



Toxics Link
for a toxics-free world

PHTHALATES

INTRODUCTION

Phthalates are esters of phthalic anhydride and belong to the family of high-volume industrial chemicals¹. They are used as plasticizers which determine the physical properties of polymer products. Phthalates were first introduced in the 1920s. The commercial availability of polyvinyl chloride (PVC) and the development of di-2-ethylhexyl phthalate (DEHP) led to the enormous growth of phthalate industry.^{2,3,4}

At present, 23–26 different types of phthalates are commercially available, which are used as plasticizers, solvents and emulsifiers. Globally, the demand for phthalates has gradually increased up to 8 million tons per year.^{5,6,7}

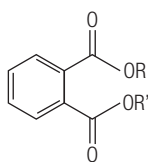


FIGURE 1
Structure of Phthalates

WHERE TO FIND PHTHALATES

- Many flexible plastics, such as:
 - Some plastic food packaging, and plastic food storage containers, specifically containers with a #3 label
 - Tubing and containers used in medical care
 - School products, like binders, art supplies, and lunch boxes
 - Soft plastic and inflatable toys
 - Water bottles
 - Plastic clothes, such as raincoats, backpacks, Shower curtains foot wears
- Fragrances found in some perfumes/colognes, lotions, deodorants, soaps and shampoos, hair sprays, air fresheners, and similar products.
- Nail polish, cosmetics
- Some household products and car care products, such as paints, flooring, adhesives, automobile interiors, sealants and blinds
- Some medications and dietary supplements
- Diapers and sanitary napkins
- Insecticides
- Dielectric fluid in capacitors

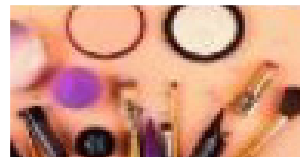


Ingestion

Dermal absorption

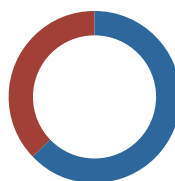


Inhalation



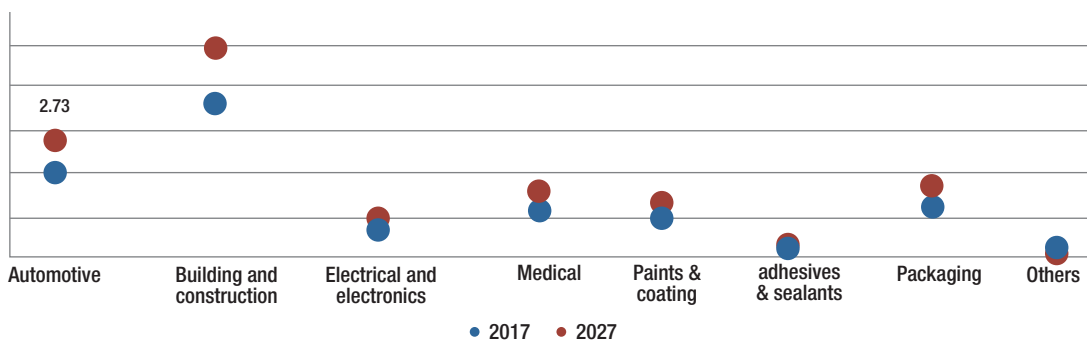


2019-2027, the market will **ACCELERATE** at a CAGR of **3.8%**



63.0%
of the total phthalate plasticizers market is occupied by High phthalates segment.

The Market dominance of the High phthalates segment is attributed to the rising demand for PVC in various industries where it finds applicability in plasticizing PVC.

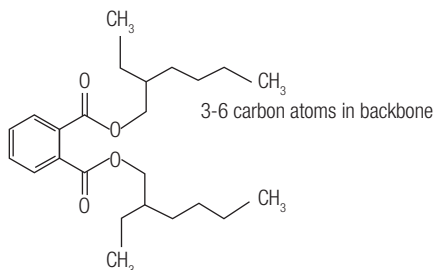


Phthalates are added to plastics to increase their flexibility, transparency, durability, pliability and elasticity.⁸ When added to plastics, phthalates allow the long polyvinyl molecules to slide against one another. They are blended within the plastic article during the manufacturing process.⁹

CHARACTERIZATION

Phthalates are categorized as low and high, on the basis of their molecular weight. Depending upon their molecular weight, phthalates have different industrial applications and impact on environment and health.

Low molecular weight (LMW) phthalates contain less than 7 carbon atoms in their backbone. They are often used in non-PVC applications such as solvents or viscosity controlling agents in personal-care products, lacquers, some pharmaceuticals, etc.¹⁰ Examples of LMW phthalates are diethyl phthalate (DEP), dibutyl phthalate (DBP) and di-iso-butyl phthalate (DiBP).



High molecular weight (HMW) phthalates contain 7–13 carbon atoms or a ring structure in their chemical backbone which gives them increased permanency and durability. Common types of HMW phthalates are di-2-ethylhexyl phthalate (DEHP), diisononyl phthalate (DiNP) and diisodecyl phthalate (DiDP). They are primarily used as plasticizers during the manufacturing of flexible PVC used in consumer products, flooring and wall coverings, building products, food contact applications and medical devices.^{11,12,13}

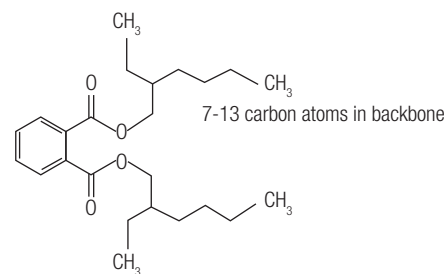


TABLE 1:
Ten commonly used phthalates

Low Molecular weight phthalates	High molecular weight phthalates
di-methyl phthalate (DMP)	di-2-ethylhexyl phthalate (DEHP)
di-ethyl phthalate (DEP)	di-n-octyl phthalate (DnOP)
di-butyl phthalates (DBP)	di-isononyl phthalate (DiNP)
di-isobutyl phthalate (DiBP)	di-isodecyl phthalate (DiDP)
benzyl butyl phthalate (BBP)	Benzyl butyl phthalate (BBzP)
Paper and packaging	Yes

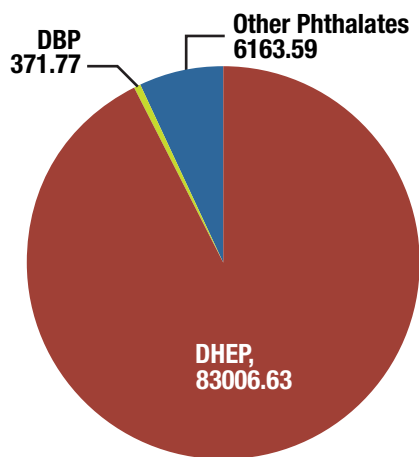


FIGURE 2
Phthalates imported by India in last five years. (Quantity in thousands; unit in Kgs)

PHthalATES: A HEALTH HAZARD

Phthalates are ubiquitously present and are well known endocrine disrupting chemicals. They are generally effective at very low concentration and are particularly harmful during critical phases of life such as pregnancy (fetal development), infancy, early childhood and adolescence. The hormone system is not fully developed at these stages, and effects could be irreversible and visible only in later phase of life. Phthalates can cross the placental barrier and have been measured in the amniotic fluid in humans. Such an exposure can lead to placental DNA mutation.^{14,15}

The different sizes and shapes of phthalates have different effect on hormone receptor proteins and enzymes involved in the synthesis or activation of hormones.¹⁶

TABLE 2:
Potential source of exposure and health impacts of few commonly used phthalates

Phthalates	Molecular weight	Source of Exposure	Health effect
DE	Low	Personal care products, dyes, coatings, insecticides	Reduced growth rate, increased weight
DBP	Low	Personal care products, lacquers, varnishes, cellulose acetate plastics	Reduced fetal weight, reproductive defects in male child, hepatic and renal effects
BBP	Low	Vinyl flooring, adhesives and sealants, plastics toys, personal care products, synthetic leather, industrial solvents, food packaging	Testicular toxicity, reproductive defect, teratogenic
DEHP	High	PVC plastics, food packaging, medical devices, sanitary, napkins, industrial plastic products	Testicular toxicity, teratogenic hepatocellular carcinoma, reduced fetal growth

HEALTH IMPACTS

- Endocrine disruptor
- Liver/kidney/lung damage
- Cancer
- Altered reproductive development & male fertility issues
- Type II diabetes & obesity
- Attention-deficit/hyperactivity disorder(ADHD)
- Neuro developmental issues
- Increased allergic symptoms
- Metabolic disorders
- Autistic behaviors
- Lower cognitive and motor development

LMW PHthalATES ARE HIGHLY TOXIC

The phthalates are non-covalently bound to plastics because of which they can easily leach out of the products; however, due to the low molecular weight, LMW phthalates are more susceptible to migration from plastics in comparison to HMW phthalates.^{17,18}

Moreover, the studies have confirmed that the toxicity impact of LMW phthalates is much higher than the HMW phthalates. Therefore, a majority of LMW phthalates are classified as substances of very high concern (SVHC) in EU REACH regulation, and restrictions have been placed on their use and applications in various products.¹⁹ Similarly, US EPA issued an action plan to prioritize eight phthalates, the majority of which are LMW.²⁰

PVC can contain
10%-60%
phthalates by weight

EXPOSURE ROUTE TO PHTHALATES

People can be exposed to phthalates primarily by eating foods and drinking water & other beverages that have been in contact with containers and products containing these chemicals. Phthalates are not chemically bound to the plastic products and they leach out of products over time and evaporate into the air, water, food, house dust, soil, and living organisms, particularly under conditions involving heat.

Several studies have reported leaching of phthalates specially in fatty foods such as milk products, fish, sea foods, oils, etc. Which are packaged in plastics.^{21,22} As per US EPA (2015) the most common exposure to DEHP comes through food with an average consumption of 0.25 mg per day. According to Swedish Chemical Agency and several research data, young children are at greater risk of exposure to phthalates as children eat more in relation to their size than adults do, have a high respiratory rate, are often close to the floor and frequently put objects in their mouth. Moreover, hand to mouth behavior is also a contributing factor for high content of phthalates in the young children.^{23,24}

REGULATION ON PHTHALATES

There are a large number of commercially used phthalate congeners. However, based on extensive research studies on human, environment and

animals in addition to the bio monitoring data, few congeners are banned or restricted from children products, medical devices, etc. Though there is no universal ban, each country has different guidelines on these congeners and have restricted their use in products considering the health hazards and environment implications.

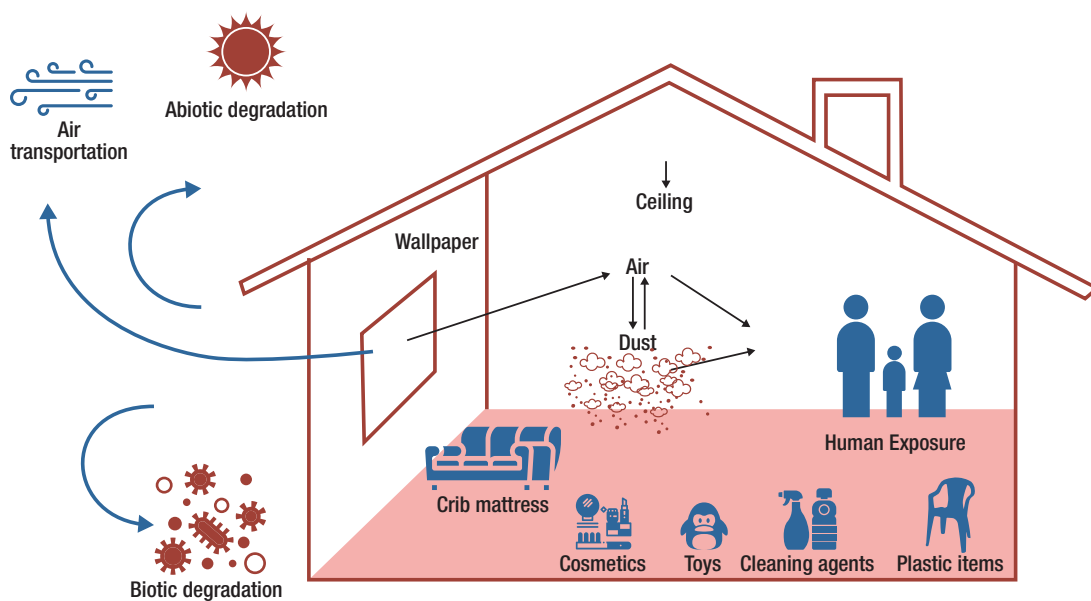
DEHP, commonly used phthalate, is considered a hazardous pollutant in several countries as a number of studies have reported health concerns associated with this chemical.

Most of LMW phthalates such as Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), and Dicyclohexyl phthalate (DCHP) are identified as SVHC by the Commission Implementing Decision (EU) 2017/1210 and Commission Implementing Decision (EU) 2018/636 according to Article 57(f) of REACH Regulation (EC) 1907/2006, due to their endocrine disrupting properties with probable serious effects to humans.²⁵

Similarly, HMW phthalates such as BzBP, DnOP, DiNP, DiDP, DnHP, DCHP, etc. are in use as alternatives to DEHP or depending upon their molecular weights have different applications. However, mostly are restricted in children products in various countries or requires authorization for manufacturing because of their toxicity associated with reproduction and endocrine systems.^{26,27}

- EU REACH has limited DEHP, DBP, DiBP and BBP concentrations to less than 0.1% in all

Graphical representation of the occurrence of phthalates in air and dust.



the cosmetic products, children toys, electronic products and medical devices.²⁸

- US EPA has classified DEHP and BBP as probable and possible human carcinogens, respectively.²⁹ In California, DEHP is classified as a “chemical known to the State of California to cause cancer and birth defects or other reproductive harm”.³⁰
- Many countries have restricted the use of phthalates in manufacturing soft polyvinyl toys for children.

TABLE 3:
Standards on Phthalates in children toys

Phthalates	Country	Standards in children toys
DEHP, DBP, BBP, DINP, DIDP, DNOP, DIBP	EU ³¹	banned
DEHP, DBP, BBP, DINP, DIDP, DNOP	US	<0.1%
DINP, DEHP	Japan ³²	prohibited
Phthalates	Indonesia ³³	<0.1%
DEHP, BBP, DBP, DNOP, DINP	Brazil	<0.1%
DNOP, DIDP (Diisodecyl phthalate), DINP	Canada ³⁴	<0.1%
DEHP, DBP, BBP, DIDP, DNOP & DINP	India	<0.1% (teethers as well)

- Since 2008-09, EU has also limited the use of phthalates in plastic materials which directly come in contact with food.³⁵ Similarly, Chinese authorities have prohibited the use of 4 phthalates – DEHP, DBP, DiBP and BBP in food packaging material.³⁶
- Korea and Japan have banned phthalates in baby disposable diapers, while such guidelines are lacking in other countries.^{37,38}
- Concerned with the leaching tendency of phthalates, the US EPA has set the limits for DEHP in drinking water as 6 ppb.³⁹ While the limit prescribed by WHO (2003) is 8 ppb. In the EU, limit for DEHP is 1.3ppb.
- Similarly, U.S. agency OSHA has set the limit 5 mg/m³ for occupational exposure in air.⁴⁰

TOLERABLE DAILY INTAKES OF PHTHALATES

USEPA and European Food safety has specified tolerable daily intakes (TDI) for few phthalates.

Country/ Organization	Phthalates	TDI value (µg kg ⁻¹ bw day ⁻¹)
European Food safety	DBP	10
	DEHP	50
USEPA	DEP	800
	DBP	100
	BBP	200
	DEHP	20

CIRCULAR ECONOMY AND PHTHALATES

Governments around the globe are focusing on circular economy by promoting sharing, reuse, repair and recycling of products, especially plastic products and components. However, it is of great concern as large volumes of phthalates are present as plasticizers and additives in these products.⁴¹ The improper disposal of plastic waste as well as the recycling and reuse of such products can lead to continuous circulation of harmful additives into the environment, threatening plant and animal lives and human health.⁴²

A study has demonstrated that the increased use of recycled paperboard and PET bottles in food packaging materials causes a significant increase up to 18% during childhood exposure to DBP and DEHP.⁴³ Similarly, studies have established that phthalates re-enter the product cycle during recycling of plastics and paper.^{44,45}

However, some countries have adopted standards on recycling of phthalate-containing products. For example, DEHP is banned in several products in the EU since 2015, but is allowed in recycled PVC extensively. Therefore, to make circular economy environmentally friendly as well as economically feasible, it is important to come up with proper regulations for recycling technologies and products as well.⁴⁶

INDIAN SCENARIO

Considering the harmful impacts of phthalates and global actions on it, Government of India via regulatory agencies has come up with certain guidelines to regulate phthalates in products.

- Under IS 9873-9-2017: Safety of toys- Part 9, Bureau of Indian Standards (BIS) has restricted DEHP, DBP, BBP, DIDP, DNOP & DINP in children toys and teethingers in 2017.⁴⁷
- Food Safety and Standards (Packaging) Regulations, 2018, has excluded the use of DINP and DBP from use in printing ink for food packaging materials. DINP and DBP are most commonly used phthalates in printing ink.
- Draft Chemicals (Management and Safety) Rules 2019, Indian Government has listed almost 15 phthalates such as DEHP, DiDP, DiBP, BBP, DiOP, DiNP etc under Schedule-II list of priority substances.
- In India, there are no standards for phthalates in other commonly used products or standards for drinking water, air etc. Guidelines also needed on labelling of phthalates on products.

ALTERNATIVES TO PHTHALATES

Non-phthalates are adipates, benzoates, trimellitates, epoxies, citrates, bio-based plasticizers, Dioctyl terephthalate (Dotp) and others. According to a market survey agency, non-phthalate plasticizers will experience growth of 6.91% CAGR.⁴⁸ This shows that the alternatives are available and their market share is increasing with time as consumers are getting aware of the harmful effects of phthalates, governments are banning and restricting their uses and companies are self-phasing out phthalates.

HOW TO AVOID

- Choose non-plastic products
- Avoid flexible vinyl plastics, labeled as
- PVC or "3"
- Avoid heating food in plastic containers
- Avoid products that contain phthalates in the list of chemicals
- Reduce use of fragrance products
- Reduce use of processed and packaged foods
- Because phthalates come out of products and get collected in dust, clean floors regularly and use a damp cloth to dust.

ENDNOTES

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