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# BOTTLES CAN BE

An investigative study on migration of Bisphenol A (BPA) in baby feeding bottles and sippy cups in India PARTI

## **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 toxic. We have taken 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 a unique expertise in 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 stakeholder groups.

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# CONTENTS

Acknowledgement	iii
Introduction	1
Baby Feeding Bottles	1
How does BPA get into the body?	1
Health Impacts	2
Impacts on Children	2
Literature review	3
Global developments on BPA	5
Rationale of the study	7
Objectives of the study	7
Sampling and Analysis	8
Sampling	8
Procedure for the analysis of BPA migration in baby feeding bottles and sippy cups	9
Results and Discussion	10
Conclusion and Recommendation	13
References	14
Annexures	
Annexure I	15
Annexure II	16

## List of Tables

Table 1:	Release of BPA per day (µg/dm2/day) during hydrothermal exposure in 14 days at	
	90 °C at alkaline conditions	3
Table 2:	Tolerable daily intake (TDI) limits for BPA in some countries	5
Table 3:	Global and national regulation of BPA in baby feeding bottles	5
Table 4:	Global Regulations of BPA in Sippy Cups	6
Table 5:	Details of BPA migration in first and second extraction in baby feeding bottles	11
Table 6:	Details of BPA migration in first and second extraction in sippy cups	12
Table 7:	Total BPA concentration in baby feeding bottles (2014)	15
Table 8:	Total BPA concentration in sippy cups (2016)	15

# List of Figures

Figure 1:	Exposure sources and route of exposure to BPA	1
Figure 2:	Highest to lowest BPA migration in ppb	12

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# ABBREVIATIONS

°C	Degree Celsius
μg	Microgram
μL	Microliter
BIS	Bureau of Indiand Standards
BPA	Bisphenol A
CAGR	Compound Annual Growth Rate
cm	Centimeter
EFSA	European Food Safety Authority
ER	Estrogen Receptor
FDA	Food and Drug Administration
g	gram
GC-MS	Gas chromatography-mass spectrometry
h	Hour
HPLC	High-performance liquid chromatography
IMS	Infants Millk Substitutes
kg	Kilogram
L	Liter
mL	Milliliter
ng	Nanograms
PC	Polycarbonate
PES	Polyethersulfone
PP	Polypropylene
ppb	Parts per billion
Ppm	Parts per million
US\$	US Dollar

feeding bottles in 2017 US\$ 2,469.9 million

# INTRODUCTION

## **Baby Feeding Bottles**

Plastic bottles have been the most preferred and widely available option for most parents. These bottles are lightweight and not brittle, which make them convenient to use and easy to carry while traveling. The global baby bottles market is foreseen to see growth on the back of the willingness of new parents to spend more on baby foods. It is also forecasted

for the global baby bottles market to grow at a CAGR of 3.97% during 2017-2022.1  $\,$ 



Global revenue generated from baby feeding bottles market was around US\$ 2,469.9 million by the end of 2017, which is expected to increase at a CAGR of 4.7% over the forecast period. Global baby feeding bottles market is expected to be valued at US\$ 3,556.4 million by the end of 2025.<sup>2</sup>

## How does BPA get into the body?

The primary source of exposure to BPA for most people is through eating food and drinking liquids that were in contact with BPA. While air, dust, and water are other possible sources of exposure, BPA in food and beverages accounts for the majority of daily human exposure. Bisphenol- A can leach into food from the protective internal epoxy resin coatings of canned foods and from consumer



<sup>1</sup> https://www.prnewswire.com/news-releases/world-baby-bottle-market-to-grow-at-408-cagr-to-2021-598853291.html

<sup>2</sup> https://www.transparencymarketresearch.com/baby-feeding-bottles-market.html

products such as polycarbonate tableware, food storage containers, water bottles, and baby bottles. BPA present in the lining of baby bottles may seep into the contents of the bottle after constant reheating, mechanical pressure, or exposure to high pH detergents. The degree to which BPA leaches from polycarbonate bottles into liquid may depend more on the temperature of the liquid or bottle, than the age of the container. BPA can also be found in breast milk.<sup>3</sup>

## **Health Impacts of BPA**

This BPA is a harmful chemical and is known to mimic a hormone in the body which activates the progression of cancer and interferes with the development of the reproductive system.

BPA is associated with the increased risks of breast and prostate cancer, brain and thyroid abnormalities, infertility, heart diseases, diabetes, early puberty, and obesity. The chemical is also considered to be a developmental, neural, and reproductive toxicant that mimics estrogen and interferes with healthy growth and body functions.<sup>4</sup>

## **Impacts on Children**

The epidemiological studies found correlations between BPA exposure and heart diseases, liver toxicity and metabolic syndrome (diabetes obesity).<sup>5</sup> Researchers have reported that exposure to low doses of BPA leads to disruptive effects in androgen or estrogen-responsive tissues, within the immune system, the thyroid, and the developing nervous system.<sup>6,7</sup> Due to the structural similarity of BPA with 17  $\beta$  estradiol, the former compound binds with the estrogen receptor (ER) and alters its functions.<sup>8,9,10</sup> Hence continuous use of such plastic containers for food preparation and storage is likely to add up the body burden to a level that causes hormone-related problems; the impacts of BPA chemical residues on endocrine system vary with the dosage, body weight and synergistic actions of hormones.

<sup>3</sup> https://www.niehs.nih.gov/health/topics/agents/sya-bpa/index.cfm

<sup>4</sup> https://www.prnewswire.com/news-releases/world-baby-bottle-market-to-grow-at-408-cagr-to-2021-598853291.html

<sup>5</sup> Newbold RR, Padilla-Banks E, Jefferson WN, (2009a) Environmental estrogens and obesity. Mol Cell Endocrinol, 304(1-2): 84-9.

<sup>6 16.</sup> Richter CA, Taylor, Ruhlen RL, Welshons WV, vomSaal FS, (2007) Estradiol and Bisphenol A stimulate androgen receptor and estrogen receptor gene expression in fetal mouse prostate mesenchyme cells. Environ Health Persp, 115 (6).

<sup>7</sup> Vandenberg LN, Chahoud I, Heindel JJ, Padmanabhan V, Paumgartten FJR, Schoenfelder G, (2010) Urinary, circulating, and tissue biomonitoring studies indicate widespread exposure to Bisphenol A. Environ Health Persp, 118 (8).

<sup>8</sup> Kitamura, S., Jinno, N., Suzuki, T., Sugihara, K., Ohta, S., Kuroki, H. and Fujimoto, N., (2005) Thyroid hormone- like and estrogenic Biedermann- Brem, S. and Grob, K., (2008) Release of bisphenol A from polycarbonate baby bottles: water hardness as the most relevant factor. Eur. Food Res. Technol. 228, 679–684.

<sup>9</sup> Xu, L. C., Sun, H., Chen, J. F., Bian, Q., Qian, J., Song, L. and Wang, X. R., (2005) Evaluation of androgen receptor transcriptional activities of bisphenol A, octylphenol and nonylphenol in vitro. Toxicology, 216, 197–203.

<sup>10</sup> Sun, C., Leong, L. L. and Barlow, P. J., (2006) Single laboratory validation of a method for the determination of bisphenol A, bisphenol A diglycidyl ether and its derivatives in canned foods by reversedphase liquid chromatography. J. Chromatogr. A, 1129, 145–148.

# LITERATURE REVIEW

 In 2015 The Danish Environmental Protection Agency published a study on the migration of Bisphenol- A from polycarbonate plastics of different quantities. In the study, baby bottles along with the other material that includes PC plates, PC drinking glasses, PC bowl and DVD were tested for BPA migration in its hydrothermal exposure in 14 days at 90 °C at alkaline conditions. All these samples showed the migration of BPA. The details are as follows.<sup>11</sup>

Samples	Day 1	Day 2 and 3 <sup>**</sup>	Day 4to 6**	Day 7 to 8	Day 9 to 10	Day 11 to 14
PC1	60.4	89.6	96.7	-	-	125
PC3	12.8	-	12.6	45.1	491	1916*
Drinking glass K-14-0009	16.3	12.3	-	12.7	19.4	11.9
Baby Bottles 2008-176	108	108	-	252	137	47.5
DVD	2.3	1.4	1.5	2.8	6.8	-

# Table 1 Release of BPA per day ( $\mu$ g/dm²/day) during hydrothermal exposure in 14 days at 90 °C at alkaline conditions

- For sample PC3 the BPA release was controlled by an extra measurement of BPA release of 1705  $\mu g/dm^2$  at day 15.

• For sample PC1 day 3 and 6 were day 2 and 5 respectively

A study conducted in India in **2014** at Department of Environmental Management, Bharathidasan University, Tiruchirappalli, observed BPA migration in feeding bottles collected from the Indian market. In their study three different popular brands of PC baby feeding bottles were tested and it was found that 19ng of BPA per ml of milk were leached.<sup>12</sup>According to the European Commission's Scientific Committee on Food, an infant of 4.5 kg could consume about 700 ml of milk per day<sup>13</sup> if the present BPA migration level of 19 ng/ ml exists, an infant by feeding through such PC bottle is likely to get 2.9 µg of BPA/d/kg of its body weight. It can be argued that the container may not leach the same amount of BPA every time. But there are evidences for continuous and enhanced level of BPA migration due to the effect of temperature, pH of food and age of the container.

<sup>11</sup> https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-24-7.pdf

<sup>12</sup> N. D. Shrinithivihahshini, D. Mahamuni and N. Praveen, (2014) Bisphenol A migration study in baby feeding bottles of selected brands available in the Indian market, Current Science, VOL. 106, NO. 8

<sup>13</sup> Scientific Commission on Food, Opinion of the Scientific Commission on Food on bisphenol A. SCF/CS/ PM/3936 Final. European Commission Health and Consumer Protection Directorate-General; http://ec.europa.eu/food/fs/sc/ scf/out128\_ en.pdf (accessed during June 2012)

- In 2009 Kubwaboa conducted a BPA migration study at Canada,, in which the variety of plastic containers, including polycarbonate baby bottles, non-PC baby bottles, baby bottle liners, and reusable PC drinking bottles were analyzed. Water was used to simulate migration into aqueous and acidic foods, 10% ethanol solution to simulate migration to low- and high-alcoholic foods and 50% ethanol solution to simulate migration to fatty foods. By combining solid-phase extraction, BPA derivatization and analysis by GC-EI/MS/MS, a very low detection limit at the ng per lit level was obtained. Migration of BPA at 40°C ranged from 0.11 mg per lit in water incubated for 8 h to 2.39 mg per lit in 50% ethanol incubated for 240 h. Residual BPA leaching from PC bottles increased with temperature and incubation time. In comparison with the migration observed from PC bottles, non-PC baby bottles and baby bottle liners showed only trace levels of BPA.<sup>14</sup>
- In 2008 Environmental Defence, tested plastic baby bottles in the United States and Canada, including products made by Gerber, Avent, Playtex, Evenflo, Disney and Dr. Brown, for leaching of Bisphenol A. The study observed leaching of significant levels of Bisphenol A (5-8 parts per billion) when heated. In the study, the bottles of Avent brand showed the overall highest levels of Bisphenol A, while Playtex brand bottles showed the overall lowest levels of leaching in Canadian bottles and the levels of Bisphenol- A leaching increased exponentially when the bottles were heated, with higher concentrations reported from Avent brand bottles. These findings were significant as the general use of baby bottles includes heating them and using them to store warm liquids.<sup>15</sup>
- Tan and Mustafa in 2003 investigated the possibility of the leaching of Bisphenol A from polycarbonate babies' bottles and feeding teats collected at Malaysia. Bisphenol A was extracted from water samples exposed to the bottles and teats using liquid-liquid extraction. Bisphenol A was analyzed by gas chromatography mass spectrometer with quadrupole detector in selected ion monitoring mode. Mean leaching of Bisphenol A from 100 used babies' bottles when filled with water at 25°C and 80°C were 0.71±1.65 ng/cm<sup>2</sup> (mean ±standard deviation) and 3.37±5.68 ng/cm<sup>2</sup> respectively. Mean leaching of Bisphenol A from 30 new babies' bottles when filled with water at 25°C and 80°C were 0.03±0.02 ng/cm and 0.18 ±0.30 ng/cm<sup>2</sup> respectively. Bisphenol A was observed to have leached from babies' feeding teats into 37°C water ranged from non-detectable to 22.86 ng/g.<sup>16</sup>

<sup>14</sup> C. Kubwaboa, I. Kosaraca, B. Stewarta, B.R. Gauthiera, K. Lalondea and P.J. Lalondeb. Migration of bisphenol A from plastic baby bottles, baby bottle liners and reusable polycarbonate drinking bottles. Food Additives and Contaminants Vol. 26, No. 6, June 2009, 928–937

<sup>15</sup> Environmental Defence, Toxic Nation (www.toxicsnation.ca). Toxic Baby Bottles in Canada-Bisphenol A Leaching from Popular Brands of Polycarbonate Baby Bottles. February 2008

<sup>16</sup> B. L. L. Tan, A. M.Mustafa. Leaching of Bisphenol Afrom New and Old Babies'Bottles, and New Babies'Feeding Teats. Asia-Pacific Journal of Public Health 2003

BPA can leach from polycarbonate into liquid foods because of two different processes: diffusion of residual BPA present in polycarbonate after the manufacturing process and hydrolysis of the polymer catalyzed by hydroxide (OH<sup>-</sup>) in contact with aqueous food and stimulants.<sup>17,18</sup> For dry foods diffusion is the only relevant process. Release of BPA from polycarbonate containers into food depends on the contact time, temperature, and type of food. Food stimulants are often used in release studies to represent the different types of food e.g. 50% of ethanol in water is the food stimulant for milk, and 3% of acetic acid in water is the stimulant for fruit juice.<sup>19</sup>

## **Global developments on BPA**

Today BPA has been accepted as the chemical of concern. Therefore the countries across the globe have taken concerted action to phase out BPA from products. The movement started in Europe, later the U.S. Food and Drug Administration (FDA) banned BPA in the manufacture of all baby bottles and Sippy cups.<sup>20</sup> Subsequently many countries across the globe have phased out BPA baby feeding bottles and other children products. In India, according to Bureau of Indian Standards (BIS)<sup>21</sup>, the materials used for plastics feeding bottles and accessories excluding teats should be of no health hazards to babies and shall not contain Bisphenol A (BPA). The other global regulations are presented in table no. 3.

#### Table 2: Tolerable daily intake (TDI) limits for BPA in some countries

Country/Organization	TDI (µg∕kg w∕day)
European Food Safety Authority (EFSA)	4
Australia	50
Chinese	50
Korean Food Safety Authority	50
India	No standards

#### Table 3: Global and national regulation of BPA in baby feeding bottles

Country	Regulation of BPA in baby feeding bottles
Canada	The first country to ban the import, sale, and advertisement of baby bottles containing BPA
USA	Banned
European Union	Banned the use of Bisphenol-A (BPA).

<sup>17</sup> Ehlert K.A., Beumer C.W.E., Groot M.C.E., 2008. Migration of bisphenol A into water from polycarbonate baby bottles during microwave heating. Food Additives and Contaminants 25(7) 904–910.

<sup>18</sup> Mercea P, 2009. Physicochemical processes involved in migration of bisphenol A from polycarbonate. Journal of Applied Polymer Science 112 579–593.

<sup>19</sup> http://publications.jrc.ec.europa.eu/repository/bitstream/JRC58897/eur%2024389\_bpa%20%20baby%20bottles\_chall%20 %20persp%20%282%29.pdf

<sup>20</sup> https://www.babycenter.com/0\_are-plastic-baby-bottles-safe\_14387.bc

<sup>21</sup> Bureau of Indian Standards; PLASTICS FEEDING BOTTLES (First Revision) BIS 2015

Country	Regulation of BPA in baby feeding bottles
Australia	The Australian Govt. has introduced a voluntary phase-out of BPA use in baby feeding bottles. Australia and New Zealand Food Safety Authority (Food Standards Australia New Zealand) suggest the use of glass baby bottles.
Japan	Voluntary phase out by the industries
France	Banned
Germany	Banned
Denmark	Banned
Belgium	Banned
China	Banned
Malaysia	Banned
South Africa	Banned
Turkey	Banned
India	Restricted

## Table 4 -Global Regulations of BPA in Sippy Cups<sup>22</sup>

Country	Regulation No.	Limit	Effective Date
FDA, US	21 CFR 177.1580	Prohibited	July 12, 2012
Canada	Order Amending Schedule 1 to the Hazardous Products Act (bisphenol A)	Prohibited	March 31, 2010
European Union	EU No. 321/2011	Prohibited	May 1, 2011
Denmark	Danish Veterinary & Food Admin- istration	Prohibited	July 1, 2010
France	Act 2010-729	Prohibited	June 30, 2010
Argentina	Regulation 1207/2012	Prohibited	April 3, 2012
Brazil	Resolution No. 41 of September 16, 2011	Prohibited	January 1, 2012
Ecuador	Resolution 29 of October 31, 2011	Prohibited	Oct, 2011
China		Phased out	-
Japan		Voluntary phased out	-
Australia		Voluntary phased out	-
India	With regards to standard on Baby Sippy Cups, it is informed that IS 14625, in line with the definition of feeding bottles given in the IMS act. The proposed definition of feeding bottle in the IMS act is as follows; "any bottle or receptacle used for the purpose of feeding infant milk substitutes through a teat or drinking accessory attached or capable of being attached to such bottle or receptacle." (This is in draft stage)		

<sup>22</sup> http://www.mts-global.com/en/news\_details.html?id=122

# RATIONALE OF THE STUDY

Toxics Link undertook the first study in India on the presence of BPA in baby feeding bottles and found high presence of BPA in the samples tested. Subsequently Bureau of Indian Standard (BIS) revised the standard for baby feeding bottles in 2015 as per IS 14625:2015. and prohibited the use of BPA in baby feeding bottles. Further in consequence to the study report of BPA in other children product "Sippy cups" the Ministry of child Welfare as per the section no. 4.1 of IS 14625:2015, has clearly mentioned that, "the material used for plastic feeding bottles and accessories excluding teats shall be of polypropylene conforming to IS 10910 or polyethersulfone (PES) or any other olefin based polymer, Co-polyester material or other raw material as given in Annex II for manufacture of plastic feeding bottle. **The materials used should be of no health hazards to babies and shall not contain Bisphenol A (BPA)**." Besides this, it was also suggested by the concerned ministry to phase out BPA from cup, spout, and straw with the possible amendment into the definition of feeding bottle in the Infant Milk Substitutes (IMS) act.

In this context to see the compliance of the rule, the present study was undertaken with the following objectives;

## **Objectives of the study**

To analyze the impact of BIS regulation to prohibit the use of Bisphenol-A (BPA) in baby feeding bottles and Sippy cups sold in the Indian market To assess the possibility of leaching of BPA form the feeding bottles and Sippy cups To find the truth to the claim of "BPA free" baby feeding bottles being sold in the market

# SAMPLING AND ANALYSIS

## Sampling

A set of twenty samples of baby feeding bottles and Sippy cups (14 nos. and 6 nos. respectively) were randomly collected from Gujarat, Rajasthan, Kerala, Andhra Pradesh, Jharkhand, Maharashtra, Manipur and Delhi.

The collected samples include both branded and local feeding bottles and sippy cups of different brands. Seven samples were made with polypropylene (produced between 2017 and 2018), three samples were made with polycarbonate (produced between 2013 and 2017) and other ten samples had no information mentioned. Seven baby feeding bottles and three sippy cups were labeled 'BPA free' or 0% BPA.

The samples were then sent to the Indian Institute of Technolgy Guwahati for the analysis of migration/leaching of BPA from feeding bottles and sippy cups.



# Procedure for the analysis of BPA migration in baby feeding bottles and sippy cups

- Initially, the baby feeding bottles were rinsed with hot water to remove the attached solids particles and bacteria.
- Milli-Q water was taken in a 1L borosilicate beaker and heated to 90°C using thermostatically controlled mantle.
- Next, 200 mL of hot water was transferred into the different brands of baby bottles and was made to stand for 1 h.
- → After 1 h, the water was transferred into a 250 mL separating funnel, to which 20 mL of 99% ethyl acetate was added; the contents were swirled gently for 30 seconds and finally left undisturbed for the formation of clear and distinct organic and aqueous layers.
- The organic phase was collected in a glass test tube and the aqueous phase was drained out into a beaker for the second and third-time extractions, each with 20 mL of ethyl acetate.
- The collective 60 mL of the organic phase (ethyl acetate extract) was evaporated to dryness at 60°C using a water bath. The dried residue was dissolved in 1 mL of acetonitrile and then filtered through 0.2 μm syringe filter using a glass syringe.
- The filtered extracts were transferred into 5 mL amber-colored glass vials and stored at 4°C for further analyses.
- For compound identification through HPLC, BPA stock solution was prepared by dissolving 1 mg of analytical grade BPA in 1 mL of acetonitrile. From this, 5, 10, 15, 25, 50 and 100 ng/mL of external standards were prepared.
- Both the external standards and the unknown samples were tested in the HPLC System, equipped with C18 analytical column and UV photo diode array (PDA) detector.
- ➔ Acetonitrile-water was used as mobile phase at a flow rate of 1 mL/min.
- ➔ The elution was achieved through isocratic mode at 80:20 (acetonitrile/water; v/v).
- $\rightarrow$  The injected sample volume was 20 µL.

# RESULTS AND DISCUSSION

In the present study, two different types of bottles ' baby feeding bottles and sippy cups were purchased for the assessment of Bisphenol A migration. A total of 20 samples were collected and analyzed from eight states of India. Eight out of 20 samples were made up of polypropylene (PP), three were made up of polycarbonate (PC) and the other samples were not labeled for the type of plastic.

It is important to note that, the baby feeding bottles with polycarbonate are still available (mfg date 11/2015 and 03/2017) in the market even though it was clearly mentioned that, "the material used for plastics feeding bottles and accessories excluding teats shall be of polypropylene conforming to IS 10910 or polyethersulfone (PES) or any other olefin based polymer, Co-polyester material or other raw material as given in Annex II for manufacture of plastic feeding bottle. as per the section no. 4.1 of IS 14625:2015.

The migration was analyzed two times (1<sup>st</sup> extraction and 2<sup>nd</sup>extraction) (fig. 2) its detailed results are presented in the table no. 3 and 4. From the results, it was observed that all 20 samples (made up of PP and PC) showed various levels of Bisphenol A migration in the first and second extraction experiment. Only one sample of baby feeding bottles showed no level of Bisphenol A migration in its second extraction, the same sample showed the lowest concentration in the first extraction. The results suggested that there may be chance of having more total Bisphenol A in the containers. In the earlier studies the total Bisphenol level in baby feeding bottle was detected between 0.1 and 98.4 ppm (Table 6, Annexure II)<sup>23</sup> while in sippy cups it was detected between below detectable level to 14.9 ppm. (Table 7, Annexure II).<sup>24</sup>

## **BPA migration in baby feeding bottles**

- The bottles made from polypropylene also showed the presence of Bisphenol- A
- In first extraction, the maximum Bisphenol A migration concentration was 10.5 ppb and for second extraction it was 3.25 ppb. This sample was purchased from Gujarat
- In first extraction the minimum Bisphenol A migration concentration was 0.9 ppb and for second extraction, it was not detected. This sample was purchased from Kerala
- In second extraction, the maximum BPA migration concentration was 3.46 ppb of another sample which showed 9.4 ppb in its first extraction This sample was purchased from Delhi

<sup>23</sup> http://toxicslink.org/docs/BPA-study-report.pdf

<sup>24</sup> http://toxicslink.org/docs/BPA-Sippy-Cups-2016.pdf

## **BPA migration in sippy cups**

- In first extraction, the Bisphenol A migration concentration was varied between 1.3 ppb and 5.5 ppb. These samples were purchased from Delhi
- In second extraction, the maximum Bisphenol A migration concentration was 2.1 but two samples did not observe the migration. These samples were purchased from Delhi

#### Table 5: Details of BPA migration in first and second extraction in baby feeding bottles

SN Code		Sampling Location	Sample Type	Material (PC/ PP)/Mfg dt.	BPA free mark/ISI	BPA migration (in ng/mL or ppb)	
					Mark	1 <sup>st</sup> extraction	2 <sup>nd</sup> extraction
1	TLFB-1	Gujarat	Feeding Bottle	PP 5/1-2018	Yes/Yes	10.5 ppb	3.25 ppb
2	TLFB-2	Rajasthan	Feeding Bottle	PC 7/11-2015	No/Yes	5.7 ppb	2.77 ppb
3	TLFB-3	Rajasthan	Feeding Bottle	No/No	No/No	4 ppb	2.85 ppb
4	TLFB-4	Kerala	Feeding Bottle	PP 5/12-2017	Yes/Yes	0.9 ppb	ND
5	TLFB-5	Kerala	Feeding Bottle	PP 5/12-2017	Yes/Yes	3.8 ppb	1.24 ppb
6	TLFB-6	Andhra Pradesh	Feeding Bottle	PP 5/06-2017	Yes/Yes	3.1 ppb	1.13 ppb
7	TLFB-7	Andhra Pradesh	Feeding Bottle	PP 5/02-2018	No/Yes	4.8 ppb	2.11 ppb
8	TLFB-8	Andhra Pradesh	Feeding Bottle	PC 7/03-2017	No/No	5.7 ppb	1.54 ppb
9	TLFB-9	Jharkhand	Feeding Bottle	No/No	No/No	4.3 ppb	1.1 ppb
10	TLFB-10	Maharashtra	Feeding Bottle	PP 5/6-2016	Yes/Yes	4.8 ppb	1.9 ppb
11	TLFB-11	Manipur	Feeding Bottle	-	-	1.8 ppb	0.008 ppb
12	TLFB-13	Delhi	Feeding Bottle	PC 7/7-2013	No/Yes	9.4 ppb	3.46 ppb
13	TLFB-14	Delhi	Feeding Bottle	PP 5/10-2017	Yes/Yes	3.2 ppb	1.87 ppb
14	TLFB-15	Delhi	Feeding Bottle	PP 5/12-2017	Yes/Yes	3.6 ppb	0.71 ppb

SN	Code	Sampling Location	Sample Type	Material (PC/PP)/	BPA free mark/ISI	BPA migration (in ng/mL or pj	ob)
	Mfg dt.	Mark	1st extraction	2nd extraction			
15	TLSC-16	Delhi	Sipper	No	Yes/No	5.5	2.1
16	TLSC-12	Manipur	Sipper	-	-	3.2	1.73
17	TLSC-17	Delhi	Sipper	No	Yes/No	1.6	ND
18	TLSC-18	Delhi	Sipper	No/2017	Yes/No	2.1	0.91
19	TLSC-19	Delhi	Sipper*	No	No/No	1.3	ND
20	TLSC-20	Delhi	Sipper#	No	No/No	1.8	0.62

#### Table 6 Details of BPA migration in first and second extraction in sippy cups

#### Figure 2: Highest to lowest BPA migration (first and second extraction) in ppb



■ 1st Extraction ■ 2nd Extraction

# CONCLUSION AND RECOMMENDATION

The use and the presence of Bisphenol A in different products could be harmful to human and environmental health. The products specifically meant for children could be more impactful for them. The studies have confirmed that BPA even in low dose leads to disruptive effect and affects the immune system, the thyroid, and the developing nervous system.

As per the current BIS regulations, the use of BPA is prohibited but the current study observed the migration of BPA in baby feeding bottle samples. Earlier the baby feeding bottles, sippy cups were manufactured with polycarbonate in which BPA was the main constituent (BPA is the building block for polycarbonate), however after the prohibition of BPA from the baby feeding bottles, it is quite surprising that the traces of BPA is still being found in the bottles. Similarly, the traces of BPA are also detected in the sippy cups, hence it raises questions on the material being used in baby feeding bottles and sippy cups.

Therefore in the context of the present study, following actions can be initiated so that the BPA can be phased out completely from the baby bottles and children products.

- 1. **Monitoring**: It is very important that suitable mechanism should be in place to monitor the products periodically. The concerned agencies should also test the samples and publish the report in the public domain so that consumers can make an informed choice on the use of the baby feeding bottles and sippy cups.
- 2. Actions to phase out BPA: BPA is a chemical widely known for its EDC properties, so proper action should be mooted to phase out the chemical not only from the children's products but also from the other products including the Sippy cups.
- **3.** Awareness generation among the consumers: Awareness generation is the key drive for the change. Though during the study, we found that some level of awareness is there among the consumers in the cities, the consumers from the rural and semi-urban areas should also be informed about the issue so that they can get the safe products.
- 4. **Penal provisions:** The Government should carry forward their own research and moot for penal action for violation of the standards. It will act as a deterrent and the manufacturers will be cautious on their products while selling them in the market.
- **5. Role of the industries:** The role of the industries are very crucial and they need to come forward as its a children health issue and they should take appropriate precautions to prevent the contamination of BPA in the whole supply chain. The manufacturers need to stop the production of polycarbonated baby feeding bottles as it is prohibited as per the Indian standards.

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# Table 7: Total BPA concentration in baby<br/>feeding bottles (2014)

Samples	Concentration of BPA (PPM)
TLS-1	0.1
TLS-2	3.8
TLS-3	0.1
TLS-4	9.4
TLS-5	0.1
TLS-6	0.98
TLS-7	0.88
TLS-8	0.7
TLS-9	0.22
TLS-10	2.44
TLS-11	0.86
TLS-12	0.54
TLS-13	0.44
TLS-14	2.98

# Table 8: Total BPA concentration in sippy cups (2016)

Samples	Instructions	Results in ppm
TL-02	No instructions	ND
TL-03	No instructions	ND
TL-04	BPA free	ND
TL-05	No instructions	0.3
TL-22	No instructions	1.3
TL-23	0% BPA	14.9
TL-24	BPA free	0.05
TL-25	0% BPA	1.4
TL-26	No instructions	6.3
TL-27	No instructions	1.5
TL-28	BPA free	1.6
TL-29	BPA/Phthalate/ PVC free	2.0
TL-30	No information	9.3

# **ANNEXURE II**

(Clause 4.1)

## LIST OF MATERIAL FOR MANUFACTURE OF PLASTIC FEEDING BOTTLES (Based on Malaysian

Standard, MS 735 and US FDA Regulations)

(1)(i) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

### 21 CFR 177.1520

- (a)(3)(i) Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of: (i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:
- (a)(1) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;
- (2) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 shall contain not less than 80 but not more than 90 weight percent of polymer units derived from ethylene.
- (3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.
- (4) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.
- (b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;
- (c)(1) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4- trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;
- (2) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and butene-1 shall contain greater than 15 but not greater than 35 weight percent of polymer units derived from butene-1 with the remainder being propylene.

- (d) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.
- (e) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1, or ethylene, octene-1, and either hexene-1, butene-1, propylene, or 4- methylpentene-1 shall contain not less than 80 weight percent of polymer units derived from ethylene.
- 21 CFR 177.1520 (b)
- (b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

ltem (1)	Olefin polymers (2)	Density (3)	Melting Point (MP) or softening point (SP) in °C (4)	Maximum extractable fraction (expressed as percent by weight of the polymer) in n- hexane at specified temperatures (5)	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures (6)
1.1a	Polypropylene described in paragraph (a)(1)(i) of this section	0.880 - 0.913	MP: 160- 180°C	6.4 percent at reflux temperature	9.8 percent at 25°C
3.1a	Olefin copolymers described in paragraph (a)(3) (i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking; except olefin copolymers	0.85 - 1.00		5.5 percent at 50°C	30 percent at 25°C described in paragraph (a) (3)(i)(a)(3) of this section and listed in item 3.1c of this table and olefin copolymers described in paragraph (a)(3)(i) (e) of this section and listed in item 3.1b of this table

## 21 CFR 177.1520 (c) Specifications



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