

WHAT'S DIAPER?

phthalates

Presence of Phthalates in Baby Diapers A study by Toxics Link

About Toxics Link

Toxics Link is an Indian environmental research and advocacy organization set up in 1996, engaged in disseminating information to help strengthen the campaign against toxic pollution, provide cleaner alternatives and bring together groups and people affected by this problem. Toxics Link's mission statement-"Working together for environmental justice and freedom from toxics. We have taken it upon ourselves to collect and share both information about the sources and the dangers of poisons in our environment and bodies, and information about clean and sustainable alternatives for India and the rest of the world." Toxics Link has unique expertise in the areas of hazardous, medical and municipal wastes, international waste trade, and the emerging issues of pesticides, Persistent Organic Pollutants (POPs), hazardous, heavy metal contamination etc. from the environment and public health point of view. We have successfully implemented various best practices and have brought in policy changes in the aforementioned areas apart from creating awareness among several stakeholders.

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Abbreviations

°C	Degree Celsius
μg	Microgram
μL	Microliter
BIS	Bureau of Indiand Standards
BBP	Benzyl butyl phthalate
CAGR	Compound Annual Growth Rate
cm	Centimeter
DBP	Di-butyl phthalate
DEHP	Bis(2-ethylexyl) phthalates
DIBP	Di-isobutyl phthalate
DiDP	Diisodecyl phthalate
Dinp	Diisononyl phthalate
DnOP	Di-n-octyl phthalate
EFSA	European Food Safety Authority
ER	Estrogen Receptor
FDA	Food and Drug Administration
GC-MS	Gas chromatography-mass spectrometry
HPLC	High-performance liquid chromatography
kg	Kilogram
L	Liter
MBP	Mono-n-butyl phthalate
MBzP	Monobenzyl phthalate
MEP	Monoethyl phthalate
MEHP	Mono-(2-ethylhexyl) phthalate
MiBP	Monoisobutyl phthalate
mL	Milliliter
MFDS	Korean Ministry of Food & Drug Safety
ng	Nanograms
ppb	Parts per billion
ppm	Parts per million
ppt	Part per trillion

Polyvinyl chloride
Super absorbent polymer
Tolerable daily intake
US Dollar

Introduction

About Baby Diapers

The use of disposable diapers have been the standard for baby hygiene for many years. However, the easy availability and increased hygiene concern among parents has increased the popularity and demand of diapers. Diaper is a type of napkin that absorbs urine or faeces and keeps babies dry and comfortable without soiling their clothes or surroundings. Diapers are light, very absorbent, and resistant to leaks. Besides, cloth diapers are also available in the market but they need to be removed and washed immediately. Disposable diapers are thrown away after use and hence provide hygiene, skin protection to the baby and thereby convenience for a mother.

In general, a newborn baby wears 8-9 diapers per day in the first year which approximately turns out to be 3100 First disposable diaper was developed by Marion Donovan in 1949. She was granted 20 patents for her innovation with diapers from 1951 to 1996.



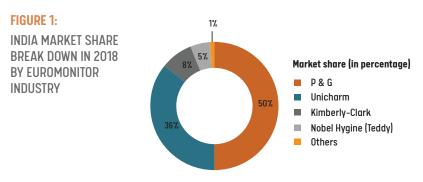
pieces in a year. This number decreases with the age of kids and eventually from the second year it become 5-6 diapers a day which on yearly basis is approximately 1950 pieces. Babies wear diapers upto the age of 3-4 years. On average any branded diaper costs approximately Rs 10, which means a baby in his/her 3 years of age uses diapers amounting from Rs 65,000- Rs 1, 00,000.

Age of the baby	Diaper usage per day (app.)	Diaper usage in a year (app.)
0-1 year	8-9	3100
1-2 years	5-6	1950
2-3 years	3-4	1300

TABLE 1: USAGE OF DIAPER PER DAY

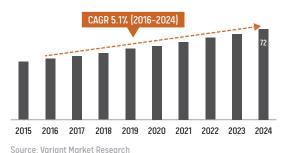
Though awareness on personal hygiene has increased, lifestyle and purchasing power of the consumers have increased yet to spend approximately Rs 3000 per month on diapers only is a fairly big amount in India. Several locally produced or unbranded products are available in

the market which cost approximately Rs 4-5 per unit. However, major share of the market is taken up by Pampers (Procter & Gamble Hygiene & Health Care Ltd), Mamypoko (Uni-Charm Corp) and Huggies (Kimberly-Clark Lever Ltd)¹.



A global market survey agency has reported that "The diaper market in India reached a volume of 4.7 billion units in 2018. The market is further projected to reach a volume of 7.4 billion units by 2024, expanding at a CAGR of more than 8% during 2019-2024."² Similarly, another agency has forecasted that "In India revenue in the baby diapers segment amounts to be US\$5,428m in 2020 and the market is expected to grow annually by 4.9% (CAGR 2020-2023).^{3.4}



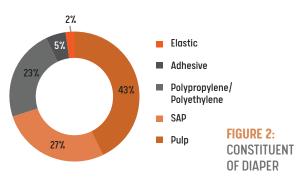


The diaper market in India reached a volume of **4.7 billion units** in 2018. The market is further projected to reach a volume of **7.4 billion units by 2024**, expanding at a CAGR of more than 8% during 2019–2024.

- 1 https://www.business-standard.com/article/companies/why-major-dryprofitability-making-firms-are-exiting-baby-diaper-market-118070800444_1.html
- 2 https://www.imarcgroup.com/diaper-market-india
- 3 https://www.statista.com/outlook/80050000/119/baby-diapers/india
- 4 https://www.variantmarketresearch.com/report-categories/consumergoods/baby-diapers-market

Composition of Diaper

Diapers are made up of special polymer materials including cellulose, polypropylene, polyester, super absorbent polymer (SAP: acrylonitrile) and polyethylene which are arranged in different layers (inner layer or top sheet, absorbent core, waterproof outer shell) to provide optimal absorption of urine and faeces [Annex I].⁵



Among polymers used in diapers (SAP, polyethylene and polypropylene)Phthalates are generally used as plasticizers and catalysts for the polymerization. Phthalates provide flexibility & durability to these polymers because of which they are used in the manufacturing of diapers. As Phthalates are non-covalently bound to these polymers, they are easily released out of these polymers as well as from the diapers. As a diaper is in direct contact with the external genital of infants and toddlers for several months to years, there is a possibility that Phthalets get into the body of babies by dermal absorption.^{6,7}

As Phthalates have been characterized as an endocrine disrupting chemical, the use of Phthalates in the diapers raises concern of possible health impacts on children.

There are global studies which have established the presence of various forms of phthalates in baby diapers; however, there are no India specific studies available in the public domain. In this context the present study intends to explore the presence of phthalates in diapers available in the Indian market. Further the study also analyzed the possible impact of phthalates on the health of the children, and the overall environment as well.

Global Studies on Phthalates in Diapers

The possible impacts of Phthalates on the children are well-documented. There are several studies that have been carried out on the presence of Phthalates in children products and the possible health exposure from these products.

Park *et.al* (2019) from The University of Illinosis Chicago had quantified phthalate contents in baby diapers collected from Korea, Japan, Finland, France, Greece, and the United States. They have detected DBP and DEHP in every diaper. The highest concentration of phthalates that they reported is 1,609.7ppb. [Table2]. They have inferred that as diapers are in direct

⁵ https://indiantextilejournal.com/articles/FAdetails.asp?id=1078

⁶ Niermann S., Rattan S., Brehm E., Flaws J.A. 2015. Prenatal exposure to di-[2-ethylhexyl]phthalate [DEHP] affects reproductive outcomes in female mice. Reprod. Toxicol.53: 23-32.

⁷ JMHLW, 2015a. Japan Ministry of Health, Labour and Welfare, Phthalate Esters, Review of Amendment by Public Comment, etc. http:// www.mhlw.go.jp/shingi/ 2010/02/dl/s0222-6g.pdf

contact with the skin of babies for a longer period, there is a possibility that significant amount of phthalates could be absorbed into the reproductive system through the skin.⁸

Number	n	DBP	DEHP	DEP	BBP
Α	3	13.4	12.6	BD	BD
В	3	984.5	30.1	BD	BD
C	3	1609.7	42.2	0.8	BD
D	3	1005.8	62.8	2.9	BD

TABLE 2: PHTHALATE CONTENT IN BABY DIAPERS

BD- below detection limit (detection limit 0.1ppb for DBP,DEHP, DEP; 0.05ppb for BBP

In 2018 Swiss Federal Food Safety and Veterinary Office (FSVO) in collaboration with a Swiss consumer association (FRC) had carried out tests with 21 disposable diapers available in the Swiss market. They have tested many other chemicals alongwith DIBP. DIBP was quantified in one product only.⁹

Razavia *et al.*(2017) from Iran University had detected the phthalates in the topsheet of the baby diapers using nanoparticles of magnetic polyaniline-coated chitosan.¹⁰

Simiarly, Ishii et al.(2015)¹¹ from Chemicals Evaluation and Research Institute Japan had screened seven phthalates in the topsheet of five disposable diapers sold in Japan. They have also estimated amounts of phthalates to which newborn babies were exposed by wearing diapers. DEHP and DBP were detected in samples respectively in the concentration ranges of 0.1 to 0.6 ppm and 0.1 to 0.2 ppm.

Phthalates	Exposed amounts/day (mg/kg/day)
DEHP	2.23 x 10- ⁸
DBP	2.98 x 10- ⁶
BBP	4.34 x 10- ⁷
DINP	3.41 x 10- ¹⁰
DIDP	2.17 x 10- ¹⁰
DNOP	1.86 x 10- ¹⁰
DIBP	1.49 x 10- ¹⁰

TABLE 3: THE EXPOSED AMOUNTS PER DAY OF DEHP BY WEARING PAPER DIAPERS

⁸ Park C.J., Barakat R., Ulanov A., Li Z., Lin P.C., Chiu K., Zhou S., Perez P., Lee J., Flaws J., and Ko C.J. 2019. Sanitary pads and diapers contain higher phthalate contents than those in common commercial plastic products. Reprod Toxicol. 84:114-121.

⁹ FRC. (2018). Couches-culotte. Au sec etensécurité. Frcmiuexchoisir. 2018,112 : 16-17.

¹⁰ https://profdoc.um.ac.ir/paper-abstract-1064640.html

¹¹ Ishii S.,Katagiri R.,Minobe Y.,Kuribara I., Wada T., Wada M., and Imai S. 2015. Investigation of the amount of transdermal exposure of newborn babies to phthalates in paper diapers and certification of the safety of paper diapers. Regulatory Toxico.Pharmaco. 73: 85-92.

Phthalates and its impact on human health & environment

Phthalates

Phthalates are a family of high volume chemicals. They are used as plasticizers which determine the physical properties of polymer products. Phthalates are used in a range of commercial products. They accounted for 70% of the world consumption of plasticizers in 2014 and are forecasted to account for 65% of world consumption in 2020¹².

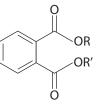


FIGURE 3: GENERAL STRUCTURE OF PHTHALATE. R AND R' REPRESENTS ALKYL AND BENZYL GROUP

Phthalates are added to plastics to increase their flexibility, transparency, durability, pliability and elasticity. They are primarily used to soften polyvinyl chloride (PVC). Other uses include applications such as viscosity control agents, solvents, and glues. Phthalates may also be present in various types of paints and adhesives for binders.

First introduced as plasticizer in 1920s

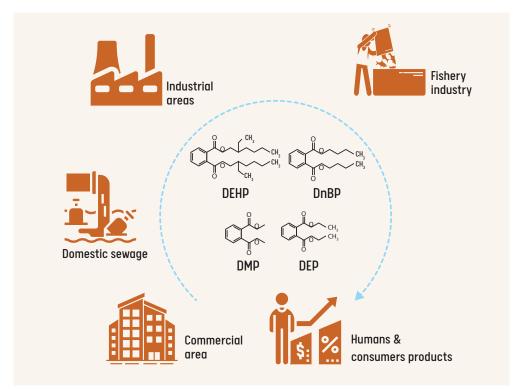
¹² https://www.industryarc.com/Report/11717/plasticizers-market-analysis.html

These Phthalates are categorized as high and low, depending on their molecular weight.

TABLE 4: EXAMPLES OF 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)

There are various forms of Phthalates in use; however DEHP i.e., Di-2-ethylhexyl phthalate is the most commonly used plasticizer in consumables be it household items, cosmetics, personal care products, sanitary napkins or plastic toys for children. It is also used as solvents in glowsticks and as an excipient in pharmaceutical formulations. As per the market survey report, DEHP makes up for the majority of the PAEs market as well as the highest global plasticizers market proportion (37.1%, more than 3 million tons per year)¹³.



¹³ RenL., Lin Z., Liu H., and Hu H. 2017. Bacteria-mediated phthalic acid esters degradation and related molecular mechanisms. ApplMicrobiolBiotechnol. 102[3]: 1085-1096

Exposure pathway to human beings

Phthalates are not chemically bound to products and are continuously released into the air, soil & water sources. They also leach out after repeated use, heating, and/or cleaning of the products. Humans are exposed to phthalates through **ingestion**, **dermal transfer**¹⁴, and **inhalation**.¹⁵

There are studies available reporting phthalates in different products and their exposure thereof. Wormuth et al(2006) have reported phthalates, ranging from 1–15,000 mg/kg, in personal care products and disposable napkins.¹⁶ Sathyanarayana et al(2008) had detected seven phthalate metabolites in 163 infants who were exposed to infant care products within 24 hours of urine collection.¹⁷

The higher molecular phthalates such as DEHP have been reported in fat-rich foods such as poultry, dairy products, yogurts and oils. Phthalates can also leach to food from food processing equipment and packaging¹⁸.

As per US EPA (2015) the most common exposure to DEHP comes through food with an average consumption of 0.25 milligrams per day¹⁹. This is also scientifically reported.²⁰

Health Impact of Phthalates on Children

There is enough evidence on the impact of Phthalates in human health. Toxicological and epidemiological studies have found that some phthalates have estrogenic and/ or anti-androgenic properties that can lead to reproductive effects. Therefore Phthalates have been considered as endocrine disrupting chemicals (EDCs).

The scientific studies have revealed that phthalate exposure may be associated with

HEALTH IMPACT

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

¹⁴ Ashworth M. J., Chappell A., Ashmore E., and Fowles J. 2018. Analysis and Assessment of Exposure to Selected Phthalates Found in Children's Toys in Christchurch, New Zealand. Int J Environ Res Public Health. 15[2]: 200.

¹⁵ https://chemicalwatch.com/42920/skin-absorption-of-phthalates-as-significant-as-inhalation#overlay-strip

¹⁶ WormuthM.,ScheringerM., VollenweiderM., and. HungerbuhlerK. 2006. "What are the sources of exposure to eight frequently " used phthalic acid esters in Europeans? Risk Analysis. 26 [3]: 803-824.

¹⁷ Sathyanarayana S., Karr C.J., Lozano P., Brown E., Calafat A.M., Liu F., and Swan S.H. 2008. Baby care products: possible sources of infant phthalate exposure. Pediatrics 121(2):e260-8.

¹⁸ Schettler T. 2006. Human exposure to phthalates via consumer products. Int J Androl. 29(1):134-139.

¹⁹ OW, US EPA. "Basic Information about Di(2-ethylhexyl) phthalate in Drinking Water". water.epa.gov. Retrieved 2015-10-27.

²⁰ Sathyanarayana S., Alcedo G., Saelens B.E., Zhou C., Dills R.L., Yu J. and Lanphear B. 2013. Unexpected results in a randomized dietary trial to reduce phthalate and bisphenolA exposures. J ExpSci Environ Epidemiol. 23: 378-384.

diabetes & insulin resistance, breast cancer, obesity, metabolic disorders, and immune function.^{21,22,23} The studies of Stojanoska et al(2017) reviewed that phthalates together with bisphenol-A have a role in the development of obesity and glucose metabolism disorders.²⁴ Similarly, Lien et al (2015)²⁵ and Tonk et al (2012)²⁶ had reported that early life exposure to DEHP is responsible for adverse effects on neurodevelopment, immune system and reproductive organ development.

Sathyanarayana et al [2013] in their cohort studies on 10 families had reported that diet is also a source of exposure for phthalates and by reducing the processed foods, canned foods, plastic-stored foods it is possible to reduce the exposure.

Moreover, the studies have established that exposure to phthalates can lead to irreversible impact on children's health.²⁷ Berger et al(2018) had reported asthma and respiratory allergies in children who had prenatal exposure to higher molecular weight phthalates.²⁸

Similarly epidemiological studies by Nordkap et al(2012)²⁹, Swan et al(2015)³⁰, and Ginsberg et al(2016)³¹ have reported that exposure to phthalates leads to decline in male fertility,decreased anogenital

Phthalates are non-persistent Endocrine Disruptor

distance and testicular dysgenesis syndrome in male infants.In another study Balalian et al(2019)³² published a study on 209 mother-child samples representing effects of prenatal phthalates exposure on motor skills development, cognitive socio-emotional functioning and behavior of children.

²¹ Giulivo M., Lopez de Alda, Miren: Capri E., Barceló D.2016. Human exposure to endocrine disrupting compounds: Their role in reproductive systems, metabolic syndrome and breast cancer: A review. Environ. Rese. 151: 251-264.

²² Bansal A., Henao-Mejia J., and Simmons R. A. 2018. Immune System: An Emerging Player in Mediating Effects of Endocrine Disruptors on Metabolic Health. Endocrinol. 159 (1): 32-45.

²³ https://www.nature.com/articles/pr201716

²⁴ Stojanoska M.M., Milosevic N., Milic N., and Abenavoli L. 2017. The influence of phthalates and bisphenol A on the obesity development and glucose metabolism disorders. Endocrine. 55:666-681.

²⁵ Lien Y.J., Ku H.Y., Su P.H., Chen S.J., Chen H.Y., Liao P.C., Chen W.J., andWang S.L. 2015. Prenatal exposure to phthalate esters and behavioral syndromes in children at 8 years of age: Taiwan Maternal and Infant Cohort Study. Environ. Health Perspect. 123, 95-100.

²⁶ Tonk E.C., Verhoef A., Gremmer E.R., van Loveren H., andPiersma A.H. 2012. Relative sensitivity of developmental and immune parameters in juvenile versus adult male rats after exposure to di[2-ethylhexyl] phthalate. Toxicol. Appl. Pharmacol. 260, 48–57.

²⁷ Daston G., FaustmanE., Ginsberg G., Fenner-Crisp P., Olin S., and Sonawane B., et al. 2004. A framework for assessing risks to children from exposure to environmental agents. Environ Health Persp. 112: 238–256.

²⁸ https://onlinelibrary.wiley.com/doi/pdf/10.1111/pai.12992

²⁹ NordkapL., JoensenU.N., Blomberg Jensen M., and Jørgensen, N. 2012. Regional differences and temporal trends in male reproductive health disorders: semen quality may be a sensitive marker of environmental exposures. Mol. Cell. Endocrinol. 355:221-230.

³⁰ SwanS. H., SathyanarayanaS., and BarrettE. S. 2015. First trimester phthalate exposure and anogenital distance in newborns. Human Reproduction. 30 [4]: 963-972.

³¹ Ginsberg G, Ginsberg J, and Foos B. 2016. Approaches to Children's Exposure Assessment: Case Study with Diethylhexylphthalate (DEHP). Int J Environ Res Public Health. 13(7): E670

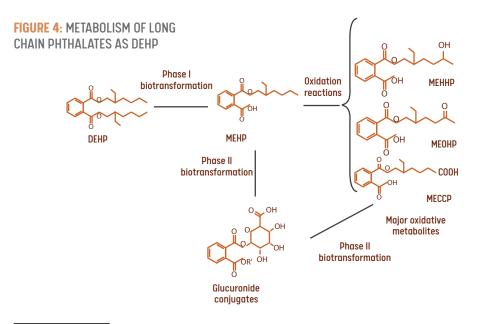
³² Balalian A. A., Whyatt R. M., Liu X., Insel B. J., Rauh V. A., andHerbstman J. 2019. Factor–Litvak, Pam. Prenatal and childhood exposure to phthalates and motor skills at age 11 years. Environ. Res. 171: 416–427.

Children are more vulnerable to phthalate exposures because of their hand-tomouth behaviors, floor play, and developing nervous and reproductive systems. Phthalates in disposable diapers are also a concern for babies as diapers are in direct contact with their skin for a long period of time each day for 2-3 years.

Similarly, there are few studies on children of the age group of 4-11 years representing that higher phthalates exposure are responsible for attention-deficit/hyperactivity disorder (ADHD), lower IQ, behavioral deficits, including effects on attention, conduct, and social behaviors in children.^{33, 34}

METABOLISM OF PHTHALATES

Once they enter the body, phthalates undergo a series of phase I hydrolysis and phase II conjugation reactions and are subsequently excreted in faeces and urine. The extent of phase I and phase II reactions depends on the alcohol moiety in phthalates as well as the physiological characteristics of humans. The metabolism of higher molecular weight phthalates is slower than that of lower weight phthalates. For example, only 2-7% of the ingested DEHP is excreted as the monoester with an elimination half-life of about 12 h while elimination of short chain as DiBP is 5h.



³³ Cho S.C., BhangS.Y.,HongY.C., ShinM.S., KimB.N., KimJ.W., YooH.J., Chol.H., and KimH.W. 2010. Relationship between environmental phthalate exposure and the intelligence of school age children. Environ. Health Perspect.118 (7):1027-32.

³⁴ Engel S.M., MiodovnikA., CanfieldR.L, ZhuC., SilvaM.J., CalafatA.M, and WolffM.S. 2010. Prenatal phthalate exposure is associated with childhood behavior and executive functioning. Environ. Health Perspect. 118 (4):565-71.

Fate of Phthalates in Environment

The soiled diapers which are dumped in landfills and garbage-bins are the source of phthalates in the environment. As phthalates are not chemically bound to the materials used in manufacturing of diapers, it can easily leach out to the soil. Also Phthalates can reach out to the environment during the manufacture of diapers &/or the absorbent sheet as well. Besides, phthalates contaminate the environment through leaching, migration and oxidation from manufacturing sites of various plastic and personal products, warehouses, and landfills.

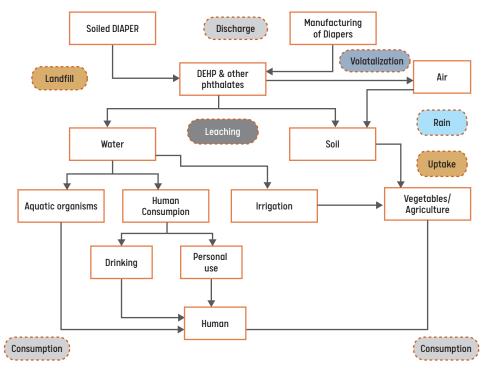


FIGURE 5: DEHP IN DIFFERENT ENVIRONMENTAL COMPARTMENTS

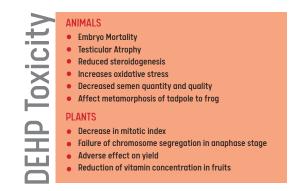
Phthalates have been detected in different compartments of the environment at concentrations ranging from 0.3 to 77 ng m⁻³ in the atmosphere, from 0.3 to 98 μ g L⁻¹ in surface water, from 0.2 to 8.4 mg kg⁻¹dw in sediment and from 28

Phthalates are estimated to have a half-life of about 12 hours in the air, 10 to 20 days in the soil, and days to weeks in water (U.S. EPA, 1987a,b). to 154mg kg⁻¹dw in sewage sludge.^{35, 36, 37, 38, 39} Lü et al (2018) had studied different phthalates and ester compounds in soil samples that they have collected from different regions of China. They have reported higher concentrations of DEHP in comparison to other phthalic acid ester compounds.⁴⁰

Similarly, Kumar D. et al (2018) and Sharma et al (2017) had done assessment of phthalates on agricultural soil and municipal solid waste in New Delhi.^{41, 42}

Phthalates may enter the atmosphere through the combustion of soiled diapers and other plastics^{43,44}.

Phthalates have relatively high vapor pressure because of which it can easily volatize to the atmosphere and get trapped in cloud masses. With rainfall these phthalates reach and add to the pollutant levels of surface water. It also absorbs both freshwater and marine sediments where it may serve as a long-term sink.^{45, 46,}



Oehlmann,et al(2009) in their eco-toxicity studies on aquatic organisms annelids, molluscs, crustaceans, insects, fishes and amphibians reported adverse effects of phthalates DEHP,

³⁵ https://www.degruyter.com/downloadpdf/j/eces.2016.23.issue-2/eces-2016-0024/eces-2016-0024.pdf

³⁶ Cai Q.Y., Mo C.H., Wu Q.T., Zeng Q.Y., and Katsoyiannis A. 2007. Occurrence of organic contaminants in sewage sludges from eleven wastewater treatment plants, China. Chemosphere 68(9):1751-1762

³⁷ P.-C. Huang, C.-J. Tien, Y.-M. Sun, C.-Y. Hsieh, and C.-C. Lee, "Occurrence of phthalates in sediment and biota: relationship to aquatic factors and the biota-sediment accumulation factor," Chemosphere, vol. 73, no. 4, pp. 539-544, 2008.

³⁸ Net, S.: Delmont, A.: Sempéré, R.: Paluselli, A.: Ouddane, B. Reliable quantification of phthalates in environmental matrices (air, water, sludge, sediment and soil): A review. Sci. Total Environ. 2015, 515-516, 162-180.

³⁹ Clara M, Windhofer G, Hartl W, Braun K, Simon M, Gans O, et al. Occurrence of phthalates In surface runoff, untreated and treated wastewater and fate Turing wastewater treatment. Chemosphere. 78: 1078-1084.

⁴⁰ Lũ H., Mo C.H., Zhao H.M., Xiang L., Katsoyiannis A., Li Y.W., Cai Q.Y., and Wong M.H. 2018. Soil contamination and sources of phthalates and its health risk in China: a review. Environ. Res. 164, 417-429.

⁴¹ Kumar V., Sharma N., Maitra S.S. 2017. Comparative study on the degradation of dibutyl phthalate by two newly isolated Pseudomonas sp. V21b and Comamonas sp. 51F. Biotechnol Rep (Amst). 2017 Apr 28:15:1-10.

⁴² Dharmendra Kumar, Livleen Shukla, Surender Singh, Lata, Shashi Bala Singh, Shalendra Kumar Jha, G Prakash and Mandeep Bal. 2018. Assessment of diverse phthalate esters (PAEs) from irrigated agriculture soil under protected cultivation in IARI, New Delhi. International Journal of Chemical Studies 2018; 6(3): 3432-3435

⁴³ https://www.who.int/ipcs/publications/cicad/en/cicad52.pdf

⁴⁴ Simoneit BR, Medeiros PM, Didyk BM. (2005). Combustion products of plastics as indicators for refuse burning in the atmosphere. Environ Sci Technol., 39(18), pp6961-70.

⁴⁵ USEPA, 2007. Phthalates. TEACH Chemical Summary Environmental Protection Agency, Washington, DC.

⁴⁶ Gani K.M., TyagiV.K., and Kazmi A.A. 2017. Occurrence of phthalates in aquatic environment and their removal during wastewater treatment processes: A review. Environ. Sci. Pollut. R. 24: 17267-17284.

DEP, DMP and BBP.47 Several studies have been done on rats, zebrafish, guinea pigs and lactating cows to understand the effect of phthalates. $4^{8, 49, 50}$

Similarly, various scientific studies are available representing uptake of phthalates and its adverse effects in plants. Sun *et al*(2015) had detailed out metabolism of phthalates in lettuce, strawberry, and carrot plants.⁵¹ Studies show that DEHP can easily be taken up and accumulated by plants, including various vegetables, capsicum and rice etc. ^{52, 53, 54}

Cartwright et al(2009) had reported that high level contamination (>1 mg/g) would have a significant impact on the microbial community and environmental processes mediated by it.

This wide distribution of DEHP and other phthalates is partly due to their widespread uses and continuous release, and partly because of their high hydrophobicity and poor biodegradability.

All the available scientific studies and investigations emphasize on the great urgency needed to remove DEHP including other higher molecular phthalates from the contaminated environment.

Das et al in 2014 studied daily integrated exposure levels of fifteen phthalate congeners in the adult urban population of Delhi, India. The exposure media samples were collected from Jawaharlal Nehru University campus and Okhla industrial area. The combined daily intake of 15 phthalates (CDI15) in JNU and Okhla was 120.849 mg/kg/d and 388.123 mg/ kg/d respectively. DHEP was a major contributor in both the places.

⁴⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2873012/

⁴⁸ https://www.hindawi.com/journals/bmri/2018/1750368/

⁴⁹ Jia P.P., Ma Y.B., Lu C.J., Mirza Z, Zhang W, Jia Y.F, Li W.G., D S. 2016 The effects of disturbance on hypothalamus-pituitary-thyroid (HPT) axis in zebrafish larvae after exposure to DEHP. PLoS ONE. 11(5): e0155762.

⁵⁰ Kalo D., Hadas R., Furman O. et al. 2015. Carryover effects of acute DEHP exposure on ovarian function and oocyte developmental competence in lactating cows. PLoS ONE. 10[7]: e0130896.

⁵¹ Sun J, Wu X, and Gan J. 2015. Uptake and Metabolism of Phthalate Esters by Edible Plants. Environ Sci Technol. 49[14]:8471-8.

⁵² Singh J., and Thakur J.K. 2018. Biotic and abiotic stress tolerance in plants. Photosynthesis and Abiotic Stress in Plants, Singapore. Springer. 27-46.

⁵³ Cai Q.Y., Xiao P.Y., Chen T., Lü H., Zhao H.M., Zeng Q.Y., Li Y.W., Li H., Xiang L., and Mo C.H. 2015. Genotypic variation in the uptake, accumulation, and translocation of di-[2-ethylhexyl] phthalate by twenty cultivars of rice (Oryza sativa L.). Ecotoxicol. Environ. Safe. 116: 50–58.

⁵⁴ Kumari A. and Kaur R. 2019. Modulation of biochemical and physiological parameters in HordeumvulgareLseedlings under the influence of benzyl-butyl phthalate. PeerJ. 7: e6742.

PHTHALATES IN ENVIRONMENT: BIODEGRADATION

Studies have demonstrated that phthalates with low molecular weight can biodegrade in environment particularly in soil. On the other hand, phthalates with higher molecular weight such as DHP, DOP, DEHP etc are less susceptible to biodegradation.⁵⁵

Generally, the phthalates biodegradation pathways consist of two processes: primary biodegradation (from PDEs to PMEs and then to Pthalic Acid) and ultimate biodegradation (from Pthalic Acid to benzoic Acid to CO_2 and/or CH_4).⁵⁶ The photolysis or hydrolysis degradation of phthalates is not possible or very slow under natural conditions so the microbial degradation is the most important and only route for the breakdown of DEHP and other harmful PAEs.

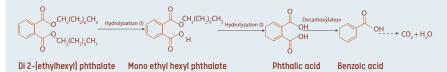


FIGURE 6: THE PROPOSED DEGRADATION PATHWAY OF DEHP.

Several PAEs-degrading strains have been isolated from different habitats but only few showed good environm ental adaptability and application potential.Phthalates degrading microorganisms isolated and studied in various environmental samples are Bacillus, Arthrobacter, Rhodococcus, Enterococcus, Acinetobacter, Agromyces, Gordonia, Brevibacterium, Microbacterium, and Pseudomonas.^{57,58,59} Studies have been done in India as well on the biodegradation of phthalates.^{60,61,62,63}

Under optimal conditions it is easy to maintain these bacterial strains and get complete biodegradation of DEHP and other higher molecular weight phthalates but such ideal conditions and that much concentration or colony of microbes are not possible to attain or maintain in landfills, waste-dump areas or contaminated surface water. Since such degradation is not possible in air, it will always be continuous sources of volatile phthalates along with other sources. Besides, phthalates do harm useful microbes as well by disrupting cell membranes.

⁵⁵ Chang B.V., Yang C.M., Cheng C.H., and Yuan S.Y. 2004 Biodegradation of phthalate esters by two bacteria strains. Chemosphere. 55:533-538

⁵⁶ Yang T., Ren L., Jia Y., Fan S., Wang J., Wang J., Nahurira R., Wang H., and Yan Y. 2018. Biodegradation of Di-[2-ethylhexyl] Phthalate by Rhodococcusruber YC-YT1 in Contaminated Water and Soil. Int J Environ Res Public Health. 15[5]: 964. Yang T., Ren L., Jia Y., Fan S., Wang J., Wang J., Nahurira R., Wang H., and Yan Y. 2018. Biodegradation of Di-[2-ethylhexyl] Phthalate by Rhodococcusruber YC-YT1 in Contaminated Water and Soil. Int J Environ Res Public Health. 15[5]: 964.

⁵⁷ Li F., Liu Y., Wang D., Zhang C., Yang Z., Lu S., and Wang Y. 2018. Biodegradation of di-[2-ethylhexyl] phthalate by a halotolerant consortium LF. PLoS ONE. 13[10]: e0204324.

⁵⁸ Ahuactzin-Pérez M., Tlecuitl-Beristain S., García-Dávila J., Santacruz-Juárez E., González-Pérez M., Gutiérrez-Ruíz M.C., Sánchez C. 2018. A novel biodegradation pathway of the endocrine-disruptor di [2-ethyl hexyl] phthalate by Pleurotusostreatus based on quantum chemical investigation. Ecotoxicol. Environ. Saf. 147:494-499.

⁵⁹ Li Q., Wang C., Hua M., Shuang C., Li A., and Gao C. 2018. High-efficient removal of phthalate esters from aqueous solution with an easily regenerative magnetic resin: Hydrolytic degradation and simultaneous adsorption. J. Clean. Prod. 175:376–383.

⁶⁰ Pradeep S., Josh M.S., Binod P., Devi R.S., Balachandran S., Anderson R.C., and Benjamin S. 2015. Achromobacterdenitrificans strain SP1 efficiently remediates di[2-ethylhexyl] phthalate. Ecotox. Environ. Saf. 112:114-121.

⁶¹ Kumar V., Sharma N., and MaitraaS.S. 2017. Comparative study on the degradation of dibutyl phthalate by two newly isolated Pseudomonas sp. V21b and Comamonas sp. 51F. Biotechnol Rep (Amst). 15: 1-10.

⁶² Singh N., Dalal V., Mahto J.K., and Kumar P. 2017. Biodegradation of phthalic acid esters (PAEs) and in silico structural characterization of mono-2-ethylhexyl phthalate (MEHP) hydrolase on the basis of close structural homolog. J Hazard Mater. 338:11-22.

⁶³ https://echa.europa.eu/registration-dossier/-/registered-dossier/15358/5/3/4

Diapers in Landfill: waste management

All used diapers are finally disposed in landfills. Diapers are soiled with faeces & urine which can leach into soil & groundwater causing contamination and spreading of communicable diseases.

On our discussion with ragpickers it was found that these diapers are generally dumped in landfills without any treatment. "Generally people wrap used/soiled diapers in paper or polybags and throw them away in garbage from where they get dumped in landfills. We don't treat or even touch these diapers and there is no machine or process known to us to destroy." said a rag picker.

As such polybags are itself a big environmental concern all over the world and wrapped diapers in polybags will only increase the menace.

Mauro et al., 2015, presented an assessment of the environmental aspects related to the life cycle of disposable baby diapers in Europe.⁶⁴ Disposable diapers are shown to generate significantly more solid waste, to consume greater quantities of energy and raw materials, and to generate potentially more toxic pollutants on a per-diaper-change basis.

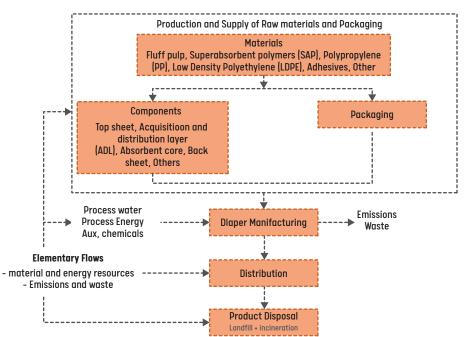


FIGURE 7: LIFE CYCLE OF DISPOSABLE DIAPERS

⁶⁴ Cordella M., Bauer I., Lehmann A., Schulz M., and Wolf O. 2015. Evolution of disposable baby diapers in Europe: life cycle assessment of environmental impacts and identification of key areas of improvement. J. Clean. Prod. 95: 322-331.

In the landfills of India disposable diapers and other waste (as single-use plastics) are subjected to intentional or incidental open-fire burning. On combustion these kinds of waste release toxics fumes of phthalates. On combustion phthalates to some extent break down into phthalic anhydride which is even more toxic. There is evidence of asthama due to these toxic fumes⁶⁵. The ash of burned waste also contains phthalates and phthalic anhydride which may be leached from remaining ash that could lead to the contamination of surface water or ground water. With time the unattended diaper waste gets buried in the ground from which phthalates leach to the groundwater and surface water.

Regulation on phthalates in products

The environment and health concern of Phthalates are well studied and therefore the countries across the globe including India have placed regulations on the use of phthalates in various products.

Some phthalates particularly DEHP, DBP, DiBP and BBP are classified as Category 1B by European authorities. These phthalates are banned from using them in producing toys, baby care products, cosmetics, and medical devices.⁶⁶ Recently EU has restricted four phthalates, DBP, DEHP, BBP, and DIBP to<0.1% in all electrical & electronic equipmentand medical devices.⁶⁷

Many countries have restricted the use of phthalates in manufacturing soft polyvinyl toys for children.

Phthalates	Country	Standard in children's toys
DEHP, DBP,BBP,DINP,DIDP,DNOP, DIBP	EU ⁶⁸	<u>≤</u> 0.1%
DEHP, DBP,BBP,DINP,DIDP,DNOP	US	<u>≤</u> 0.1%
DINP, DEHP	Japan ⁶⁹	prohibited
Phthalates	Indonesia ⁷⁰	<0.1%
DEHP, BBP, DBP, DNOP, DINP	Brazil	<0.1%
DNOP, DIDP (Diisodecyl phthalate), DINP	Canada ⁷¹	<0.1%
DEHP, DBP, BBP, DIDP, DNOP & DINP	India	<0.1% (teethers as well)

TABLE 5: STANDARDS ON PHTHALATES IN CHILDREN TOYS

⁶⁵ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2453150/

⁶⁶ Ventrice P., Ventrice D., Russo E., and DeSarro G. 2013. Phthalates: European regulation, chemistry, pharmacokinetic and related toxicity. Environ Toxicol Pharmacol. 36(1):88-96.

⁶⁷ Han A, Han E, and Han Hv E. 2011. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II).

⁶⁸ Merenyi S, REACH: Regulation (EC) No 1907/2006, (2014)

⁶⁹ http://www.mhlw.go.jp/topics/bukyoku/iyaku/kigu/dl/11.pdf

⁷⁰ https://chemicalwatch.com/15448/indonesia-to-regulate-certain-chemicals-in-toys#overlay-strip

⁷¹ https://dx.doi.org/10.3390%2Fijerph15020200

Since 2008-09 EU has also limited the use of phthalates in plastic materials which directly comes in food contacts⁷². Similarly, China authorities have prohibited the use of 4 phthalates – DEHP, DBP, DiBP and BBP in food packaging material.⁷³

USEPA and European Food safety had specified tolerable daily intakes (TDI) for few phthalates. TDI specified by European Food safety for DBP is 10µg kg⁻¹ bw day⁻¹ and for DEHP is 50 µg kg⁻¹bw day⁻¹. Reference doses suggested by USEPA for DEP (800µg kg⁻¹bw day⁻¹), DBP (100 µg kg⁻¹bw day⁻¹), BBP (200 µg kg⁻¹bw day⁻¹) and DEHP (20µg kg⁻¹bw day⁻¹)

INTERNATIONAL STANDARDS FOR DIAPERS

There are regulations in many countries to ensure availability of good quality diapers in the market.

In EU the General Product Safety Directive (2001/95/EC) is applicable to diapers which is a general regulation for products to provide risk assessment, disposal dossier and procedure to withdraw products from the market^{74,75}.

In China, there is a mandatory regulation in place for baby diapers under GB 15979-2002: Hygienic Standard for disposable sanitary products (HS Code of 9619001000 Pullup baby diapers). Though there are no specific guidelines for phthalate content but microbial indicators and other test results are necessary to be reported.⁷⁶

In Korea, Korean Ministry of Food and Drug Safety (MFDS)

regulates baby and adult diapers under "Sanitary Products"⁷⁷. The regulation has restrictions on substances such as fluorescent whitening agent, formaldehyde, chlorinated phenols, phthalates, and heavy metal contaminants. ^{78, 79}

In Japan under "Voluntary Standards for Safety and Hygiene of Nonwoven Fabrics for Disposable Diapers-2015" phthalates are classified as prohibited chemical substances and are therefore not allowed to be used in manufacturing of diapers. However, they are allowed to be used as a catalyst in the manufacturing of non-woven fabrics for diapers.⁸⁰

In India no specific guidelines are applicable on diapers.

DEHP is categorized as a possible human carcinogen and priority pollutant by China National Environmental Monitoring Center and US Environmental Protection Agency (USEPA).

In USA the maximum allowed exposure limit of DEHP in drinking water is 06 µg/L (EPA, 2012); while the limit prescribed by the WHO (2003) is 08 µg/L. In EU limit for DEHP is 1.3 µg/L.

⁷² https://doi.org/10.1080/19440049.2010.501825

⁷³ http://www.cirs-reach.com/news/Food_Contact_Material_Regulation_in_China.html

⁷⁴ https://www.anses.fr/en/system/files/CONS02017SA0019EN.pdf

⁷⁵ https://ec.europa.eu/environment/ecolabel/documents/Technical%20Report_v4.6.pdf

⁷⁶ Standardization Administration of China. GB 15979-2002: Hygienic Standard for Disposable Sanitary Products: Standardization Administration of China: Beijing, China, 2002.

⁷⁷ Korean Ministry of Food and Drug Safety (MFDS). http://www.mfds.go.kr/brd/m_543/list.do

⁷⁸ http://www.mfds.go.kr/brd/m_99/view.do?seq=40034

⁷⁹ Kim S. 2017. Reviewing the Korean episodes of environmental chemicals in summer. Korean J. Public Health. 54: 3-12.

⁸⁰ http://www.jhpia.or.jp/site_en/standard/diaper2/img/diapers2.pdf

Rationale of the Study

Phthalates are well-known endocrine disrupting chemicals (EDCs) that have adverse effect on human health especially children who are most vulnerable to its exposure. Research studies are available on leaching of phthalates from diapers as well as health impacts of phthalates on children. Although in India there is a regulation in place for phthalates in plastic toys, there are no regulations in place for diapers. Furthermore, there is no information available in India on the health issues concerning the use of diapers especially in children although India has evolved as a major market for the use of diapers. Neverthless the growing use of diapers coupled with no proper system for collection and disposal of used diapers (in most of the cases these diapers are disseminated into the surrounding environment) is contaminating the ecosystem as well as the food chain.

In this context efforts are being made focusing on qualitative and quantitative analysis of phthalates in baby diapers available in the Indian market. Perhaps this is the first-of-its-kind of study in India to raise concerns over baby diapers.

2

Objectives of the study





To detect the presence of phthalates in baby diapers available in Indian market



To highlight the need of stringent regulation in place for Phthalates in diaper



To understand the fate of used diapers in environment

Sampling and Analysis

Sampling

To carry out this study a set of twenty samples of baby diapers were randomly collected from local markets and chemist shops in Delhi. Some of the samples were purchased from commonly used E-commerce platforms. The samples include both branded and local baby diapers of different companies. Except one none of the samples mentioned about the material and chemical composition of the diapers. Only on two of the samples details of composition were labelled as non-woven polypropylene adhesive paper, pulp and absorbent polymer, polyethylene, polyurethane. While in rest of the samples labels only showed information related to price, usage, and manufacturer details (**Annex II**).

The samples were then sent to the Spectro Analytical Labs Limited, New Delhi for the qualitative and quantitative analysis of phthalates-



- Bis(2-ethylexyl) phthalates (DEHP),
- Benzyl butyl phthalate (BBP),
- Di-isobutyl phthalate (DIBP),
- Di-butyl phthalate (DBP), and
- Total phthalates.

Methodology for the analysis of phthalates in baby diapers

For phthalate analysis IS 9873- Part 6: Method-A was used.

To measure phthalate contents, each diaper was weighed before sample collection. One square centimeter (1 cm²) piece was cut from four different locations of each diaper in such a way that all four pieces were weighed together to be 1 gm. The soxhlet extraction technique was used for sample extraction. Samples were mixed with dichloromethane in a soxhlet apparatus for 6 hours. The extract was cooled and mixed with hexane. 100 μ l of the solution was mixed with 20 μ l of internal standard (BB, 50 μ g/ml) and 880 μ l of hexane in a GC-MS vial. The 1 μ l extracted samples were analyzed by gas chromatography- Mass Selective Detector (GC MSD - Agilent Technologies) equipped with ultra-inert capillary column (30 m × 0.25 µm, 0.25 µm) using hexane as a washing solvent. The chromatograms were processed using software.

Identification of phthalates was done by comparing the retention time of sample peaks with peaks of standard compounds which shall be run with the same equipment under similar conditions.

Quantitative analysis was done by:

Calculating the concentration of phthalate in the sample using the following formula:

Phthalate content, percent by mass = $\frac{A \times V}{M} \times F \times (1 \times 10^{-6}) \times 100$

Where,

A = concentration in extract, $\mu g/ml$;

V = final volume of extract in ml;

M = mass of sample in g; and

F = dilution factor.

Results and Discussion

In the current study, twenty diaper samples were analyzed for detecting four types of phthalates as well as the total phthalate content. The four phthalates DEHP, BBP, DIBP, and DBP are highly hazardous especially for children. Therefore they are banned or restricted in children toys, baby care products, cosmetics, and medical devices etc in EU, US and few other developed countries. In India too these phthalates are restricted in children's toys.

In almost all samples di-isobutyl phthalate (DIBP) and benzyl butyl phthalate (BBP) were below detection limit or not detected (table. 5). However, DEHP (2.36-264.94 ppm), DBP (2.35-37.31 ppm) and total phthalates (8.2-302.25 ppm) were present in all the samples which is a matter of concern from the children's health point of view. The highest concentration of DEHP, DBP as well as total phthalates was reported in sample TL-D 16.

Serial	Bis (2-ethylhexyl) Phthalate (DEHP)	Benzyl Butyl Phthalate (BBP)	Di-isobutyl Phthalate (DIBP)	Di-butyl Phthalate (DBP)	Total
TL-D1	47.98	BDL	12.36	3.73	64.07
TL-D 2	14.79	BDL	1.92	2.35	19.06
TL-D 3	4.96	3.24	BDL	BDL	8.2
TL-D 4	5	BDL	BDL	9.42	14.42
TL-D 5	4.98	BDL	BDL	8.36	13.34
TL-D 6	2.84	BDL	BDL	17.59	20.43
TL-D 7	5.66	BDL	BDL	19.36	25.02
TL-D 8	5.28	BDL	BDL	29.01	34.29
TL-D 9	8.37	BDL	BDL	5.3	13.67
TL-D 10	4.11	BDL	BDL	10.61	14.72
TL-D 11	7.84	BDL	BDL	2.92	10.76

TABLE 6: ASSESSMENT OF PHTHALATES IN DIAPERS AVAILABLE IN THE INDIAN MARKET

Serial	Bis (2-ethylhexyl) Phthalate (DEHP)	Benzyl Butyl Phthalate (BBP)	Di-isobutyl Phthalate (DIBP)	Di-butyl Phthalate (DBP)	Total
TL-D 12	2.36	BDL	BDL	9.93	12.29
TL-D 13	9.52	BDL	BDL	10.76	20.28
TL-D 14	45.03	BDL	BDL	17.09	62.12
TL-D 15	5.89	ND	BDL	8.51	14.4
TL-D 16	264.94	ND	BDL	37.31	302.25
TL-D 17	4.59	ND	BDL	6.99	11.58
TL-D 18	88.26	ND	BDL	19.13	107.39
TL-D 19	62.02	BDL	9.05	7.31	78.38
TL-D 20	12.8	ND	BDL	7.33	20.13

Note: BDL is below detection limit ND is not detected

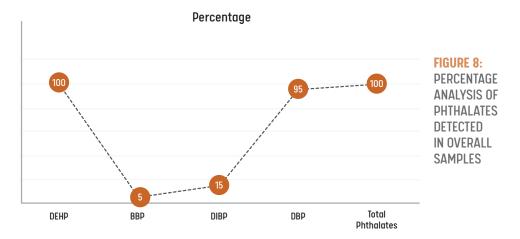
- DEHP has been reported in all the 20 samples analyzed ranging between 2.36-264.94ppm
- BBP was not detected or below detection limit in all samples except TL-D 3 in which BBP was found to be 3.24 ppm
- DIBP was detected in TL-D 1, TL-D 2 and TL-D 19.
- DBP and total phthalate content was reported in all the 20 samples

Total phthalates detected

TABLE 7: PHTHALATES DETECTED IN TOTAL SAMPLES

Phthalates	Numbers	Percentage
DEHP	20	100
BBP	1	5
DIBP	3	15
DBP	19	95
Total Phthalates	20	100

- DEHP and total phthalates had been reported in 100% of the samples sent for analysis
- The analysis of the data shows that BBP was found in only 5% of the samples while DIBP and BBP were found in 15% and 95 % of the samples.



Analysis of DEHP in diaper samples

TABLE 8: BIS (2-ETHYLHEXYL) PHTHALATE (DEHP) DETECTED IN DIAPER SAMPLES (MG/KG OR PPM)

Serial	Bis (2-ethylhexyl) Phthalate (DEHP) [mg/kg]
TL-D1	47.98
TL-D 2	14.79
TL-D 3	4.96
TL-D 4	5
TL-D 5	4.98
TL-D 6	2.84
TL-D 7	5.66
TL-D 8	5.28
TL-D 9	8.37
TL-D 10	4.11
TL-D 11	7.84
TL-D 12	2.36
TL-D 13	9.52
TL-D 14	45.03
TL-D 15	5.89
TL-D 16	264.94
TL-D 17	4.59

Serial	Bis (2-ethylhexyl) Phthalate (DEHP) [mg/kg]
TL-D 18	88.26
TL-D 19	62.02
TL-D 20	12.8

- Table 6 represents the comparative analysis of DEHP among diapers so tested.
- Max value of DEHP was reported to be 264.94 ppm in sample TL-D16 followed by 88.26ppm in sample TL-D 18 while the lowest value of DEHP that was detected was 2.36 ppm in TL-D 12.
- Sample TL-D 16 is a branded diaper and high level of DEHP being detected therein is quite a big concern as DEHP can easily leach out of the diapers and is a well- known endocrine disruptor as well as reasonably anticipated to be a human carcinogen.
- 90 FIGURE 9: GRAPHICAL 80 REPRESENTATION 70 OF VALUES OF 60 DEHP DETECTED 50 IN DIAPER 40 SAMPLES 30 20 10 N 11-D15 1L-D18 TL-D12 TL-D13 rl-D14 [L-D10 [L-D11 L-D17 IL-D1 IL-D2 IL-D3 IL-D4 IL-D5 IL-D6 lL-D8 rl-D9 L-D7
- The average concentration reported was 30.36 ppm

Analysis of DBP in diaper samples

TABLE 9: DI-BUTYL PHTHALATE DETECTED IN DIAPER SAMPLES (MG/KG OR PPM)

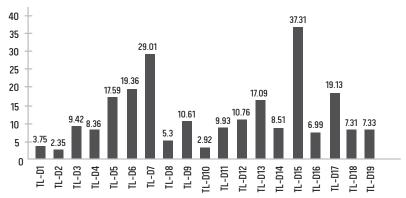
Serial	Di-butyl Phthalate (DBP)
TL-D1	3.73
TL-D 2	2.35
TL-D 4	9.42
TL-D 5	8.36
TL-D 6	17.59
TL-D 7	19.36
TL-D 8	29.01
TL-D 9	5.3
TL-D 10	10.61
TL-D 11	2.92
TL-D 12	9.93
TL-D 13	10.76
TL-D 14	17.09
TL-D 15	8.51
TL-D 16	37.31
TL-D 17	6.99
TL-D 18	19.13
TL-D 19	7.31
TL-D 20	7.33

The maximum level of DBP was reported to be 37.31 ppm in TL-D 16 followed by 29.01 ppm in sample TL-D 8. These are significantly higher than average (12.26 ppm) of all the diapers that were examined.

The minimum concentration of DBP was reported to be 2.35 ppm in samples TL-D 2.

The sample TL-D 16 is a famous brand and highest concentration of both DEHP as well as DBP were reported in it.

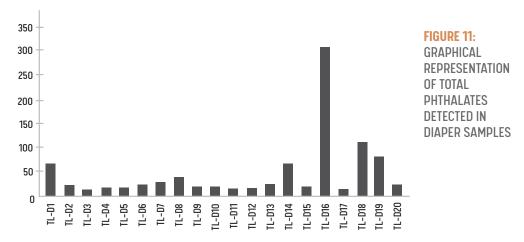
FIGURE 10: GRAPHICAL REPRESENTATION OF VALUES OF DBP DETECTED IN DIAPER SAMPLES



Analysis of total phthalates in diaper samples

Serial	Total Phthalates
TL-D 1	64.07
TL-D 2	19.06
TL-D 3	8.2
TL-D 4	14.42
TL-D 5	13.34
TL-D 6	20.43
TL-D 7	25.02
TL-D 8	34.29
TL-D 9	13.67
TL-D 10	14.72
TL-D 11	10.76
TL-D 12	12.29
TL-D 13	20.28
TL-D 14	62.12
TL-D 15	14.4
TL-D 16	302.25
TL-D 17	11.58
TL-D 18	107.39
TL-D 19	78.38
TL-D 20	20.13

- Test analysis shows that concentration of total phthalates is higher in sample TL-D 16 i.e., 302.25 ppm which is quite higher than the average value (43.34 ppm)
- The minimum concentration 8.2 ppm was reported in sample TL-D 3

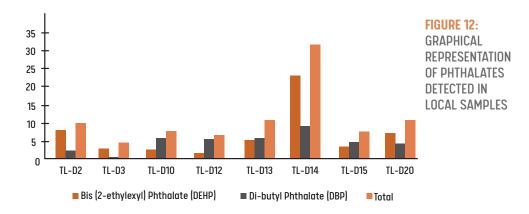


Analysis of samples collected from the local market

 TABLE 11: PHTHALATE ANALYSIS IN DIAPER SAMPLES COLLECTED FROM THE LOCAL MARKET (MG/KG OR PPM)

Serial	Bis (2-ethylhexyl) Phthalate (DEHP)	Di-butyl Phthalate (DBP)	Total
TL-D 2	14.79	2.35	19.06
TL-D 3	4.96	BDL	8.2
TL-D 10	4.11	10.61	14.72
TL-D 12	2.36	9.93	12.29
TL-D 13	9.52	10.76	20.28
TL-D 14	45.03	17.09	62.12
TL-D 15	5.89	8.51	14.4
TL-D 20	12.8	7.33	20.13

- Total 8 samples were purchased from the local market
- DEHP, DBP and total phthalates were reported to be maximum in sample TL-D 14; 45.03, 17.09 & 62.12 ppm respectively
- DBP was not detected in sample TL-D 3



Conclusion and Suggestions

The study was an attempt to get an understanding on the presence of phthalates in diapers that are available in the Indian market. There are global studies which have raised concerns over the presence of phthalates in diapers. Therfore the study was an attempt to get an overview on the presence of phthalates in diapers in the Indian context. The study has also established that most of the diapers contain phthalates like DEPH and DBP which are well-known endocrine disruptors. The sample TL-D 16 has the highest concentration of DEHP, DBP and total phthalates of 8.2 -302.25 PPM, which is notably higher than the recent published studies by Ishi et al 2015 on DEHP (0.1-0.6 ppm) and DBP (0.01-0.2 ppm) in baby diapers available in Japan and Park et al 2019 of the level of DEHP (0.01-0.06 ppm) and DBP (0.01-0.16 ppm) in diapers in Netherlands. Incidently most of the samples studied in India have high phthalate levels than the available global studies conducted on phthalates in diapers. Therefore the present study raised concerns on the quality of the products available in the Indian market and also the possible unimaginable risks that these products can pose to children.

Moreover due to lack of a suitable disposal mechanism in place, mostly diapers end in the landfills or the surrounding open spaces of our neighbourhoods . As the diapers contain high level of phthalates, there is every possibility that these phthalates are being leached out to the surrounding environment and impacting the overall ecosytems including the ground water. And this can pose huge health hazards to the surrounding community as well.

Finally the phthalates are known toxic chemicals and there are number of studies which have established that phthalates are EDCs and children are most prone to the impact of these chemicals. Presence of these chemicals have opened up a Pandora's box with colossal regulatory gaps on the safety of children's products in India. Though there are regulations on phthalates in European countries as well as in China and South Korea, in India there is no such regulation in place to check the quality of the diapers and ensure that better products are available in the market to safeguard children's health . It is to be noted that during the sampling process it was found that except one no other diaper samples had labelling.

Hence the study has proposed certain recommendations which need to be implemented to ensure that good quality products are available in India to protect children's health and the environment.

These suggestions are:

1. Research agenda on Diapers



This is the first study of its kind in India and has limitations on number of samples, therefore the concerned research institutes including ICMR need to carry out India-specific studies on phthalates in diapers and their possible health impacts on children.Further studies can be conducted on the impact of phthalates from the diapers in environmental metrics.

2. Ban and phase out phthalates from the diapers immediately.

There is no standard on phthalates in diapers in India. So considering the steps taken by the countries across the globe the Bureau of Indian Standards can notify the standards and issue ban on the use of phthalates and phthalates-linked fabrics for the manufacture of diapers in India.

3. Stringent regulation for diapers or other children products



In India standards are in place on phthalates in children's toys but still there are several children products such as diapers, personal care products which are out of the ambit of the regulation. Stating the harmul impacts of phthalates there is a need to develop a policy for phthalate-free products in the market with prioritizing the products that are being used by the children.

4. Mandatory labelling for diapers and other children products



During the study it was found that except one manufacturer no one has labelled their products. As the study has found the presence of harmful chemicals like phthalates, a mandatory regulation can be in force for proper labelling to improve transparency and consumer choice. Furthermore labelling will improve monitoring and compliance of the environmentallysafe diapers in the market.

5. Disposal of diapers in an environmentally sound manner.



Currently due to the lack of any suitable disposal mechanism in place, the used diapers ultimately reach the landfills where phthalates can be leached out into soil, surfaces and ground water and contaminate the food chain. Hence there is a need for the government to come out with a system of proper collection and disposal of used diapers in an environmentally sound manner.

6. Stakeholder Awaerness



Consumers need to be aware on the negative aspects of Phthalate-containing products especially in the products for children and in food articles. At the same time during the production process workers are possibly exposed to the phthalates and they also need to be aware of the issue to safeguard their health.

SOCIAL IMPACT AND CONCERNS

The outreach and use of diapers is on the rise in India. Their growing usage can be witnessed in all socio-economic sections of the society. It is increasingly evident that the use of diapers is no more associated with the concerns of ease in mobility and hygiene but is a reflection of enhanced status in the society. More and more families have adopted a consumerist lifestyle. They are buying and using diapers for infants with increased frequency and increased usage of time even when the majority of the diapers are not suitable for hot and humid climates due to the presence of non-breathable fabrics. These fabrics often lead to skin rashes for babies' sensitive skin.

It is critical to realize that almost all rural and urban families in India lack awareness on the health hazards associated with prolonged use of diapers on babies. Babies are exposed to the chemicals used in diapers 24 hours a day. Direct contact of chemicals in diapers with their skin enters the baby's system. It is imperative that large scale awareness and sensitization is generated among the population on the chemicals present in diapers, their health and environmental hazards and further regulated use of diapers.

Also, disposal of diapers is a major concern in the present time when the world is faced with large amount of waste generation and management, particularly of plastic waste.

The waste disposal sites and landfill sites all around the world are in the vicinity of areas wherein the marginalized population and those below the poverty line reside. The burden of environmental damage and subsequently health damage caused by the improper disposal and management of diapers is primarily beared by the communities residing near the waste dumping sites. Ragpickers, especially are exposed to these hazards.

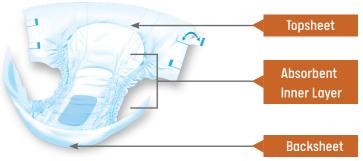
Annexure I

Anatomy of Diaper

The average diaper is comprised of 43% of fluff pulp, 27% super absorbent polymer, 15 to 23% polypropylene/polyethylene, 5% adhesive and about 1% elastic. It is made up of four layers as described below:

- Inner Layer or Top Sheet: This layer is in direct contact with skin. It consists of a thin layer of perforated polypropylene and/or polyethylene non-woven. The main function of this layer is to transfer fluids and faeces quickly to the layer beneath. Mostly, emollient or lotion is applied onto the topsheet material to provide protection from irritation and skin rashes.
- Acquisition Layer: (also called the distribution layer) This layer is composed of a cellulose and polyester non-woven sheet. It absorbs and evenly distributes the urine across the entire area of the diaper. In addition, this layer helps prevent fluid reflux by retaining the fluid.
- Absorbent Core: This layer is composed of a combination of superabsorbent polymer (SAP) granules and cellulose fluff pulp, which are encapsulated by cellulose or nonwoven polypropylene. The cellulose quickly absorbs and transfers urine to the SAP material, where it is trapped. This keeps the baby's skin dry. SAP is granules of sodium polyacrylate, and it transforms into a gel-like substance once it is wet. SAP can absorb fluid upto 30-50 times to their weight.
- Waterproof Outer Shell or backsheet: This is the outermost layer of the disposable diaper and is in direct contact with the clothes of a baby. This backsheet is typically made of a water-proof polyethylene or polypropylene film laminated with non-woven polypropylene.

This layer prevents fluid from leaking onto the baby's clothing or surrounding e n v i r o n m e n t though it allows air to pass through and hence keeps the skin drier.



Annexure II

Details of Samples purchased for analysis

Sample No.	Brand Name	Manufacturer	Marketed by	Sampling location	Material Labeling
TL-D 1	Pampers	P&G Home products Pvt Itd, plot no. 182, Sec A, industrial area, mandideep-462046, Raisen, M.P.	P&G Home products Pvt Itd	Ganpati Medicals, DDA market, Vasundhara Enclave, Delhi-96	Not mentioned
TL-D 2	Baken	Not mentioned	Nor mentioned	Local bhogal market	Not mentioned
TL-D 3	Little Angel	PAN Healthcare Pvt Ltd., C-801, The Imperial Heights, Opp. Big Bazar, 150 Feet Ring Road, Rajkot- 360005, Gujarat	PAN Healthcare Pvt Ltd.,	Localbhogal market	Not mentioned
TL-D 4	Mammypoko	Unicharm India pvt Ltd, Unit No 501 to 508, Centrum Plaza Building, Sec 53, Gurugram	Unicharm India pvt Ltd	Ganpati Medicals, DDA market, Vasundhara Enclave, Delhi-96	Non-woven Polypropylene, Paper, Pulp, Polyethylene, polyurethane
TL-D 5	Huggies	Kimberly Clark India Pvt Ltd, gate no. 934 to 937, VillSanasawadi, Tal shirur, Pune-412208	Kimberly Clark India Pvt Ltd	Flipkart, Life Health and Beauty, Sector 10/416, Indira nagar, Lucknow-16	Not mentioned
TL-D 6	Himalaya	Swara baby Products Pvt Itd, Plot No.:381-388, sec -3, Pithampura Industrial Area, dhar,454775 M.P.	The Himalaya Drug company, Makali, bengaluru 562162	Flipkart, V.S. international, 40-A, Ground Floor, Main Rd., Near HDFC Bank, Kundan Nagar, N. Delhi-92	Not mentioned
TL-D 7	Patanjali	Millennium baby care, plot No.:111, sec 2, pithampura industrial Area, dhar 454775, M.P.	PatanjaliAyurved Ltd., Patanjali food & Herbal park, Laksar road, padartha, haridwar-249404	Flipkart, R.S. international, C11/31 First Floor, rohini Sector-3, near NDPL Power limited, N.Delhi-85	Not mentioned

Sample No.	Brand Name	Manufacturer	Marketed by	Sampling location	Material Labeling
TL-D 8	teddyy	Noble Hygiene Pvt Ltd., A 70, MIDC Malegaon, Sinnar- 422113, Nashik	Nobel Hygiene Pvt Ltd	Amazon, Nobel Hygiene Pvt Ltd, Bldg A3/A4, Shree Rajlaxmi, Logistics Park Bldg A3/A4, Bhiwandi, Vadape, thane-421302	Not mentioned
TL-D 9	МееМее	Noble Hygiene Pvt Ltd., A 70, MIDC Malegaon, Sinnar- 422113, Nashik	Me N Mom's Pvt Itd, Amar Apartments, 8th Road, TPSIII, Khar (W), Mumbai 400052	Flipkart, Me N Mom Pvt Ltd, Khasra no 53/22, nanglipoona, N.Delhi-36	Not mentioned
TL-D 10	Honey Kid	PAN Healthcare Pvt Ltd, Behind Shemla Bus Stop, National Highway 27, Biliyada, rajkot-360311, Gujarat	Rich Faith Pharmaceuticals pvt Ltd, 12, Ring Road, Lajpatnagar-IV, N.Delhi-24	Paytm Mall, Rich Faith pharmaceuticals Pvt Ltd, 1146/1, SaraswatiViharSaddique Nagar meerut Road, Ghaziabad 201001	Not mentioned
TL-D 11	S.K.Soft	S.K.trading Company, 647 GaliRadhakrishanmandir, nehruKutia, Malkaganj, Near AmarnathJalebiwala, New Delhi-07	S.K. trading	Flipkart, S.K.trading Company, 647 GaliRadhakrishanmandir, nehruKutia, Malkaganj, Near AmarnathJalebiwala, New Delhi-07	Not mentioned
TL-D 12	Freshkins	Not mentioned	Not mentioned	LocalBhogal market	Not mentioned
TL-D 13	Comfort	Not mentioned	Not mentioned	LocalBhogal market	Not mentioned
TL-D 14	Genki	Not mentioned	Not mentioned	LocalBhogal market	Not mentioned
TL-D 15	Dry Feel	Not mentioned	Not mentioned	LocalBhogal market	Not mentioned
TL-D 16	Mammypoko	Unicharm India pvt Ltd, Unit No 501 to 508, Centrum Plaza Building, Sec 53, Gurugram	Unicharm India pvt Ltd	Ganpati Medicals, DDA market, Vasundhara Enclave, Delhi-96	Non-woven Polypropylene, Paper, Pulp, Polyethylene, polyurethane
TL-D 17	Himalaya	Swara baby Products Pvt Itd, Plot No.:381–388, sec -3, Pithampura Industrial Area, dhar,454775 M.P.	The Himalaya Drug company, Makali, bengaluru 562162	Ganpati Medicals, DDA market, Vasundhara Enclave, Delhi-96	Not mentioned

Sample No.	Brand Name	Manufacturer	Marketed by	Sampling location	Material Labeling
TL-D 18	Pampers	P&G Home products Pvt Itd, plot no. 182, Sec A, industrial area, mandideep-462046, Raisen, M.P.	P&G Home products Pvt Itd	Jhankar Chemist, 16, Jungpura Extension, New Delhi-14	Not mentioned
TL-D 19	Diaper pants	Safilo healthcare, N.H., 8-A, opp. Lalpar Village, lalpar, Morbi-36342, gujarat	Hands on trades pvt Ltd, 19, RPS, Sheikh sarai 1, new delhi–17	Groffers, SS Noida Commoncity Retail Private Limited, areahouse No. 4, Sec-67, Noida	non-woven polypropylene adhesive, paper, pulp and absorbent polymer, polyethylene polyurethane
TL-D 20	Comfort	Not mentioned	Not mentioned	LocalBhogalmarket	Not mentioned

Annexure III

Functions and uses of some common phthalates

Phthalate	Function(s)	Product(s)
DEHP	Primarily used as a plasticizer for PVC	Shoes, raincoats, children toys, clothing, furniture, automobile upholstery, few medical devices, tubing typically used in the milking process, lid gaskets, food-packaging films, gloves, conveyor belts etc
BBP	used as a plasticizer for PVC, polyurethane, polysulfide, & acrylic- based polymers	Automobile products, food-wrapping materials, children toys and products, vinyl flooring, sealants, adhesive
DIBP	used as a plasticizer for PVC	Vinyl fabrics, raincoats, solid rocket propellant as a fuel stabilizer, nail polish, cosmetics, lubricants, floor carpets, tapestry, clothing treatments, rubber dentistry settings, enamel paint & lacquers, printing inks
DBP	used as a plasticizer for PVC, poly vinyl alcohol and rubber, as a fixative in cosmetics and enamel paints	Cosmetics, food wrapping materials, children toys, latex adhesive, sealants, car care products, enamel paints, pharmaceutical coatings, insecticides
DIDP	used as a plasticizer for PVC	PVC flooring, electrical cords, leather for car & household furnishing
DnOP	used as a plasticizer for PVC	no known commercial uses for pure DnOP. Bottle cap liners, flooring, garden hoses, conveyer belts

Annexure IV

Research studies depicting health impacts of phthalates

Year	Author	Location	Matrix	Title	Findings
2019	Balalian A. A.,Whyatt R. M., Liu X.,Insel B. J., Rauh V. A., andHerbstman J.	Department of Epidemiology, Columbia University, New York	Children of age of 11 yrs	Prenatal and childhood exposure to phthalates and motor skills at age 11 years.	Higher prenatal exposure to specific phthalates was associated with lower motor function among 11- year old girls while higher post-natal exposure to ∑DEHP metabolites was associated with lower scores among boys
2019	Du Y, Guo N, Wang Y, Teng X, Hua X, Deng T, Yao Y, Yuan X, Li Y	Huazhong University of Science and Technology, China	Follicular fluid and urine	Follicular fluid concentrations of phthalate metabolites are associated with altered intrafollicular reproductive hormones in women undergoing in- vitro fertilization.	On cohort study on 194 females they have detected 7 phthalates. They have shown that those females having higher phthalate concentration in follicular fluids have altered levels of intrafollicular reproductive hormones representing potential deleterious effect of phthalates on human health.

Year	Author	Location	Matrix	Title	Findings
2018	Berger K., Eskenazi B.,Balmes J., Kogut K., Holland N., Calafat A.M., Harley K.G.	Center for Environmental Research and Children's Health, University of California	Children at age 7	Prenatal high molecular weight phthalates and bisphenol A, and childhood respiratory and allergic outcomes	They have concluded that phthalate was associated with lower respiratory health disorders in children
2017	Stojanoska M.M., Milosevic N., Milic N., and Abenavoli L.	University Of Novi Sad, Serbia	children	The influence of phthalates and bisphenol A on the obesity development and glucose metabolism disorders. Endocrine.	In this review article they conferred that endocrine disrupting chemicals interfere with different cell signaling pathways involved in weight and glucose homeostasis.
2016	Ginsberg G, Ginsberg J, and Foos B.	Partnership in Pediatric and Environment Health, USA	children	Approaches to Children's Exposure Assessment: Case Study with Diethylhexyl phthalate (DEHP).	The result of this methodology for DEHP is the identification of key pathways of exposure along with opportunities for lowering exposure in early life.
2016	TyeE.Arbuckle, KarelynDavis, KhristaBoylan, MandyFisher, JingshanFu	Population Studies Division and Mc Master University, Canada	children 6-11 years of age	Bisphenol A, phthalates and lead and learning and behavioral problems in Canadian children 6-11 years of age: CHMS 2007-2009	They have reported that the prevalence of any learning disability, ADD, and ADHD were 8.7%, 1.5% and 2.8%, respectively.

Year	Author	Location	Matrix	Title	Findings
2015	Ishii S.,Katagiri R.,Minobe Y.,Kuribara I., Wada T., Wada M., and Imai S	Chemicals Evaluation and Research Institute, Tokyo, Japan	Newborn babies	Investigation of the amount of transdermal exposure of newborn babies to phthalates in paper diapers and certification of the safety of paper diapers	Authors have detected DEHP & DBP in the topsheets of diapers and determined to be 0.6 mg/g and 0.2 mg/g, respectively.
2015	Lien Y.J., Ku H.Y., Su P.H., Chen S.J., Chen H.Y., Liao P.C., Chen W.J.,andWang S.L.	National Taiwan Normal University	Children ay 8 years of age	Prenatal exposure to phthalate esters and behavioral syndromes in children at 8 years of age: Taiwan Maternal and Infant Cohort Study.	Their findings suggested positive associations between maternal DEHP and dibutyl phthalate (DBP) exposure and externalizing domain behavior problems in 8-year-old children.
2015	Hannon P.R. and Flaws J.A.	Department of Comparative Biosciences, University of Illinois, USA	Ovary	The effects of phthalates on the ovary	Phthalates target the ovary to adversely affect the two essential processes of folliculogenesis and steroidogenesis. Study required to understand the combined effects of multiple phthalates
2015	Ku et al	National Defense Medical Center, Taiwan	children	Prenatal and Postnatal exposure to Phthalate Esters and Asthma: A 9-Year Follow- Up Study of a Taiwanese Birth Cohort	The study was done on 430 pregnant women and 171 (39.8%) of them had their children followed when they were aged 2, 5, and 8 years. The study concluded that prenatal exposure of phthalates is responsible for increase IgE concentration, allergies and asthma in kids.

Year	Author	Location	Matrix	Title	Findings
2015	Kim et al	Seoul National University, Seoul, Republic of Korea	Breast milk and infants	Concentrations of phthalate metabolites in breast milk in Korea: Estimating exposure to phthalates and potential risks among breast- fed infants	Metabolites of DEHP, DnBP, DiBP and DEP were detected in > 79% of breast milk samples.6% of infants exceeded the tolerable daily intake (TDI) for DnBP.
2015	Shi H., Cao Y., Shen Q., Zhao Y., Zhang Z., Zhang Y.	School of Public Health, Chinese Ministry of Education	503 children of 7-14 years of age	Association Between Urinary Phthalates and Pubertal Timing in Chinese Adolescents	The study shows significant associations of phthalates with pubertal timing both in boys and in girls, especially among girls with high body fat%.
2014	Kay, V.R.; Bloom, M.S.; Foster, W.G.	Department of Obstetrics and Gynecology, McMaster University, Canada	males	Reproductive and developmental effects of phthalate diesters in males.	They have concluded the phthalate exposure causes developmental problems and to understand the effects across generations need continued study.
2014	Litvak P.M., InselB.,CalafatA.M., Liu X.,Perera F., Rauh V.A.,Whyatt R.M.	Department of Epidemiology, Columbia University, New York	children aged 7 yrs	Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years	Studied on 328 mother-kids pair. The study concluded that DnBP and DiBP are associated with deficits in children's intellectual development such asprocessing speed, perceptual reasoning and working memory: DiBP is more responsible for lower child verbal comprehension; and BBzPfor lower child perceptual reasoning.

Year	Author	Location	Matrix	Title	Findings
2014	Kobrosly R.W., Evans S., Miodovnik A., Barrett E. S., Thurston S. W., Calafat A. M., and Swan S. H.	Department of Preventive Medicine, USA	children	Prenatal Phthalate Exposures and Neurobehavioral Development Scores in Boys and Girls at 6-10 Years of Age	The study suggests associations between exposure to certain phthalates in late pregnancy and behavioral problems in boys such as distraction, rule- breaking behavior, aggression and somatic problems.
2013	Sathyanarayana S., Alcedo G., Saelens B.E., Zhou C., Dills R.L., Yu J. and Lanphear B.	Department of Pediatrics, University of Washington	Members of 10 families	Unexpected results in a randomized dietary trial to reduce phthalate and bisphenolA exposures.	Authors had reported unexpected increases in urinary phthalate concentrations and suggested that food contamination can be a major source of DEHP exposure
2012	NordkapL., JoensenU.N., Blomberg Jensen M., andJørgensen, N.	University Department of Growth and Reproduction, Denmark	male	Regional differences and temporal trends in male reproductive health disorders: semen quality may be a sensitive marker of environmental exposures.	study indicated that exposure to endocrine disrupters also in adulthood may affect semen quality and reproductive hormones. The study aksosuggestedthat standardized surveillance studies of semen quality should be ontinued to monitor the combined effects of various preventive actions.
2012	Koch H. M., Christensen K. L. Y., Harth V., Lorber M.&Brüning T.	Institute of the Ruhr-University Bochum, Germany	Man of 36 yrs	Di-n-butyl phthalate (DnBP) and diisobutyl phthalate (DiBP) metabolism in a human volunteer after single oral doses	The study reported that both DnBP and DiBP, were excreted in the first 24 h (92.2 % of DnBP, 90.3 % of DiBP respectively).

Year	Author	Location	Matrix	Title	Findings
2010	Cho et al		children	Relationship between Environmental Phthalate Exposure and the Intelligence of School-Age Children	The cohort study was done on 667 children at nine elementary schools in five South Korean cities. The study concluded that higher the concentration of phthalates lower the IQ, FSIQ, VIQ, and vocabulary and block designscores among children.
2010	Engel S.M., MiodovnikA., CanfieldR.L, ZhuC., SilvaM.J., Calafat A.M, and Wolff M.S.	Department of Preventive Medicine, USA	Children at 4-9 years of age	Prenatal phthalate exposure is associated with childhood behavior and executive functioning. Environ. Health Perspect.	The study concluded that LMW phthalates are adversely associated with conduct or attention deficit hyperactivity disorders in children who were clinically diagnosed.

Annexure V

Research studies depicting impacts of phthalates on environment

Year	Author	Location	Matrix	Title	Findings
2019	ArpanaKumari and Rajinder Kaur	Guru Nanak Dev University, Amritsar, Punjab,	Hordeum vulgare L. seedlings, Amritsar Punjab	Modulation of biochemical andphysiological parameters in Hordeum vulgare L. seedlings under the influenceof benzyl-butyl phthalate	BBP disturbed the normal physiology of barley which could also affectthe yield of the crop under field conditions.
2018	Kumar D. et al	IARI New Delhi	Agricultural soil, N. Delhi	Assessment of diverse phthalate esters (PAEs) from irrigated agriculture soil under protected cultivation in IARI, New Delhi	They have recovered DEP andDEHP in range of 90.93±0.404 to95.3±0.211. Estimated the residual PAEs in agriculture soils in range of109 ppm to 120 ppm.
2018	Lü H., Mo C.H., Zhao H.M., Xiang L., Katsoyiannis A., Li Y.W., Cai Q.Y., and Wong M.H.	South China Agricultural University, China	Soil,	Soil contamination and sources of phthalates and its health risk in China: a review.	In this review article authors concluded that urbanization and industrialization, application of plastic film and fertilizer are the major sources of PAEs in soil.

Year	Author	Location	Matrix	Title	Findings
2017	Vinay Kumar, Neha Sharma, S.S. Maitra	School of Biotechnology, Jawaharlal Nehru University, Delhi	Municipal solid waste	Comparative study on the degradation of dibutyl phthalate by two newly isolated Pseudomonas sp. V21b and Comamonas sp. 51F	it can be considered as a potential candidate for bioremediation of the sites contaminated with PAEs
2016	RadkaDaňková, Alžbeta Jarošová, Šárka Poláková	Mendel University, Czech republic	Agricultural soil,	Analysis of Phthalate Presence in Agricultural Soils in the Czech Republic	The phthalic acid ester concentrations found ranged from 0.01 to 2.48 mg/ kg of DM wt for dibutyl phthalate and from 0.05 to 1.43 mg/kg of DM wt for di2ethylhexyl phthalate. The total concentration of both phthalates ranged from 0.21 to 3.47 mg/kg of DM wt.
2016	Kankan Li, Dong Ma, Juan Wu, Chao Chai, Yanxi Shi	Qingdao Agricultural University, China	Soil,	Distribution of phthalate esters in agricultural soil with plastic film mulching in Shandong Peninsula, East China	•The total contents of the 16 PAEs ranged from 1.374 to 18.810 mg/kg with an average of 6.470 mg/kg. •The ratios of DMP, DEP, and DnBP that exceeded the allowable concentrations were 63.9-100%.

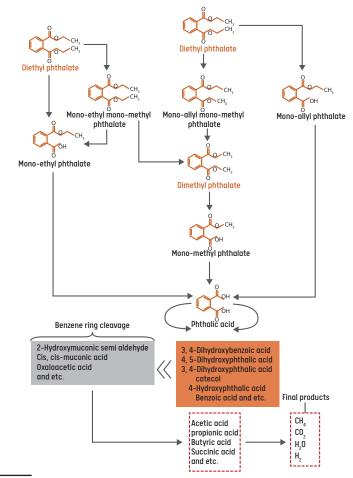
Year	Author	Location	Matrix	Title	Findings
2016	Biljana D. Škrbić, YaqinJi , NatašaĐurišić- Mladenović , Jie Zhao	University of Novi sad, Serbia	Soil & street dust,	Occurrence of the phthalate esters in soil and street dust samples from the Novi Sad city area, Serbia, and the influence on the children's and adults' exposure	Studied 6 phthalates DMP, DEP, DBP,BBP,DEHP,and DOP in soil and street dust from Serbia.PAEs were detected in all samples in the range 0.0002-4.82 mg/ kg
2015	Pradeep S., Josh M.S., Binod P., Devi R.S., Balachandran S., Anderson R.C., and Benjamin S.	Enzyme Technology Laboratory, University of Calicut, Kerala	Bacteria,	Achromobacter denitrificans strain SP1 efficiently remediates di[2-ethylhexyl] phthalate	They have reported bacterial strains which offer great potentials for efficiently cleaning the DEHP-contaminated environments such as soil, sediments and water upon its deployment.
2015	Wang et al	Chongqing Research Academy of Environmental Sciences, china	Vegetables & soil	Occurrence and risk assessment of phthalate esters (PAEs) in vegetables and soils of suburban plastic film greenhouses.	The concentration of DBP ranged from 0.083 to 6.31 µg/ kg in vegetable oils from suburbs of Xianyang, China. 79.5% of vegetable samples exceeded maximum residue limits (0.3 mg/kg) in food.
2015	Sun J, Wu X, Gan J	Department of Environmental Sciences, University of California	Carrot plant	Uptake and Metabolism of Phthalate Esters by Edible Plants.	Four phthalates were detected in the plant tissues, with the bioconcentration factors (BCFs) ranging from 0.16 ± 0.01 to 4.78 ± 0.59.

Year	Author	Location	Matrix	Title	Findings
2014	Selvaraj K.K. et al	School of Environmental Sciences, Bharathidasan University, Tiruchirappalli, Tamilnadu	Water and sediments	Phthalate esters in water and sediments of the Kaveri River, India: environmental levels and ecotoxicological evaluations	DEP and DMP were reported in every samples. The total phthalates in water samples ranged from 313to 1,640 ng/I, whereas in sediments it was 2 to1,438 ng/g dw (dry weight)
2013	Yang Hongjun, XieWenjunLiuQingLiu, JingtaoYuHongwen, LuZhaohua	Binzhou University, China	Soil,	Distribution of phthalate esters in topsoil: a case study in the Yellow River Delta, China	Concentrations of 11 PAEs are in the range of 0.794 19.504 µg g-1, with an average value of 2.975 µg g-1.
2013	Magdouli S., Daghrir R., Brar S.K., Drogui P., Tyagi R.D.	University of Quebec, Canada	Aquatic and terrestrial compartment of environment	Di 2-ethylhexylphtalate in the aquatic and terrestrial environment: A critical review	This article presents detailed review of existing treatment schemes, research gaps and future trends related to DEHP.
2011	Bergh C., Torgrip R., Emenius G, C. stman	Karolinska Institute, Stockholm, Sweden	Indoor & outdoor air & dust	Organophosphate and phthalate esters in air and settled dust - a multi-location indoor study	DMP, DEP, DIBP, DBP, BzBP, and DEHP) were found to be present at all the locations investigated in this study. The most abundant compound in dust was DEHP constituting up to 5.8 & of the dust weight.
2011	Salapasidou M, Samara C, Voutsa D	Department of Chemistry, Aristotle University, Greece	Air,	Endocrine disrupting compounds in the atmosphere of the urban area of Thessaloniki, Greece	phthalates (DMP, DEP, DBP, BBP, DEHP, DNOP) were detected with frequency 100%

Year	Author	Location	Matrix	Title	Findings
2010	Clara M., Windhofer G., Hartl W., Braun K., Simon M., Gans O., Scheffknecht C., Chovanec A.	Environmental Institute, Umweltbundesamt GmbH, Austria	untreated and treated waste water, sewage sludge, road runoff water	Occurrence of phthalates in surface runoff, untreated and treated wastewater and fate during waste water treatment	All 6 investigated phthalates reported (DEHP, DMP, DBP, BBP, DOP& DEP). DEHP was higher app 18 ng/L
2010	Srivastava A, Sharma VP, Tripathi R, Kumar R, Patel DK, Mathur PK.	Indian Institute of Toxicology Research, Lucknow	River sediments of Gomati river	Occurrence of phthalic acid esters in Gomti River sediment, India. Environmental Monitoring and Assessment.	The sediment samples were collected from 30 locations. The mean concentration values of DMP, DEP, DBP, DEHP, and DOP were found as 10.54, 4.57, 10.41, 31.61, and 5.16 microg/kg, respectively.
2010	Ruthann A. Rudel, Robin E. Dodson , laura J. Perovich Rachel Morello- Frosch, David E. Camann Michelle M. Zuniga, Alice Y. Yau, Allan C. Just, and Julia Green Brody	University of California and Columbia University	Indoor and outdoor air	Semivolatile Endocrine-Disrupting Compounds in Paired Indoor and Outdoor Air in Two Northern California Communities	DEHA, DBP, DEP, DIBP) were detected in 100% of the homes. DEHA and DIBP were detected >MRL in >90% of outdoor samples in each community; DBP and DEPwere detected in 30-70% samples.
2008	Sathyanarayana S., Karr C.J., Lozano P., Brown E., Calafat A.M., Liu F., and Swan S.H.	Department of Occupational and Environmental Health Sciences, University of Washington	Infants and lotion, powder, and shampoo :	Baby care products: possible sources of infant phthalate exposure.	Infant exposure to lotion, powder, and shampoo were significantly associated with increased urinary concentrations of phthalates, and associations increased with the number of products used.

Annexure VI

The bio-degradation pathways of selected phthalates⁸¹



⁸¹ https://www.researchgate.net/publication/313874416_Performance_kinetic_and_biodegradation_pathway_evaluation_of_ anaerobic_fixed_film_fixed_bed_reactor_in_removing_phthalic_acid_esters_from_wastewater

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