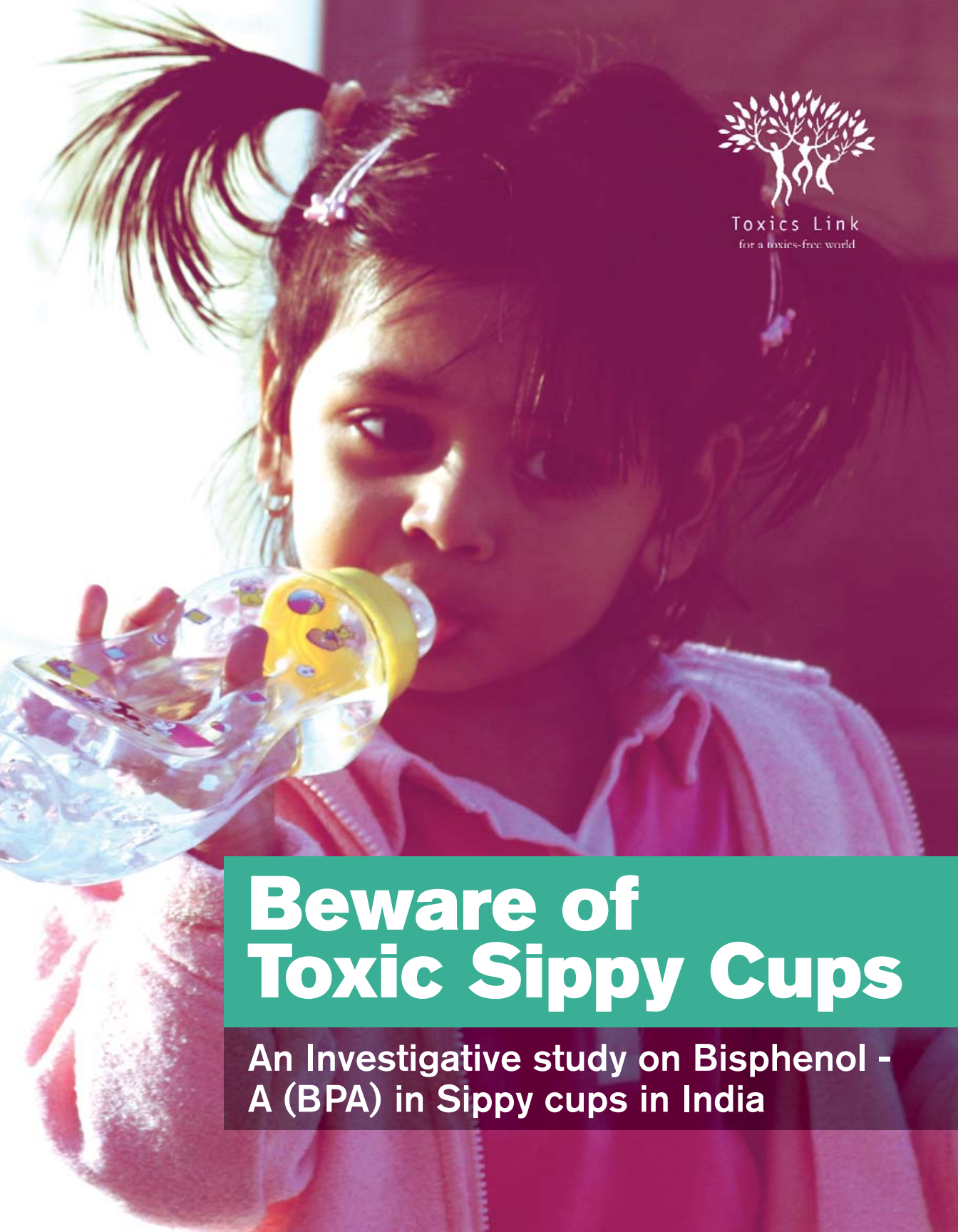

Toxics Link
for a toxics-free world

Beware of Toxic Sippy Cups

An Investigative study on Bisphenol - A (BPA) in Sippy cups in India

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 toxics 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 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 afore mentioned areas apart from creating awareness among several stakeholder groups.

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Beware of Toxic Sippy Cups

An Investigative study on Bisphenol - A (BPA) in Sippy cups in India

BACKGROUND

Bisphenol- A (BPA) is a known Endocrine Disrupting Chemical (EDC) and children are most susceptible to the health impacts of BPA. Globally, countries are taking action to phase out BPA from children products. Toxics Link has initiated work on EDC and is pushing for phase out of BPA in children products. In 2014, Toxics Link did a study and found high content of BPA in baby feeding bottles. The study also revealed that BPA was detected in some of the feeding bottles that were labeled as BPA free.

Likewise, another baby product, sippy cups has a growing market in India. The presence of BPA is a concern in these products considering its adverse impacts on children's health. Therefore, the present study was carried out with a view to get an understanding on the use of BPA in sippy cups, which is unregulated in India. Though the use of BPA has been restricted in the baby feeding bottles there is an urgent need to phase out BPA from other children products.

Acknowledgement

We take this opportunity to thank all those who were instrumental in shaping of this report.

Our sincere thanks to 'Shri Ram Institute for Industrial Research', University Road, Delhi for its support in sample analysis.

We express our sincere thanks to Swedish Society for Nature Conservation (SSNC) for their support towards this study.

We would also like to thank our fellow colleagues at Toxics Link who were equally helpful. Their comments and suggestions have been critical in understanding the issue.

Abbreviations

ASTM	American Society for Testing & Materials
BIS	Bureau of Indian Standards
BPA	Bisphenol A
EFSA	European Food Safety Authority
ER	Epoxy Resins
FDA	Food and Drug Administration
GC-MS	Gas Chromatography Mass Spectrometry Analysis
IMS	Infant Milk Substitutes
IS	Internal Standards
PC	Polycarbonate
ppm	parts per million
PVC	Polyvinyl Chloride
TCA	Tricarboxylic Acid Cycle
TDI	Tolerable Daily Intake

Contents

Foreword

Chemicals are part of our everyday life and the use of them continues to grow. While some of the chemicals have contributed to improve the quality of life, but also some of them are now being recognized as toxics posing serious human health concerns.

Some of these chemicals are today classified or termed as Endocrine Disrupting Chemicals as they interfere with body's endocrine system affecting its developmental, reproductive, neurological and immune system in a human body that leads to serious impacts on human health. These chemicals can be part of many house hold products such as plastics, packaging materials, textiles, metal cans, detergents, food etc.

While the use of such chemicals continues to grow, yet there is very little information in public domain especially in developing countries. Hence there is no conversation and discussion among consumers, industry and the government making citizens vulnerable to exposure from such chemicals. Bisphenol A (BPA) is one such EDC found in Polycarbonate plastics which is used in the manufacturing of sippy cups that are used by children to inculcate in them the habit of drinking beverage through cups. Currently, the market is flooded with such cups without adequate information on the use of BPA in them and their health effects on children.

The current report on BPA in sippy cups is perhaps first of its kind study on use of BPA in sippy cups and a serious attempt to understand the uses of such endocrine disrupting chemicals in children's products. Though the sample size of the study is small, but it does indicate the use of BPA in children's product and extremely misleading information about it to consumers. It is expected that release of this report will initiate dialogue at multiple levels and create interest among stakeholders to engage with complexities of EDC and its use in children's product.

Satish Sinha
Associate Director

The surface lining of the food containers accounted for about 50% of all Epoxy Resins (ER) consumption.

1. Introduction

1.1 About Bisphenol-A (BPA)

Bisphenol A (BPA) or 2,4-isopropylidenediphenol is a carbon-based synthetic compound with chemical formula $(CH_3)_2C(C_6H_4OH)_2$ belonging to the group of diphenylmethane derivatives and Bisphenols.[1] BPA was first synthesized in 1881 and is primarily used as a monomer for the manufacture of polycarbonates.[2]

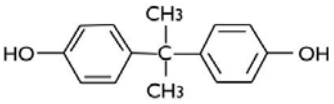


Figure 1 Chemical structure of Bisphenol A

At present two kinds of BPA based plastics are available in the market: one is **Polycarbonate (PC)** and the other one is **Epoxy Resins (ERs)**. Polycarbonates are generally used in baby feeding bottles, dental sealant, tooth coatings, carbonless paper and plastic toys.

Polycarbonates are generally used in baby **feeding bottles, dental sealant, tooth coatings, carbonless paper** and **plastic toys.**

Epoxy Resins are used as protective coatings for food and beverage container, bonding & adhesives, flooring, paving & construction, composites, electrical & electronic laminates, embedding & tooling, vinyl ester resins and other. The surface lining of the food containers accounted for about 50% of all ER consumption.

1.2 Sippy Cups and its usages

Sippy cups are generally called training cups made usually of plastic. It consists of a screw or a snap-on-lid and a spout that helps a child drink without spilling. These cups are helpful for the babies by enabling them to develop an easy transition from baby feeding bottles to a regular cup.[1] These also help to improve their hand to mouth coordination. Sippy cups can be used for drinking variety of liquids like water, juices or any other beverage. This cup an also be used to feed baby with milk.[2] The products are being marketed in India with the punch line **"Teach Your Child to Drink from Smart Sippy Cups"** as soon as possible.

1 http://www.menmomhealth.com/choose-sipper-sippy-cup-baby/
2 http://www.babycenter.com/0_sippy-cup-dos-and-donts_1439508.bc

2. Literature Review on Health Impacts of BPA

2.1 Bisphenol-A and Children Health

Bisphenol-A (BPA) is a well known Endocrine Disprupting Chemical and can impact human health. Research studies have found that children are most susceptible to the impact of BPA. Even the studies have claimed that low doses of BPA can be harmful to children's health.[3] Therefore, as a precautionary principle many countries across the globe have taken initiatives to phase out BPA from children's products.

A recent report in April 2014 published by Institute of Functional Genomics of Lyon, France & Deakin University Metabolic Research Unit, Australia, on harmful effect of BPA on unborn babies & infants, discovered a new pathway for BPA to spread through the body via a protein known as ERRγ (Oestrogen-Related Receptor). Researchers found that ERRγ was 1000 times more sensitive to BPA than oestrogen receptors. It also played an important role in metabolism and added weight possibility that BPA could be a cause of obesity and diabetes.

Research studies have found that **children are most susceptible to the impact of BPA.**

2.2 Research Studies on BPA

A recent experiment (2015) on BPA leaching from plastics indicates that plastic boiled water attenuates the protective cardiorespiratory reflexes and also produces histopathological changes in the lungs of rats.[4]

A research (2014) done by N. D. Shrinithivihahshini, in his Bisphenol A migration study in baby feeding bottles of selected brands available in the Indian market concluded that, the polycarbonate(PC) baby feeding bottles available in Indian market are likely to leach around 19 ng of BPA ml^{-1} of milk. According to the European commission's Scientific Committee on Food, an infant of 4.5 kg could consume about

3 http://www.medicalnewstoday.com/articles/221205.php

4 Toxic Chemical from Plastics Attenuates Phenylbiguanide-induced Cardio-respiratory Reflexes in Anaesthetized Rats Jayanti Pant, Mahendra K. Pant, Shikha Chouhan, Surya P. Singh and Shripad B. Deshpande, (2015) Indian J Physiol Pharmacol.;59(2):204-10.

700 ml of milk per day[5]; if the present BPA migration level of 19 ng ml^{-1} exists, an infant by feeding through such PC bottle is likely to get 2.9 µg of BPA d^{-1} kg^{-1} 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 continued and enhanced level of BPA migration due to the effect of temperature, pH of food and age of the container. In addition, the recommended TDI of BPA kg^{-1} of body weight has been recently revised to 5 µg[6] from the previous value of 50 µg. The recent change made by EFSA on TDI value of BPA outlines the increased risk of BPA on human health.[7] Hence a detailed study based on different parameters is recommended.

Another study (2014) on BPA and male rat fertility concluded that toxicity on the reproductive organ of adult male rats was induced by oral administration of Bisphenol A (200mg/kg body weight) dissolved in corn oil (1 ml) for 30 days. There was a remarkable alteration in levels of reproductive hormones, marker enzymes, ATPases and TCA cycle enzymes due to BPA-induced toxicity mediated by oxidative stress. Captivatingly, introduction of lycopene (10 mg/kg body weight given for 30 days orally) to BPA intoxicated group III rats, brought the biochemical modifications back to normal level. This result puts forward that lycopene has an outstanding potential in the reduction of testicular damage.[8]

An infant of 4.5 kg could consume about **700 ml of milk per day**

A research study (2012) on Bisphenol A in dental sealants and its estrogen like effect indicated that during the manufacturing process of Bis-GMA dental sealants, Bisphenol A (BPA) might be present as an impurity or as a degradation product of Bis-DMA through esterases present in saliva. Leaching of these monomers from resins can occur during the initial setting period and in conjunction with fluid sorption and desorption over time and this chemical leach from dental sealants may be bioactive. Researchers found an estrogenic effect with BPA, Bis-DMA, and Bis-GMA because BPA lacks structural specificity as a natural ligand to the estrogen receptor. There is a considerable concern regarding the safety of dental resin materials.[9]

5 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).
6 EFSA, Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food on a request from the commission related to 2,2-bis(4-hydroxyphenyl)propane (bisphenol A). Question No. EFSA-Q-2005-100. Adopted on 29 November 2006. EFSA J., 2006, 428, 1–75.
7 http://www.currentscience.ac.in/Volumes/106/08/1081.pdf
8 http://www.pubs.iscience.in/journal/index.php/jbts/article/view/248
9 Rathee M, Malik P, Singh J. Bisphenol A in dental sealants and its estrogen like effect. Indian J Endocr Metab 2012;16:339-42

The Bureau of Indian Standrad (BIS) has revised the standard for baby feeding bottle in 2015 and the notification has stated that BPA will not be used in baby feeding bottles.

3. Rationale of the Study

In India, feeding bottles are regulated by the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003 (IMS Act). The act mandates that all the baby feeding bottles to be sold in India will be subjected to standard IS-14625 specified by the Bureau of Indian Standards (BIS). The Bureau of Indian Standrad (BIS) has revised the standard for baby feeding bottles in 2015 and the notification has stated that BPA will not be used in baby feeding bottles.

Though there is a regulation for baby feeding bottles in India, however sippy cups which are meant for children use are not being regulated in India, in spite of the growing market of sippy cups. Nevertheless the sippy cups have multiple uses, including drinking milk by children.

Many countries have globally phased out BPA from sippy cups along with baby feeding bottles. Incidentally, some of the samples collected for testing have been labeled as BPA free (0% BPA). This is an indication that manufacturers are well aware of the implications of BPA on children's health and BPA free warning is helping them to attract consumers.

Table 1 Global Regulations of BPA in Sippy Cups[10]

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 Administration	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	**No Regulation**	**No Regulation**	

10 http://www.mts-global.com/en/technical_update/CPIE-018-13.html

4. Objectives

The present study has been aimed with the following objectives:

To highlight the urgent need for regulation of sippy cups in India

To find truth to the claim of "BPA free" for sippy cups being sold in India

To detect the presence of Bisphenol-A (BPA) in sippy cups sold in Indian market

5. Sampling & Methodology

5.1 Sampling

In this study, total thirteen (13) samples of sippy cups were collected randomly from different markets of New Delhi. The samples collected include both known and local brands of different companies. Out of thirteen samples, six samples have been labeled as durable, safe, non toxics, 0% BPA or Safe for baby. These samples have been manufactured during Jan 2015 -June 2015 and the cost of the samples vary between INR 55-599/- per sample. All the samples were collected in duplicate and sent to Shriram Institute for Industrial Research (an accredited laboratory) based in New Delhi for quantitative analysis of BPA.

5.2 Methodology[11]

Quantitative analysis of Bisphenol-A was performed as per the guidelines of the American Society for Testing & Materials (ASTM)-D7065-11using GC-MS.

5.3 Scope

This test method covers determination of Bisphenol-A (BPA) using gas chromatography and detected with mass selective detection.

5.4 Standard preparation

- Prepare stock solution by adding 8µl BPA (40,000 µg/ml) to 10ml of methylene chloride
- Aliquots of stock are diluted with methylene chloride to prepare the calibration level of 2,4,8,16,32 ng/l. A 0.50 mL aliquot of each diluted standard is transferred to a 2 mL crimp-top GC Autosampler vial and 6.25 µL of a 2000 ng/µL
- The Internal Standard solution is added. The internal standards (IS) to be used are acenaphthene-d10 and phenanthrene-d10. To obtain a working internal standard at a concentration of 2000 µg/ml, 1.0 ml of internal standard stock solution at 4000 µg/ml is diluted to 2 ml in methylene chloride

11 "Bottles can be Toxics" – An Investigation study on Bisphenol-A (BPA) in Baby Feeding Bottels in India, Toxics Link Study -2015

5.5 Sample preparation

- To the 2-L separatory funnel is added 1 L of sample followed by the BPA standard
- The pH is then adjusted to 2 using sulphuric acid and shaken
- The sample is extracted three times with 60 ml portions of methylene chloride
- The three 60 ml methylene chloride extracts are combined in an Erlenmeyer flask
- The water sample is then drained from the extractor and another 60 ml portion of methylene chloride is added to the separatory funnel to rinse any target analytes adhered to the surface of the glassware. This rinse is added to the extract in the Erlenmeyer flask and dried with anhydrous sodium sulphate
- The extracts are then reduced to 0.5 ml and placed in 2 ml crimp top GC vials. 6.25 µL of a 2000 ng/µl Internal Standard solution is added to vial and the vial is sealed

5.6 Calculations

The detection limit is 0.05 ppm

$$\text{Cong. } \mu g/L = \frac{(A^x)\,(I^s)\,(V^t)\,(D^f)}{(A^{is})\,(ARF)\,(V^o)\,(V^i)}$$

Where:

A^x = area of the characteristic ion for the compound to be measured,
A^{is} = area of the characteristic ion for the internal standard,
I^s = amount of internal standard injected in nanograms (ng),
V^o = volume of water extracted in milliliters (ml),
V^i = volume of extract injected in microliters (µl),
V^t = volume of the concentrated extract in microliters (µl),
D^f = dilution factor

6. Results And Discussion

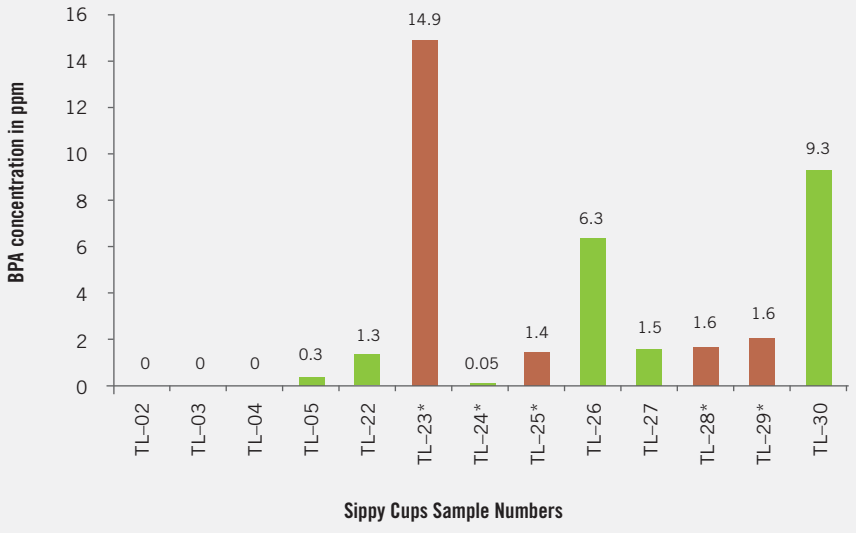
The study results for sippy cup samples (Table 2) clearly indicate that most of the sippy cups available in Delhi market contain high level of Bisphenol-A. Trace of BPA has been detected in ten samples out of the thirteen samples tested. Ironically BPA was also found in some samples which were mentioned safe, non-toxic for children (0% BPA).

- Out of the thirteen samples analysed, 77% samples contain BPA
- The maximum concentration of BPA in sippy cup was found to be 14.9 ppm (it is mentioned as **0% BPA** on the product)
- Out of six samples those have been labeled as BPA free, BPA has been detected in five samples
- BPA also detected in two samples labeled as 0% BPA
- No correlation eastablished beween the price of the cups and BPA concentration

Table 2 Concentration of BPA in sippy cups

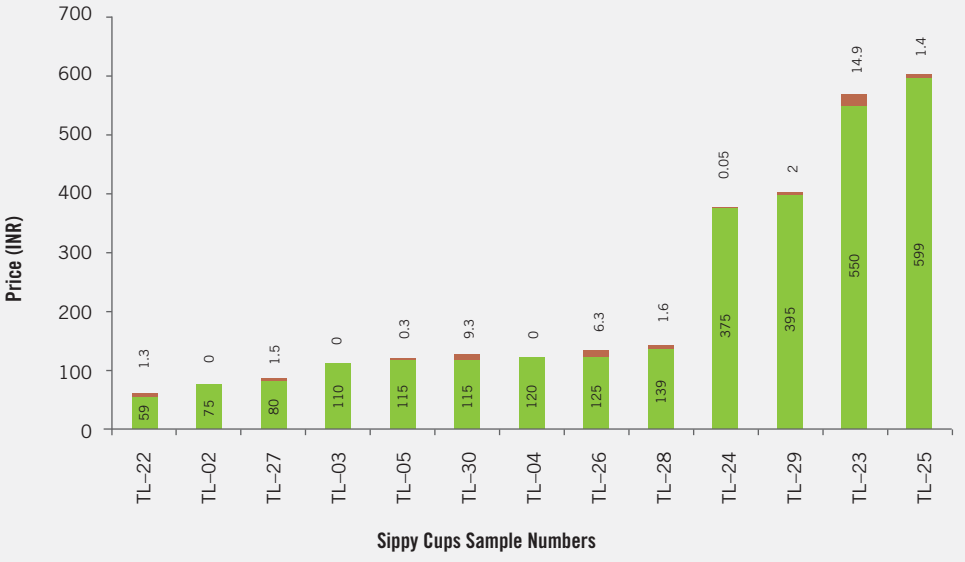
SN	Sample No	Sample Type	Instructions	Results in ppm
1	TL - 02	Sippy Cups	No Instructions	Not Detected
2	TL - 03	Sippy Cups	No Instructions	Not Detected
3	TL - 04	Sippy Cups	BPA Free	Not Detected
4	TL - 05	Sippy Cups	No Instructions	0.3
5	TL - 22	Sippy Cups	No Instructions	1.3
6	TL - 23	Sippy Cups	0% BPA	14.9
7	TL - 24	Sippy Cups	BPA Free	0.05
8	TL - 25	Sippy Cups	0% BPA	1.4
9	TL - 26	Sippy Cups	No Instructions	6.3
10	TL - 27	Sippy Cups	No Instructions	1.5
11	TL - 28	Sippy Cups	BPA Free	1.6
12	TL - 29	Sippy Cups	BPA/Phthalate/PVC Free	2.0
13	TL - 30	Sippy Cups	No Information	9.3

Figure 2 **Varied levels of BPA in sippy cups***



*(*Brown marked bars indicated that the instruction like "0% BPA" was written on the samples)*

Figure 3 **Price (INR) of the sample vs BPA concentration in ppm**



7. CONCLUSION

This study is an indication that BPA toxic chemical is being extensively used in sippy cups irrespective of the price at which the products are being sold in the market. The sippy cups claiming to be BPA free are being sold at relatively higher price. In one of these samples, concentration of BPA was found to be 14.9 ppm.

- Out of thirteen samples collected, only six samples were labeled as BPA free.
- Five of these samples were found to be containing BPA and only one sample was tested to be BPA free.

Hence claims made by brands as BPA free is misleading and do not appear to be correct

RECOMMENDATIONS

Standard for BPA: Sippy cups are widely used by children for feeding milk or any other beverage. BPA in sippy cups can be a potential source for food contamination and hence there is a need to regulate its standards as prescribed for the baby feeding bottles under the ambit of Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992. Only the IS mark sippy cups should be permitted for the sale in the market.

Monitoring: The study results of some samples have exposed the false claim of manufacturers that their products are BPA free. So a strong or robust monitoring system needs to be in place to prevent the sale of any non-standard products by manufacturers.

Creating Awareness: The study indicates that there is a consumer demand for BPA free products and such products are available in the market. Consumers should be made aware about the benefits of BPA free products. Manufacturers, consumer organizations and the government should create more awareness on BPA free products.

Research Agenda: There is a need to generate more data on BPA in consumer products and its impact on human health. The government should encourage and support such research projects on BPA and its use in consumer products

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11. “Bottles can be Toxics” – An Investigation study on Bisphenol-A (BPA) in Baby Feeding Bottels in India, Toxics Link Study -2015

Annexure I

Sample (Sippy cups) Details

Sample No	Sample Type	Instructions	Date of Manufacture	Price (INR)
TL - 02	Sippy Cups	No Instructions	Jun-15	75.00
TL - 03	Sippy Cups	No Instructions	Apr-15	110.00
TL - 04	Sippy Cups	BPA Free	Sep-15	120.00
TL - 05	Sippy Cups	No Instructions	May-15	115.00
TL - 22	Sippy Cups	No Instructions	May-15	59.00
TL - 23	Sippy Cups	0% BPA	May-15	550.00
TL - 24	Sippy Cups	BPA Free	Jan-15	375.00
TL - 25	Sippy Cups	0% BPA	Jan-15	599.00
TL - 26	Sippy Cups	No Instructions	May-15	125.00
TL - 27	Sippy Cups	No Instructions	Mar-15	80.00
TL - 28	Sippy Cups	BPA Free	May-15	139.00
TL - 29	Sippy Cups	BPA/Phthalate/PVC Free	Jan-15	395.00
TL - 30	Sippy Cups	No Information	No Information	115.00

Annexure II

Tolerable Daily Intake (TDI)

Country/Organization	TDI (µg/kg bw/day)
European Food Safety Authority (EFSA)	50 (soon to be 5.0 µg)
US (FDA)	50
Australia	50
China	50
Korean Food Safety Authority	50
India	No standards

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