of the principal phthalate used in toys stated it was “unlikely to pose a risk” even for newborns. In other words, it was a political decision, not a regulatory one based on science.

Q. The EU risk assessments studied the effects of each phthalate individually. But shouldn't their effects be added and studied as a whole, because various phthalates can act in the same ways on organisms?

- A. Even if you add up the effects of the different phthalates that might be expected to act in the same way on organisms, data from the federal government's CDC tells us that exposure is still below federal safety levels.

Q. But we are exposed to them every day, in many ways. Doesn't that add up to trouble?

- A. We are exposed to lots of things every day. But phthalates do not build up in the body the way certain other substances do. The process of breaking them down begins within minutes, and their half lives are measured in hours.

Q. Isn't it true that phthalates cause health problems in laboratory animals?

- A. Some—not all—phthalates interfere with the development of the reproductive system of male rodents when administered in huge doses—doses far larger than CDC data tells us humans experience. Rodent effects are not necessarily relevant to humans.

Q. What do phthalates do to rodents?

- A. Researchers believe that extremely large doses of certain phthalates suppress the production of testosterone, which is necessary for the normal development of the male reproductive system. The doses that result in these effects are orders of magnitude larger than the exposures humans receive. There is no evidence that this occurs in humans.

Q & A CONTINUED

Q. Does the same thing happen to humans?

A. There is no reliable evidence that it does. There is some evidence that it does not. A small study of children who were highly exposed through life saving medical devices as infants found no ill effects as teenagers.

Q. Is there any evidence that phthalates don't affect humans?

A. Tests on male marmosets, which are primates, concluded that even huge doses administered from weaning until sexual maturity had no effect on their reproductive organs. Other studies indicate that humans do not absorb phthalates as readily as rodents do. Humans break them down and excrete them much more readily than rodents do. This evidence suggests that rodent effects may not apply to humans.

Q. Haven't recent studies shown phthalates to have effects on human sexual development or function?

A. The National Institutes of Health, through its National Toxicology Program studies, has reviewed all studies claiming to show human effects, and in late 2006 called them "insufficient" to warrant drawing any conclusions. All such studies are statistical in nature—that is, they claim to show a correlation between phthalate exposure and certain health effects. But flaws are common, and in these cases, flaws make the results questionable. And none of them claims that phthalates caused any health effect—just that they are statistically correlated with the effects. Such correlations can turn out to be statistical flukes.

Q. Does that include the Swan study?

A. That's certainly what many experts think. The study claims to show certain changes—not actual damage—in the reproductive development of infants, correlated to exposure of their mothers to a combination of four phthalates. Dr. Rebecca Goldin, a Ph.D. mathematician at Statistical Assessment Services (STATS), asked about Swan's study, "how much data fiddling was required to find a result?" Others have criticized the study's methodology, its clinical data, and even its biological plausibility.

Q. Aren't phthalates endocrine disruptors?

A. In lab tests with rodents, phthalates do not block the action of male or female hormones, or mimic their behavior.

Q. Don't they cause cancer?

A. The International Agency for Research on Cancer, an arm of the World Health Organization, says DEHP is "not classifiable" as a human carcinogen. The basis for that decision is ample evidence that the biological process leading to cancer in rodents does not occur in humans.

Q. Haven't phthalates been linked to asthma?

A. Some claims to that effect have been made, but recent laboratory studies have shown that phthalates do not trigger immune responses in rodents, and do not intensify an existing asthma attack. Phthalate levels in house dust have been shown to be very low.

Q. Why do you claim that state or local bans on the use of phthalates in toys are illegal?

A. Many federal laws provide that when a federal regulatory agency has taken an affirmative action on a particular substance for a particular risk, states or localities cannot then regulate it. That is the case here—the CPSC, a federal regulatory agency, has reviewed the use of DINP, the principal phthalate used in toys, and found "no demonstrated health risk."



The six phthalates mentioned in state legislative proposals have been reviewed by various government and government-sanctioned scientific bodies. All the listed phthalates are subject to bans or restrictions in the European Union.

Phthalate
Risk Assessments
United States
and Europe

CPSC
Consumer
Product Safety
Commission

EU
European
Union

CERHR
U.S. Center for the
Evaluation of Risks to
Human Reproduction

(All CERHR reports are
expressed in
levels of concern)

CIR
Cosmetic
Ingredient
Review

CDC
Centers for
Disease Control and
Prevention biomonitoring
studies

DINP

"no
demonstrated
health risk"

"unlikely to
pose a risk for
consumers
(adults,
infants and
newborns)"¹

"minimal concern"
for children, adults and
fetuses

not detectable in most test
subjects

DIDP

no likely risks
for any groups
as currently
used

"minimal concern" for adults,
fetuses and children

not monitored; based on
physical properties and
uses, probably similar to
DINP

DnOP

not assessed

"negligible concern" for
adult reproductive system;
insufficient animal data for
other effects on adults

not detectable in most
subjects

DEHP

preliminary
conclusion:
safe for
general
public
(excluding
neonates)

"serious concern" for
critically ill neonates;
"concern" for infants under
one; "some concern" for
toddlers over one and
male offspring of exposed
pregnant women; minimal
concern for general public

average exposure 10-33
times below EPA reference
dose² (safety level)

DBP

"no concern
for consum-
ers using
nail polish
containing
DBP"

"minimal concern" for
fetal developmental
effects for pregnant women
with typical exposure; "some
concern" for male fetal
development in women with
high exposure (conclusion
based on exposure esti-
mates that turned out to be
higher than actual)

"safe as used"
in current
applications
and concen-
trations

average exposure more
than 100 times below EPA
reference dose

BBP

risk assess-
ment not yet
completed

"minimal concern" for devel-
opmental effects in children
and fetuses; negligible con-
cern for reproductive effects
in adult males.

average exposure 400 times
below EPA reference dose

FOOTNOTES:

¹ European Union risk assessments were performed by member states under the management of the European Chemicals Bureau.

² For phthalates, the EPA reference doses are calculated from the no effect level in the most sensitive rodent studies, divided by a safety factor of 100 to 1000.

ABOUT THE PANEL

The Phthalate Esters Panel (the Panel) of the American Chemistry Council is composed of all major manufacturers and some users of the primary phthalate esters in commerce in the United States.

Since the Panel's inception in 1973, members have demonstrated their commitment to the safe use of their products by sponsoring health, safety and environmental research on phthalate esters. Since its inception, the Panel has funded more than \$15 million of research, excluding research conducted by individual companies.

Results of Panel-sponsored research are routinely shared with government agencies around the globe in order to support a comprehensive and thorough assessment of the products' safety. Panel research and conclusions are peer-reviewed and published in respected scientific journals. Phthalate esters produced by Panel members have been subjected to extensive health and environmental scrutiny by both independent scientists and national and international government bodies.

The Panel is committed to research and testing of phthalate esters and will continue to work closely with government agencies so that these materials can be used safely in a wide array of products consumers find valuable in everyday life.

Panel Member Companies

BASF Corporation
Eastman Chemical Company
ExxonMobil Chemical Company
Ferro Corporation
Teknor Apex (Associate Member)

Panel Manager

Marian Stanley

