Polycarbonate Resin
&
Bisphenol A

Q & A

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Polycarbonate Resin Manufacturing Group

This is a translation of the Japanese “Q&A”.

Introduction

The Polycarbonate Resin Manufacturers Group (PCMG) provides information on Environmental Endocrine Disruptors (environmental hormones) on its website and pamphlets etc. This information is provided to reassure our clients and consumers that polycarbonates are safe to use.

The PCMG is making every possible effort to distribute the most up to date information by exchanging data with associated researchers and the mass media. The PCMG is also collecting any relevant information from experiments and their resulting scientific data.

Environmental Endocrine Disrupter issues related to polycarbonate resin are not concerning the resin itself but one of its constituents, namely bisphenol A. A Japanese translation of "Our Stolen Future", a book about the endocrine disrupter effects of bisphenol A, was published in 1997. This publication caused great concern among users and consumers of polycarbonates around 1998. Disquiet has largely subsided since safety information about polycarbonates has become publicly available.

The PCMG also organized the "PC/BPA Global Team" together with major polycarbonate resin and bisphenol A manufacturers in Europe, America and Japan. The group has been carrying out a number of scientific tests and studies to obtain relevant safety data in order to better understand any effects of bisphenol A.

It is to address any concerns about the safety of polycarbonates that we have produced this Q & A brochure.

Polycarbonate Resin Manufacturers Group

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Q1-1

Which companies manufacture polycarbonate?

A

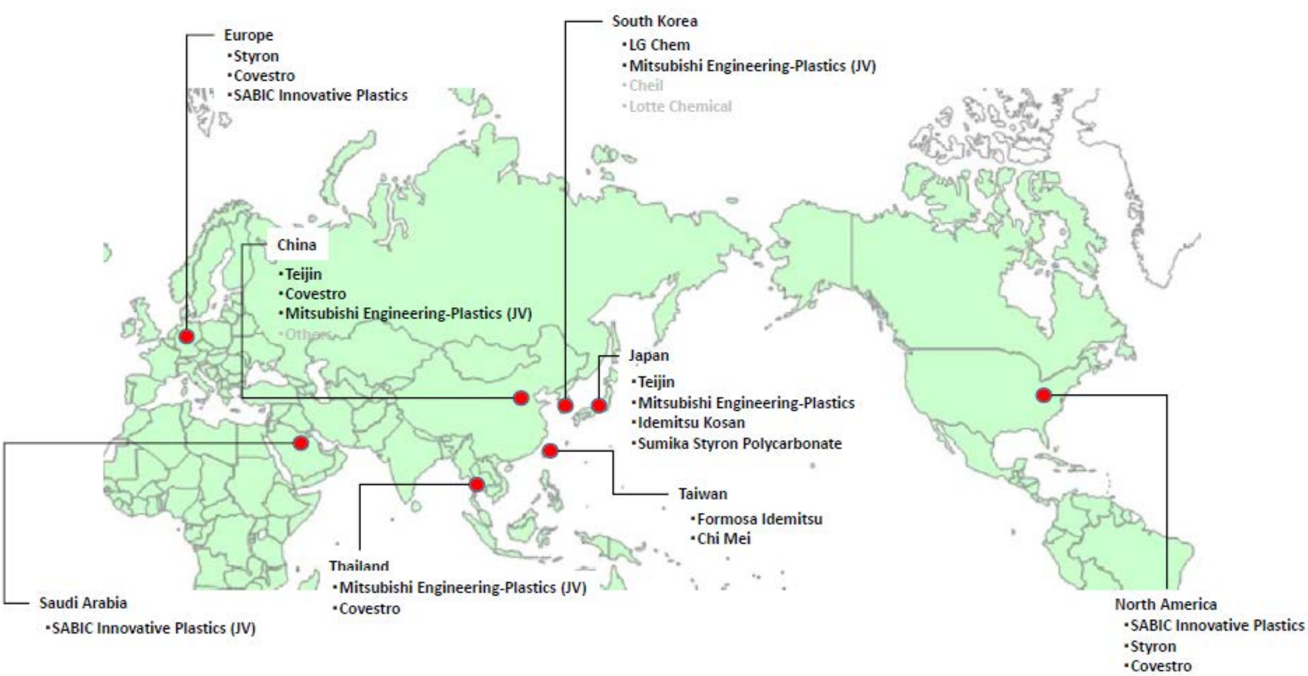
In Japan, the following six companies conduct the manufacturing, compounding and sales of polycarbonate plastics.
These companies, is the world's leading with a superior technology in manufacturing, quality control and safety management.

Polycarbonate Companies in Japan

- Idemitsu Kosan Co., Ltd.
- Sumika Styron Polycarbonate Ltd.
- Teijin Ltd.
- Mitsubishi Engineering-Plastics Corp.
- SABIC Japan LLC (Compounding)
- Covestro Japan Ltd. (Compounding)

Polycarbonate resin was developed in 1956 by Bayer in Germany. Later, companies in Europe, America and those in Japan developed their own production technologies and began manufacturing polycarbonates. The six Japanese polycarbonate resin manufacturers have organized the Polycarbonate Resin Manufacturers Group to pursue the supply of high quality products. The group has been making efforts to improve their quality control technologies and is solving the endocrine disrupter issue by conducting various tests and collecting and releasing relevant information. In addition, the group is working closely with polycarbonate resin manufacturers, bisphenol A manufacturers and related chemical industry associations in Europe and America.

◆ Polycarbonate Companies in the World ◆



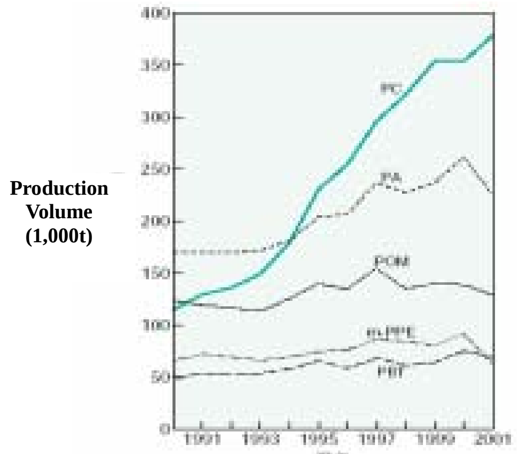
Q1-2

What is the production volume of polycarbonate resin?
What is the forecast of demand in the future?

A

Global production volume of polycarbonate resin in 2001 was estimated at about 2.2 million tons. Japan produced about 0.36 million tons and America, Europe and Asia excluding Japan produced about 0.69, 0.78, 0.33 million tons, respectively.
Since polycarbonate has been used in various applications including electronics, OA apparatus, automotive parts and building materials, medical equipment, daily necessities, etc., its production ratio is increasing at an annual rate of more than 10%. It is expected to grow further in the future.

Polycarbonate resin is one of the "5 major engineering plastics." These 5 plastics play an essential role in various areas of our life, and the demand for polycarbonate in particular is rapidly increasing. The unique features and safety of this resin contribute to an increase in global consumption. Thus, there are plans to establish new plants and expand existing plants in Asia.



(Table 1) Major Engineering Plastics' Production in Japan (1990-2001)

PC	Polycarbonate
POM	Polyacetal
PBT	Polybutyleneterephthalate
PA	Polyamide
m-PPE	Modified Polyphenyleneether

5 Major Engineering Plastics include Polycarbonate, Polyamide, Polyacetal, Modified PPE (Polyphenyleneether) and PBT (Polybutyleneterephthalate).

As engineering plastics have high mechanical strength, high physical strength and high heat resistance, these have been widely used for applications like automotive parts, machinery parts, and electrical/electronic parts.

Q1-3

What are the features of polycarbonate resin? What applications are polycarbonates used for?

A

Polycarbonate resin has very useful properties such as high impact resistance; high heat resistance; weather resistance; high transparency; high gloss; and it is non-flammable. In addition, Polycarbonate has excellent electrical properties and is safe and hygienic.

Polycarbonate resin is widely used in various industries and fields. Applications include CDs; optical fibers; electric appliances; cameras; cellular phones; OQ equipment; electronics; optical equipment; medical equipment; automobiles; goggles; baby bottles; school tableware; dome roofing (as a sheet); and windows (replacing glass).

Properties and Applications of Polycarbonate

- **Transparent, Break Resistant**
  Protective eyeglasses, sunglasses, goggles, windows, automobile lamp lenses, etc.
- **Transparent, Break Resistant, Distortion Resistant**
  CDs, CD-ROMs, MDs, etc.
- **Transparent, Lightweight, Break Resistant, Heat Resistant**
  Iron water tank, street lamp covers, electric light covers, arcades, garage roof, etc.
- **Lightweight, Break Resistant**
  Helmets, Automobile door handles, etc.
- **Lightweight, Heat Resistant, Non-Flammable, Distortion Resistant**
  PCs, cellular phone cases, camera parts, watch parts, MD cases, etc.
- **Lightweight, Safe/Hygienic**
  Baby bottles, tableware, reusable water bottles, etc.

High Performance **Polycarbonate Product**

- Transparent
- Break Resistant

Protective eyeglasses ▶

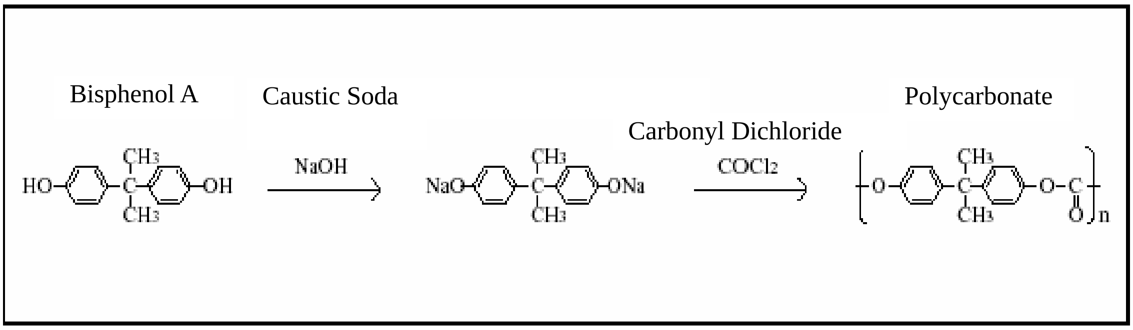
Q1-4

How is polycarbonate produced?

A

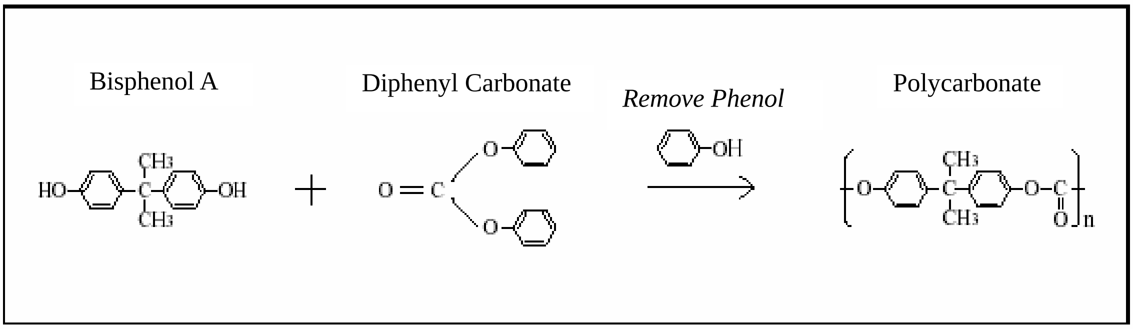
There are two polycarbonate manufacturing methods, the Solvent Method and the Melt Method (Ester Interchange Method). The Solvent Method produces polycarbonate from bisphenol A and carbonyl dichloride, while the Melting Method produces polycarbonate from bisphenol A and diphenyl carbonate. The polycarbonates produced by both methods have similar structures.

Synthesis by Solvent Method



Non-reacted bisphenol A and other by-products are removed in the separating and purifying stages of the synthetic process. Non-reacted carbonyl chloride does not remain in the resin as it is removed after 100% decomposition through reaction with caustic soda.

Synthesis by Melting Method



Non-reacted bisphenol A,diphenyl carbonate and the phenol of by-products, etc. are removed by deaeration in the molten polymerization stage.

Chemical name and chemical information on polycarbonate.

- Chemical name: poly-4, 4'isopropylidene-diphenyl carbonate
- Official gazette serial number: CDIL-SSL(7)-738
- CAS No.: 80-05-7

Q1-5

How are polycarbonate resin pellets for molding and extrusion produced?

A

Additives and coloring agentg are added to polycarbonate resin (base polymer), synthesized by the methods described in Q1-4, before particle-shaped molding materials, called pellets, are made by melt-extrusion using an extruder.

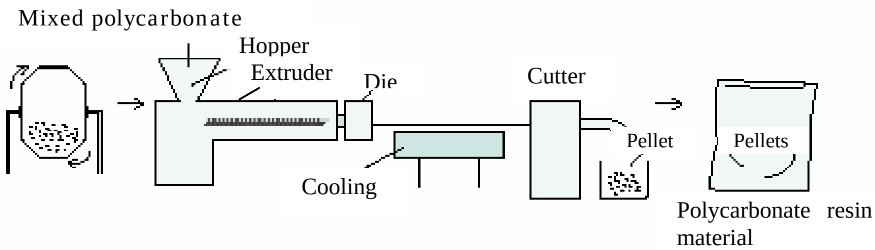
An outline of the equipment for making pellets is shown below.
The base polymer is mixed with additives, and coloring agents, then melted and extruded in a string-shape and cut into particle-shapes called pellets using a pelletizer. As shown in the photograph, the pellet is cylindrical, about 3 mm in diameter and about 3 mm in length.

Pellet Making Process

Polycarbonate resin (base polymer)
Additives
Coloring agents

↓

weighing → Mixing → Extruding (pelletizer) → Pellets → Packaging (paper bag, etc.)



Q1-6

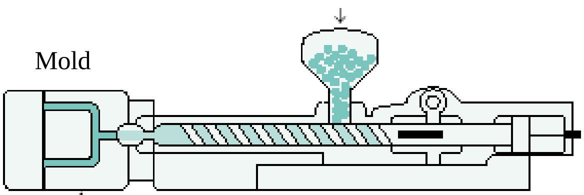
How are polycarbonate products produced?

A

Polycarbonate resin, in the form of pellets, is melted at a high temperature (280°C–300°C), then injection-molded to make everyday products and industrial goods and parts. For making sheets and films an extruder is used. Bottles are made by blow molding.

Injection Molding (Typical Molding Method):

Polycarbonate is a thermoplastic resin, which is a solid at normal temperatures, but melts at high temperatures and solidifies at low temperatures. Molders melt pellets at a high temperature before the same amount as that of the weighed product is poured into a mold under high pressure, then cooled and removed from the mold. (Fig. 1 & 2)



(Fig. 1)
Injection Molding

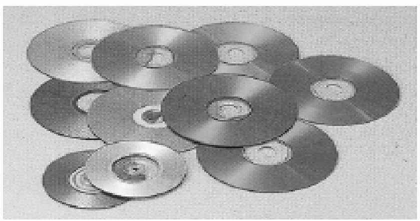
Dry pellets
↓
Melted at a high temperature (280-300°C)
↓
Weighed, the amount needed to make the product
↓
Poured into a mold under high pressure
↓
Cooled (around 80°C)-solidified
↓
Removed from the mold

(Fig. 2)
Production Process of Polycarbonate Products

High Performance | **Polycarbonate Product**

- Transparent
- Break Resistant
- Distortion Resistant

CD, CD-ROM ►



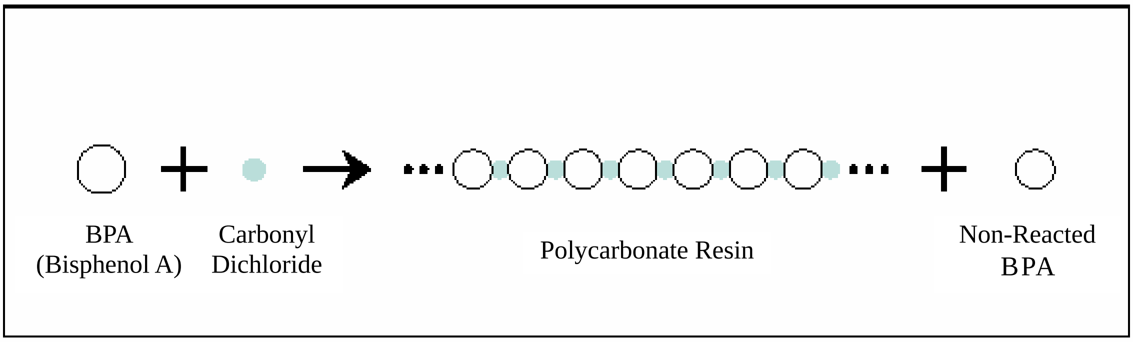
Q2-1

Why does bisphenol A remain in polycarbonate products?

A

In the polycarbonate production process, there is a stage to remove non-reacted bisphenol A and other non-reacted substances, but they cannot be removed completely. That is why trace amounts of bisphenol A remain in polycarbonate products.

In the process of polycarbonate production, for example, in the solvent method, it is necessary for bisphenol A molecules to be brought into contact with carbonyl dichloride molecules. Immediately after the reaction starts, the reaction of the bisphenol A and carbonyl dichloride proceeds rapidly. However, as the reaction proceeds, the increasing presence of polycarbonate polymers reduces the frequency of bisphenol A and carbonyl dichloride reactions. The reaction is accordingly slowed and finally stops. Therefore some trace amounts of non-reacted bisphenol A and carbonyl dichloride remain in the polycarbonate.



(Fig. 3)
Molecular reaction during polycarbonate resin production process

Q2-2

Does bisphenol A increase during the molding process of polycarbonate products?

A

During the molding process of polycarbonate, bisphenol A may be generated when decomposition occurs under temperatures higher than normal processing temperatures. It has been confirmed in some cases that decomposition is enhanced by a formulating ingredient used in the processing stage. In other words, it may be possible that bisphenol A is generated due to the decomposition of polycarbonate when something goes wrong in the processing stage

The decomposition that may occur during the molding process is attributable to the following.

1) The moisture content in the polycarbonate resin is too high.

2) The temperature for the molding process is too high and/or the dwell time is too long.

3) Additives or coloring agents, or other compounding agents that may enhance decomposition are used.

To prevent decomposition in the molding stage, molding companies take the following countermeasures.

1) Polycarbonate is preliminarily dried before molding so that the moisture in the material can be removed.

2) Appropriate processing temperatures are advised by polycarbonate manufacturers.
Processors set appropriate processing temperatures for each product based on the advice and carefully manage production.

3) Polycarbonate manufacturers conduct preliminary tests so that only additives, coloring agents, etc. that do not enhance decomposition are used. The Polycarbonate Resin Manufacturers Group provides information for selecting proper additives, coloring agents, etc. as guidelines for processors who independently add those agents.

High quality products are supplied by fully coping with the above circumstances when manufacturing polycarbonate products. Naturally, there is no decomposition when polycarbonate products are handled under normal conditions.

Q2-3

What methods are used to measure the bisphenol A remaining in polycarbonate resin?

A

Normally, measurement is performed by the method specified in Notification No. 370 issued by the Ministry of Health and Welfare (MHW). Basically, bisphenol A is separated from polycarbonate resin, and this bisphenol A is measured using an analytical method known as high-speed liquid chromatography. Measurement is expressed in units* of ppm and ppb.

The measurement method (material quality tests) specified by Notification No. 370 issued by the MHW is as follows. (Note: The name of MHW was changed to MHLW (Ministry of Health, Labor and Welfare)

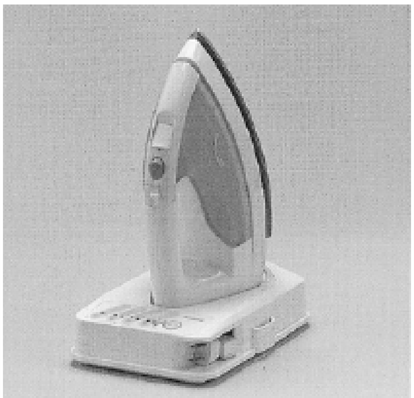
1) Melt polycarbonate product in a specified amount of dichloromethane.
2) Instill the melted polycarbonate in acetone solvent to extract polycarbonate (polymer)
3) Separate polycarbonate (polymer) by centrifugal separator
4) Measure the amount of bisphenol A melted in acetone by high-speedliquid chromatography.

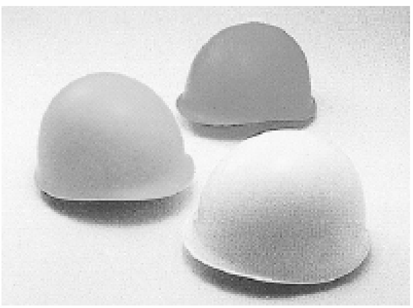
* Units: ppm: parts per million (=1g in 1 ton)
ppb: parts per billion (=1g in 1000 tons)

High Performance **Polycarbonate Product**

- Transparent
- Lightweight
- Break Resistant
- Heat Resistant

Iron Water Tank ▶





- Lightweight
- Break Resistant

◀ Helmets

Q2-4

What does "migration of bisphenol A from polycarbonate products" mean?

A

It means that a trace amount of bisphenol A that exists near the surface of a polycarbonate container shifts to the contents, such as water, that is in contact with the product.
Since bisphenol A shifts into the contents, the word "migration" is used.

The following shows 3 ways that bisphenol A migration from a polycarbonate product may occur.

1) Bisphenol A that remains close to the surface of a polycarbonate resin and migrates (see Q2-7 and Q2-8).

2) When polycarbonate product is in contact with alkali and/or heated water, the polycarbonate at the surface of the product decomposes (hydrolyzes), and thereby releases bisphenol A that migrates. This phenomenon varies, depending on temperature, time, etc. (see Q2-10).

3) When both 1) and 2) occur.

High Performance **Polycarbonate Product**

- Lightweight
- High Heat Resistant
- Distortion Resistant
- Non-Flammable

Note PC Housing ▶

- Lightweight
- Break Resistant

◀ Automobile Door Handles

Q2-5

What methods are used to measure the amount of bisphenol A that migrates from polycarbonate products? How accurate and sensitive in the test?

A

Measurement is performed by the test method specified in Notification No.370 issued by the MHW (See Q2-3). The test method makes it possible to measure up to 0.5 ppm. There are cases where test measurements were able to detect up to 0.5-0.01 ppb under more stringent conditions.

According to the test method specified by Notification No. 370（1959）and No. 18 (1994) issued by the MHW, a polycarbonate product is immersed in the pseudo solvent shown in the table and allowed to migrate bisphenol A under the conditions shown in the table before the bisphenol A migrated is calculated by high-speed liquid chromatography.

(Table 2) BPA Migration Tests and Regulation
Ministry of Health and Welfare Notice No.18 (January, 1994) – Individual Standard for Apparatus and Container/Wrapping made of Polycarbonate Resin

Test	Compounds	Solvent	Condition	Regulation (ppm)	
				Use at <100℃	Use at >100℃
Material	Cd and Pb	Dichloromethane	RT	< 100	< 100
	Heavy metals	4% acetic acid	60℃ x 30min.	< 1	—
			95℃ x 30min	—	< 1
	KMnO4 Consumption	Water	60℃ x 30min.	< 10	—
			95℃ x 30min	—	< 10
	Amines	Dichloromethane	RT	< 1	< 1
	Diphenylcarbonate			< 500	< 500
	BPA(include phenol and p-t-butyl phenol)			< 500	< 500
Migration	Evaporated residues	n-heptane	25℃ x 60min.	< 30	< 30
		20% ethanol	60℃ x 30min.	< 30	< 30
		Water	60℃ x 30min.	< 30	—
			95℃ x 30min	—	< 30
		4% acetic acid	60℃ x 30min.	< 30	—
			95℃ x 30min	—	< 30
	KMnO4 Consumption	Water	60℃ x 30min.	< 30	—
			95℃ x 30min	—	< 10
	BPA (include phenol and p-t-butyl phenol)	n-heptane	25℃ x 60min.	< 2.5	—
		20% ethanol	60℃ x 30min.	< 2.5	—
		Water	60℃ x 30min.	< 2.5	—
			95℃ x 30min	—	< 2.5
		4% acetic acid	60℃ x 30min.	< 2.5	—
			95℃ x 30min	—	< 2.5

Q2-6

How are the standards for polycarbonate resin used for food contact applications decided?

A

The specification standard for plastics is regulated in accordance with the Food Hygiene Law. Bisphenol A contained in polycarbonate products is specified to be not more than 500 ppm in the material quality test standard and not more than 2.5 ppm in the migration test standard. The Polycarbonate Resin Manufacturers Group independently established a self-standard for material quality test, that is not more than 250 ppm.

Note) Material quality test standard: See Q2-3
Migration test standard: See Q2-5

Since it is not possible to establish a migration test standard from experiments on human beings, data on daily intake not affecting long-term health (No Observed Effect Level) has been obtained from animal experiments. Safety levels have been extrapolated from such data by converting figures for animals into humans in view of safety, and 1/1000 of the figure thus obtained is treated as a safety coefficient.
The migration test standard of bisphenol A is common worldwide, but the Japanese standard is the strictest level in the world, since Japan specifies the material quality standard in particular.

(Table 3) Comparison of Allowable Standards of Bisphenol A among the EU, U.S. and Japan

	Standards of Bisphenol A	
	Material quality test	Migration test
EU	None	Migration standard: Allowable concentration, 3 mg/kg (EC instruction) (TDI*: 0.05 mg/kg/day)
U.S.	None	Migration standard: None (TDI: 0.05 mg/kg/day)
Japan	Not more than 500 ppm	Migration standard: Not more than 2.5 ppm (TDI: 0.05 mg/kg/day)

*TDI = Tolerable Daily Intake

High Performance **Polycarbonate Product**

- Lightweight
- Safe/Hygienic

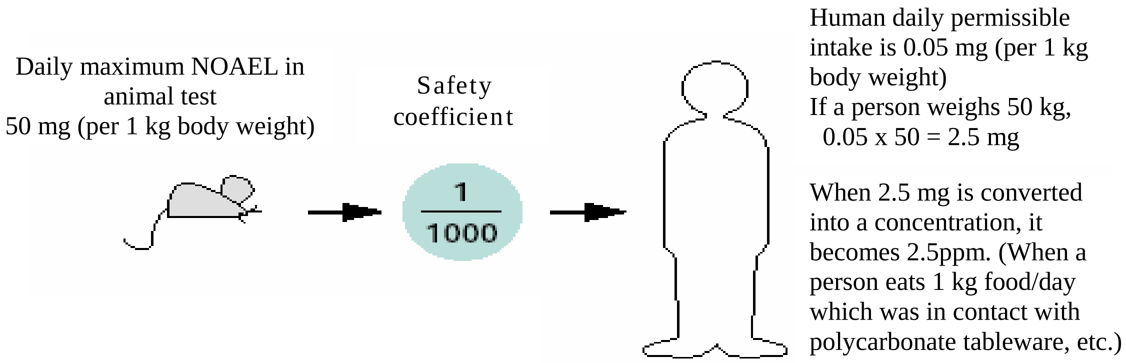
School Lunch Tableware ▶

The regulation on bisphenol A migration is determined by the following method.

- No observed adverse effect level (NOAEL) in animal test: 50mg/kg/day
  - Test results in the U.S. and EU.
    No adverse effect observed over a lifetime even with 50 mg bisphenol A per 1kg body weight per day.

- Conversion coefficient (safety coefficient) from animals to humans: 1/1,000
  - Normal safety coefficient is 1/100, but the U.S. Environmental Protection Agency (EPA) set the stricter 1/1,000 coefficient.

- Human permissible intake per 1kg body weight per day (TDI):(50mg/kg/day)x(1/1,000)=0.05mg/kg/day
  <Bisphenol A migration regulation applies 1/1,000 of the amount for which safety was confirmed in animal tests>



- Permissible Bisphenol A intake for Japanese people (TDI): 2.5 mg/day
  (0.05 mg/kg/day) x 50 kg = 2.5 mg/day → Bisphenol A intake which has no adverse effect on an average Japanese person even when ingested daily over a lifetime.

- Amount of food eaten a day which is in contact with polycarbonate tableware, etc: 1 kg
  (Although according to statistical data, Japanese people eat 700g of food a day which is in contact with plastics. This was assumed to be 1kg and that all plastics in contact with foods are polycarbonate.)

2.5 mg/1 kg (1,000,000 mg) = 2.5 ppm (2.5 parts per million)

→ Permissible Bisphenol A concentration in food when a person who weighs 50 kg eats 1 kg of food in contact with polycarbonate tableware in a day.
→ Migration test standard

In the U.S. and the EU, there are no material quality test regulations. In Japan, the MHW (current Ministry of Health, Labor and Welfare) established limits on bisphenol A at below 500ppm in order to ensure further safety margins. This limit was established by their analysis and experimentation on products in the market.

Q2-7

How much bisphenol A is migrated from polycarbonate products?

A

Not more than 5–6 ppb under normal conditions.
Not more than 30–50 ppb when extreme conditions are present.

In view of the data so far confirmed, the amount of bisphenol A migrated from polycarbonate tableware and baby bottles is approximately 5.5 ppb at most. According to the test results carried out by Yokohama National University, there were 5.5 ppb of bisphenol A detected from polycarbonate baby bottles filled with 95˚C water and allowed to stand overnight, but there was no bisphenol A found in the same tests using water of normal temperature.

(Table 4-1) Test Results of Bisphenol A Migration from Polycarbonate Products

<table>
<tr><th>Product</th><th>Research Institute</th><th>Test Condition</th><th>Migration Amount</th><th>Detection Limit</th></tr>
<tr><td rowspan="7">Baby Bottle</td><td rowspan="2">Yokohama National Univ. (2)</td><td>hot water 95°C,
left overnight</td><td>3.1 ~ 5.5 ppb</td><td rowspan="2">0.2 ppb</td></tr>
<tr><td>water 26°C,
left for 5 hrs</td><td>Not detected</td></tr>
<tr><td>FDA (3)</td><td>practical trial condition</td><td>Not detected</td><td>2 ppb</td></tr>
<tr><td>British Ministry of Agriculture, Fisheries and Food (4)</td><td>milk, fruits juice,
micro waved for 30sec.</td><td>Not detected</td><td>30 ppb</td></tr>
<tr><td rowspan="2">National Institute of Health Science (5)</td><td>hot water 95°C x 30min.</td><td>0.5 ppb</td><td rowspan="2">0.2 ppb</td></tr>
<tr><td>20% ethanol
60°C x 30 min.</td><td>Not detected</td></tr>
<tr style="display:none"><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="7">Tableware</td><td>National Institute of Health Science (5 specimens) (5)</td><td>hot water 95°C,
20% ethanol</td><td>Not detected ~ 5 ppb</td><td>0.5 ppb</td></tr>
<tr><td rowspan="2">Saitama Prefecture
(50 specimens each) (6)</td><td>n-heptanes</td><td>Not detected ~ 1.9 ppb</td><td rowspan="2">1 ppb</td></tr>
<tr><td>hot water 95°C,
20% ethanol
4% acetic acid</td><td>Not detected ~ 11 ppb *</td></tr>
<tr><td rowspan="4">Yokohama City
(5 specimens each) (7)</td><td>See Q2-5, Table 2</td><td>Not detected ~ 1 ppb</td><td>0.5 ppb</td></tr>
<tr><td>water 80°C,
left for 30 min.</td><td>Not detected</td><td>0.5 ppb</td></tr>
<tr><td>soup 80°C,
left for 30 min.</td><td>Not detected</td><td>10 ppb</td></tr>
<tr><td>Olive oil 60°C,
left for 30 min.</td><td>Not detected</td><td>50 ppb</td></tr>
<tr><td>Water Bottle</td><td>FDA (3)</td><td>immersed in water for 39 weeks</td><td>4.6 ~ 4.7 ppb</td><td>2 ppb</td></tr>
<tr><td>Returnable Bottle</td><td>Returnable Bottle Assoc. (8)</td><td>Alkali washing 15 times
See Q2-5, Table 2
Used over 100°C</td><td>Not detected ~ 6 ppb</td><td>5 ppb</td></tr>
</table>

* 23 ~ 67 ppb detected from only specific specimen

.(1) Takashi Tatsuno, Hiroyuki Nakazawa: Endocrine Disrupter Chemicals & Food Contact Containers, Yuki Publishing Co.
(2) Mainichi Newspaper, Morning edition of 9/26/1997
(3) J.A. Biles. Et al: Journal of Agricultural and Chemistry, vol. 45,3541
(4) Central Science Laboratory Report FD 97/08 MAFF R&D and Surveillance Report 253 (1997)
(5) Hitoshi Kawamura: Food Hygienics (3), 206, (1998)
(6) Saitama Prefecture Health & Welfare section: press release, 6/30/1998
(7) Yokohama City Education Committee: press release, 8/31/1998
(8) PC Returnable Bottle Association report, Agency of Environment (Ministry of Environment)

(Table 4-2) Bisphenol A not Migrated at Normal Temperatures
(Migration Test Data for Baby Bottles)

Unit: ppb

	95°C water / left overnight	Normal temperature
①	3.3	Not detected (<0.2)
②	3.1	Not detected (<0.2)
③	5.5	Not detected (<0.2)
④	3.9	Not detected (<0.2)
⑤	4.5	Not detected (<0.2)
⑥	3.9	Not detected (<0.2)

①-⑥ Baby bottles available in the market
(Yokohama National University, Environmental Science Research Center, 9/17/1997)

High Performance Polycarbonate Product

- Lightweight
- Safe/Hygienic

Sealable Containers, Lunch Boxes, Baby Bottle Steamers ▶

Q2-8

Why is the migration amount of Bisphenol A from Polycarbonate Products small?

A

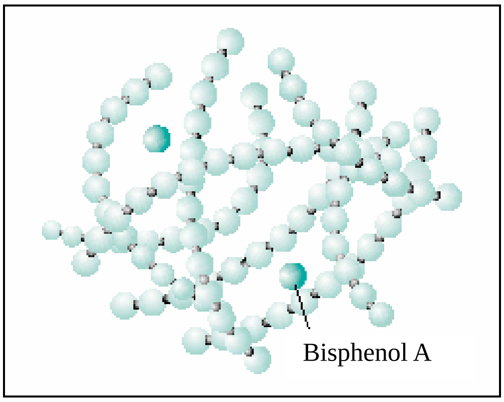
The following reasons are offered:

- Polycarbonate resin and bisphenol A attract each other.
- It is difficult for non-reacted bisphenol A contained in polycarbonate products to move to the surfaces of the products

Polycarbonate and bisphenol A contained in polycarbonate products are quite similar when expressed by a chemical formula. The only difference is that the molecular weight of polycarbonate resin is larger than that of bisphenol A. They attract each other because of their similar structures. This kind of chemical relationship is scientifically known as "favorable compatibility." The Bisphenol A contained in polycarbonate is like an "unwelcome houseguest who feels comfortable staying in a relative's house and is reluctant to leave."

Another reason that only trace amounts of bisphenol A migrates from polycarbonate products is that polycarbonate occurs in a state of intertwined long strings in which it is difficult for bisphenol A to exit (Fig. 4). In addition, since the molecular movement of polycarbonate ceases under normal temperatures (below 145˚C), bisphenol A contained in the polycarbonate finds it very difficult to move.

There was almost no detection in the migration test data of polycarbonate products, and, if any, only 5 ppb or below were detected, corresponding to 1/500 of the national specification standard.
Thus, it is assumed from the data that non-reacted bisphenol A near the surface of the product migrated.
It has also been reported that there is no further migration from the polycarbonate products that generated the trace amount of migration after being washed several times.



(Fig. 4) Illustration of Polycarbonate Inside

(Fig. 5) Migration Findings of Bisphenol A after Repeated Washes Unit: ppb

	Before Wash	1st Wash	2nd Wash	3rd Wash	4th Wash	5th Wash
Tableware	39.1	26.3	3.4	2.4	1.7	1.5
Baby Bottles	3.9	0.5	N/D	N/D	N/D	N/D

Remaining Bisphenol A:
599 ppm for Tableware
20 ppm for Baby Bottles
Detection Limit: 0.5 ppb

N/D = Not Detected

(Hitoshi Kawamura: Food Hygienics (Vol.39,No.3, 6/1998)

Q2-9

What kind of practices/methods have been employed when producing polycarbonate resin for food contact applications?

A

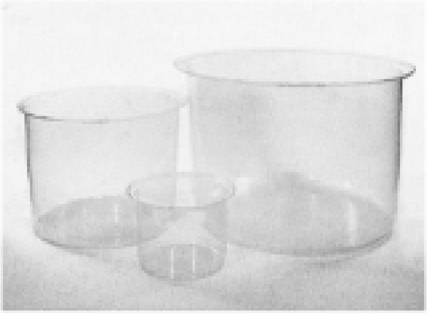
Self-standards have been established for amounts of bisphenol A to be contained in polycarbonate for food contact applications so that people can feel safe using the polycarbonate products. Polycarbonate and other materials to be molded for food contact applications are controlled by distinguishing methods.

The amount of bisphenol A to be contained in polycarbonate for food contact applications is independently fixed at 1/2 of the material quality standard level, namely, below 250ppm, and is voluntarily managed.
The distinguishing methods (grade name, color number, etc.) have been implemented so that resin not designated for food contact applications are not delivered by mistake. In addition, additives that may increase the contained amount of bisphenol A are carefully classified to prevent their erroneous use.

High Performance **Polycarbonate Product**

- Lightweight
- Heat Resistant
- Non-Flammable
- Distortion Resistant

Cellular Phone Housing ▶



- Lightweight
- Safe/Hygienic

◀ Measuring Cups

Q2-10

Does polycarbonate resin decompose and generate bisphenol A during use of polycarbonate products?

A

Yes, bisphenol A may be generated when polycarbonate is decomposed.
Thus, manufacturers that supply polycarbonate resin give usage precautions in their catalogs and technical materials, advising against use under conditions in which it can be decomposed (hydrolyzed).

Depending on conditions for use, polycarbonate is hydrolyzed and generates bisphenol A when it comes into contact with hot water or alkaline chemicals. Thus, precautions are given in catalogs and technical materials advising against use under the following conditions.

(1) Depending on temperature or time, polycarbonate is hydrolyzed when it comes into contact with alkaline solutions such as sodium hydroxide, ammonium, etc. Thus, its use is limited depending on the pH level of a chemical solution, the temperature and the time.

(2) Polycarbonate is also gradually decomposed by hot water. There is no problem, however, in using it for baby bottles, tableware, coffee servers, drinking water containers, etc. as long as the handling precautions are observed, but use in hot water over many hours is not advised.

High Performance **Polycarbonate Product**

- Transparent
- Break Resistant

Free Way “Sound Insulation Wall” ▶

Q2-11

Is Bisphenol A migrated when food in a polycarbonate container is microwaved?

A

The amount of bisphenol A migrated into water is not more than 2 - 4 ppb (2 - 4 µg/L) when a polycarbonate container (tableware) that contains water is heated by microwave oven in the most extreme conditions. This amount is about 1/500 of the standard migration level specified in Notification No. 370 issued by the Ministry of Health and Welfare (current Ministry of Health, Labor and Welfare).

Polycarbonate Resin Manufacturers Group conducted the following tests with microwave ovens. The results obtained showed a trace amount of migration, in levels safe for use.

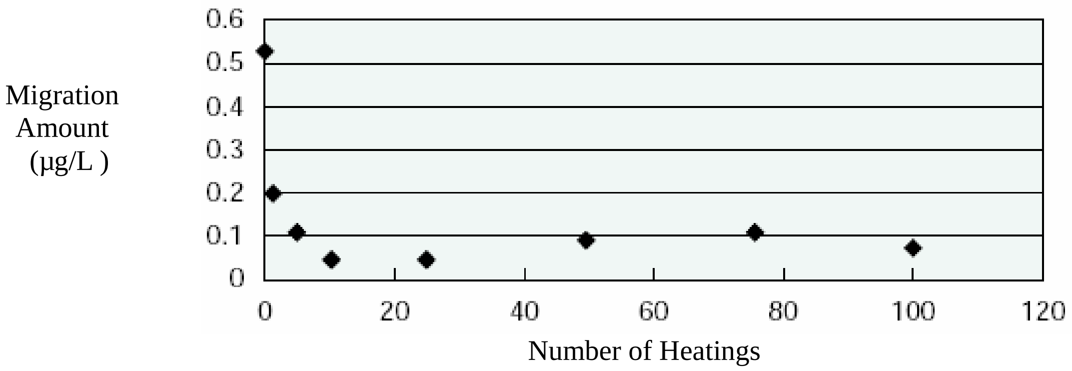
A. Repeated heating tests by microwave oven

1) Method

Sample:	Polycarbonate tableware A bowl of a volume of 187 cm^3 (upper diameter, 12.5 cm, lower diameter, 7.5 cm and height, 4.5 cm) The amount of bisphenol A contained in the bowl, 100-130 ppm.
Contents:	160 ml of water (80% of the container)
Heating conditions:	The amount of bisphenol A migrated into the (hot) water was measured after heating for 4 min. by microwave oven.
Test method:	Same bowl was repeatedly heated for 4 minutes, changed with fresh water each time. The migration amount was measured in each cycle.
Measurement method:	GC/MS method

2) Results

The migration amount obtained after repeatedly microwaving the bowl up to 100 times is shown in Fig.5. As with the results of normal migration tests, the initial amount was relatively high, but it decreased after repeating several times, and tended to show a fixed level thereafter.



(Fig. 5) Repeated heating by microwave oven – (0-100 times)

B. Heating time by microwave oven and migration amount

1) Test method

- Five sheets of polycarbonate test specimen (6 cm x 4 cm x 0.3 cm) were placed in a glass laboratory dish (180 mm diameter, 50 mm height) containing 540 ml distilled water and microwaved (rated power consumption: 840 W, rated high- frequency output: 400 W).
- The amounts of bisphenol A contained in the test specimens were purposely fixed at three levels of 20 ppm, 100 ppm and 390 ppm.
- Measurement by GC/MS method.

2) Results

The results are shown in Table 6.

As shown in this table, the following tendencies are recognized.

- The longer the heating time, the larger the migrated amount
- The greater the amount of bisphenol A in the test specimens, the greater the migrated amount.

Overall, the migration amount is about 3.64 μg/L (3.64 ppb), even under the most extreme conditions, approximately 1/500 of the migration standard (2.5 ppm).

(Table 6) The influence of bisphenol A (BPA) content and heating time

Test specimen (BPA content)	Migration amount (μg/L)	
	Heating time (3 min.)	Heating time (5 min.)
Below 20 ppm	0.35	0.83
100 ppm	0.80	0.74
390 ppm	1.52	3.64

High Performance **Polycarbonate Product**

- Transparent
- Break Resistant

Automobile Lamp Lenses ▶

Q3-1

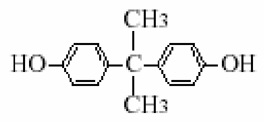
What is bisphenol A?

A

Bisphenol A is a white, solid substance at room temperature (23°C) and a low volatile substance having the physical properties of a high melting point and a high boiling point. Extremely small amounts of Bisphenol A dissolve in water.
Bisphenol A is a chemical substance widely used for polycarbonate resin, epoxy resin, polyarlyate and polysulfone as a raw material (monomer).

Chemical name: 2, 2-bis (4- hydroxyphenyl) propane

Molecular structure:



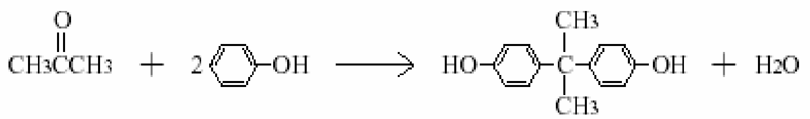
Typical properties:

(Table 7) Bisphenol A's Typical Properties

Substance Name	Melting Point (°C)	Boiling Point (°C)	Vapor Pressure (Pa)	Solubility in Water (mg/L)
Bisphenol A	150	250-252	$5x10^{-6}$	120

Official gazette serial number: CDIL – SSL (4) – 123
CAS NO.: 80-05-7

Bisphenol A is composed of phenol and acetone.



Acetone Phenol Bisphenol A Water

Q3-2

I heard that even trace amounts of environmental hormones are hazardous. Is bisphenol A also hazardous?

A

Trace amounts of bisphenol A are not hazardous. Some reports claiming that even trace amounts of bisphenol A are hazardous can be attributed to confusion with TBT (tributyl), dioxin, DDT, PCB, etc.

Opinions that even trace amounts of bisphenol A are hazardous have resulted from confusion with TBT (tributyl, a coating paint for the bottom of boats to prevent shellfish adherence), extremely low concentrations of which exhibit strong toxicity in aquatic creatures, as well as dioxin, DDT, PCB, etc.
The governments of a number of countries believe that bisphenol A in amounts migrated from polycarbonate products causes no problems to human health. As shown in Table 8-1, no biological concentration (an accumulation of hazardous substances in high concentrations through food linkage) occurs since environmental remnants or accumulations of bisphenol A are extremely low.

(Table 8-1) Comparison of Environmental Hormonal Properties

Environmental Hormonal Properties	Dioxin	DDT	TBT	PCB	Plant Estrogen	Bisphenol A
Strength of hormonal action	Strong	Weak	Strong	Weak	Moderate	Weak
Intake	Small	Small	Small	Small	Large	Small
Accumulation	Large	Large	Large	Large	Small	Small
Effects on wild animals	Reported	Reported	Reported	Reported	Reported	Not Reported

[Policies & Programs of Ministry of Environment]
Strategic Programs on Environmental Endocrine Disrupters 1998 (SPEED'98)

The Exogenous Endocrine Disrupting Chemical Task Force established by the Environmental Agency (current Ministry of Environment) published an interim report (1998). In the report about 70 substances (or groups of substances) are suspected of having endocrine disrupting effects. The number of these substances is expected to increase in the process of future study and research. It is hoped that future study and research will make it easy to identify the existence of such effects and measure the strength of disruptive effects. It has to be noted that the restrictions and environmental monitoring were not implemented from the standpoint of coping with endocrine disrupting effects. It is therefore necessary to review the present restrictions and monitoring activities, while enhancing our scientific knowledge.
"Chemicals Suspected of Having Endocrine Disrupting Effects" was revised to be 65 substances in the year 2000. There are some substances in the table that were selected based on scientific documents (not based on scientific test results) and bisphenol A was categorized the same as dioxins, PCB, DDT that clearly have toxicity.

Based on the table, 12 substances in 2000, 8 substances in 2001 and 8 substances in 2002 were selected as the prioritized substances for risk assessment tests. Bisphenol A as one of 8 substances in 2001 was selected and has being tested.

(Table 8-2) Chemicals Suspected of Having Endocrine Disrupting Effects

Substances	Use	Restrictions
1. Dioxins and furans	(Unintended product)	APL, WDPCL, LCSMAD, POPs, PRTR Class Ⅰ
2. Polychlorinated biphenyl (PCB)	Heat medium, non-carbon paper	stopped production in 1972, LCERMCS Class I in 1974, WPCL, MPPL, WDPCL, EQSGWSWP, POPs, PRTR Class Ⅰ
3. Polybromobiphenyl (PBB)	Fire retardant	
4. Hexachlorobenzene (HCB)	Bactericide, organic synthetic raw material	LCERMCS Class I in 1979 unregistered in Japan, POPs
5. Pentachlorophenol (PCP)	Antiseptic, herbicide, bactericide	Lapsed in 1990, WPACPDSL, PRTR Class Ⅰ
6. .2,4,5-Trichlorophenoxyacetic acid	Herbicide	Lapsed in 1975, PDSCL, FSL
7. 2,4-Dichlorophenoxyacetic acid	Herbicide	Registered, PRTR Class Ⅰ
8. Amitrole	Herbicide, disperse dye, hardener for resins	Lapsed in 1975, FSL, PRTR Class Ⅰ
9. Atrazine	Herbicide	Registered, PRTR
10. Alachlor	Herbicide	Registered, MPPL, PRTR Class Ⅰ
11. Simazine (CAT)	Herbicide	Registered, WPCL, EQSGWSWP, WDPCL
12. Hexachlorocyclohexane, Ethyl parathion	Insecticide,	Hexachlorocyclohexane lapsed and banned sales in 1971, ethyl parathion lapsed in 1972
13. Carbaryl	Insecticide	Registered, PDSCL, FSL, PRTR Class Ⅰ
14. Chlordane	Insecticide	lapsed in 1968, LCERMCS Class I in 1981, PDSCL, POPs
15. Oxychlordane	Chlordane metabolite	
16. trans-Nonachlor	Insecticide	Nonachlor unregistered in Japan, Heptachlor lapsed in 1972
17.1,2-dibromo- chloropropane	Insecticide	Lapsed in 1980
18. DDT	Insecticide	lapsed and banned sales in 1971, LCERMC Class I in 1981, FSL, POPs
19. DDE and DDD	Insecticide (DDT metabolite)	Unregistered in Japan
20. Kelthane (Dicofol)	Acaricide	Registered, FSL, PRTR
21. Aldrin	Insecticide	Lapsed in 1975, LCERMC Class I in 1981, SAC, PDSCL、POPs
22. Endrin	Insecticide	Lapsed in 1975, LCERMC Class I in 1981, CPAC, PDSCL, FSL, POPs
23. Dieldrin	Insecticide	lapsed in 1975, LCERMC Class I in 1981, SPAC, PDSCL, FSL, HSCHPCL, POPs
24. Endosulfan (Benzoepin)	Insecticide	PDSCL, WPAC , PRTR Class I
25. Heptachlor	Insecticide	lapsed in 1975, LCERMC Class I in 1986, PDSCL, POPs
26. Heptachlor epoxide	Heptachlor metabolite	
27. Malathion	Insecticide	Registered, Food Sanitation Law , PRTR
28. Methomyl	Insecticide	Registered, PDSCL
29. Methoxychlor	Insecticide	Lapsed in 1960

30. Mirex	Insecticide	Unregistered in Japan, POPs
31. Nitrofen	Herbicide	Lapsed in 1982
32. Toxaphene (Camphechlor)	Insecticide	Unregistered in Japan, POPs
33. Tributyltin	Antifouling paints on ships, antiseptic for fishnets	LCERMC in 1990 (TBTO: Class I, the remaining 13 substances: Class II), PRTR
34. Triphenyltin	Antifouling paints on ships, antiseptic for fishnets	lapsed in 1990, LCERMC Class II in 1990, PRTR
35. Trifluralin	Herbicide	Registered , PRTR
36. Alkyl phenol (from C5 to C9) Nonyl phenol /Octyl phenol	Raw material for surface -active agents decomposition product	MPPL, PRTR
37. Bisphenol A	Raw material for resins	Food Sanitation Law, PRTR
38. Di-(2-ethylhexyl)phthalate	Plasticizer for plastics	Monitoring substances in water environment, PRTR
39. Butyl benzyl phthalate	Plasticizer for plastics	MPPL, PRTR
40. Di-n-butyl phthalate	Plasticizer for plastics	MPPL, PRTR
41. Dicyclohexyl phthalate	Plasticizer for plastics	
42. Diethyl phthalate	Plasticizer for plastics	MPPL
43. Benzo(a)pyrene	(Unintended product)	
44. Dichlorophenol	Dye intermediate	MPPL
45. Diethylhexyl adipate	Plasticizer for plastics	MPPL, PRTR
46. Benzophenone	Synthetic raw materials for medical products, perfume, etc.	
47. 4-Nitrotoluene	2,4-dinitrotoluene intermediate	MPPL
48. Octachlorostyrene	(By-product of organic chlorine compound)	
49. Aldicarb	Insecticide	Unregistered in Japan
50. Benomyl	Bactericide	Registered
51. Kepone (Chlordecone)	Insecticide	Unregistered in Japan
52. Manzeb (Mancozeb)	Bactericide	Registered, PRTR
53. Maneb	Bactericide	Registered, PRTR
54. Metiram	Bactericide	Lapsed in 1975
55. Metribuzin	Herbicide	Registered, FSL
56. Cypermethrin	Insecticide	Registered, PDCL, FSL, PRTR
57. Esfenvalerate	Insecticide	Registered, PDSCL
58. Fenvalerate	Insecticide	Registered, PDSCL, FSL, PRTR
59. Permethrin	Insecticide	Registered, Food Sanitation Law
60. Vinclozololin	Bactericide	Lapsed in 1998
61. Zineb	Bactericide	Registered, PRTR
62. Ziram	Bactericide	Registered, PRTR
63. Dipentyl phthalate		Not produced in Japan
64. Dihexyl phthalate		Not produced in Japan
65. Dipropyl phthalate		Not produced in Japan

(1) Besides the above substances, cadmium, lead, and mercury are also suspected of having endocrine disrupting effects.

(2) In the environmental investigation column, (2 indicates that the substance has been detected and indicates that it has not been detected. Substances with no mark have not been investigated.

(3) The laws described in the restrictions column indicate that the substance is subject to restrictions under such laws.

(4) "Registered", "lapsed", "unregistered in Japan," "Soil-persistent Agricultural Chemicals," "Crop-persistent Agricultural Chemicals," "Water-pollutant Agricultural Chemicals" are based on the Agricultural Chemicals Regulation Law

(5) POPs are residual organic pollutants specified in the "World Action Plan Concerning the Protection of the Marine Environment by Conducting Environmental Protection Activities on Land".

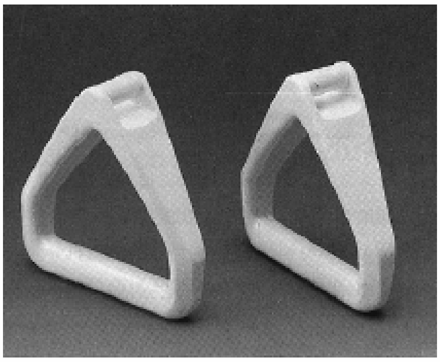
(6) Abbreviated Word of Law, Regulation, Standard and Restriction

APL : Air Pollution Law,
WDPCL : Waste Disposal and Public Cleaning Law
EQSASWP : Environmental Quality Standards for Air Pollution, Soil Pollution, and Water Pollutants
LCSMAD : Law Concerning Special Special Measurers Against Dioxins
POPs: Persistent Organic Pollutants
PRTR: Pollutant Release and Transfer Register
LCERMCS : Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances
WPCL : Water Pollution Control Law
EQSGWSWP: Environmental Quality Standards for Groundwater, Soil Pollution, and Water Pollutants,
MPPL : Marine Pollution Prevention Law
WPACPDSL : Water-pollutant Agricultural Chemicals
PDSCL : Poisonous and Deleterious Substances Control Law,
FSL : Food Sanitation Law
WWL : Waterworks Law
SAC : Soil-persistent Agricultural Chemicals
CPAC : Crop-persistent Agricultural Chemicals
HSCHPL : Harmful Substance Containing Household Products Control Law

High Performance Polycarbonate Product

- Lightweight
- Break Resistant

Handle ▶



Q3-3

How safe is bisphenol A?

A

The allowable intake of bisphenol A, agreed upon by the governmental organizations of Japan, U.S. and Europe based on the accumulated scientific knowledge, is 0.05 mg/kg-bw/day. Any intake below this level is not hazardous even when this substance is consumed everyday throughout life.

Bisphenol A (BPA) has been used safely as an industrial chemical for nearly 50 years. The effects of BPA have been extensively studied by industry, government and academic research groups in short and long term animal tests, including several reproduction and developmental studies, multi-generation exposure studies, and a cancer bioassay, all of which are part of the open scientific literature. Importantly, none of the validated research results suggest that BPA would cause adverse effects from exposure through consumer products or normal industrial production and use.

Summary of the BPA organization team (http://www.bisphenol-a.org/team.html) is as follows.

Endocrine Disruption and Bisphenol A (1), (2)
Effects have been observed in compromised laboratory animals given high doses of bisphenol A. However, reproduction and development are not affected by relatively high levels of bisphenol A in multi-generational studies, which are designed to detect disruptions in normal hormone activity (doses are compared to the extremely low levels of possible consumer exposure).

Estrogenic Activity of Bisphenol A (3), (4), (5)
Bisphenol A exhibits extremely weak hormonal activity in test tube assays and in the rat dose test.
The estrogenic activity of BPA (in vitro study) has a potency of 10,000 times less than estradiol.
In addition, estrogenic activity was observed in animals administered large doses of BPA or animals exposed via only experimental routes of exposure

Reproductive and Developmental Toxicity (1), (2), (6), (7), (8), (9)
Bisphenol A has been extensively studied for reproductive and developmental toxicity in experimental animals and has not shown a reproductive or developmental toxicity that produced fetal morphological abnormalities. For risk assessment purposes, the lowest no effect level (NOEL) when considering all studies for either maternal or fetal effects is 50 mg/kg/day. BPA does not cause reproductive or developmental effects at any realistic dose .

Carcinogenicity (7), (8), (9)
Bisphenol A is not a carcinogen, that is, it does not cause or induce cancer in laboratory animals. One of the most thorough studies in this area was performed by the U.S. National Toxicology Program. Based on lifetime exposure cancer bioassays, the authors found that "there was no convincing evidence that bisphenol A was carcinogenic for rats or mice of either sex" (NTP, 1982).
The conclusion of the International Agency for Research on Cancer and the United States Environmental Protection Agency's National Center for Environmental Assessment is, "BPA is not a carcinogenic risk to humans."

Metabolism (10)

Bisphenol A is rapidly metabolized in live animals and extensively excreted in urine and feces. A study conducted by The Society of the Plastics Industry shows that levels of bisphenol A in the blood were much lower for oral doses than for other routes of administration, such as injection in the abdominal cavity or under the skin. Bisphenol A has not been shown to accumulate in test animals.

(1) Ema M. Fujii, et al., Rat two-generation reproductive toxicity study of Bisphenol A, Reproductive Toxicoloty, 15(5) 502-523, September-October 2001

(2) Tyl, R.W. et al., Three-Generation Reproductive Toxicity Study of Dietary Bisphenol A in CD Sprague-Dawley Rats", Toxicological Science, 68, 121-146 (2002)

(3) Dodds, E.C. and Lawson, W. 1936. Synthetic estrogenic agents without the phenanthrene nucleus. Nature 137: 996.

(4) A.V.Krishnan, et.al., Endocrinology. 132(6), 2278-2286 (1993)

(5) S.R.Milligan, et.al., Environ. Health Perspect, 106.23-26 (1998)

(6) Environ. Health Perspect, 105(Sup.1), 273-274 (1995)

(7) BUA Report 203, Bisphenol A, p75-85 (December 1995)

(8) SPI: Bisphenol A: Summary of the toxicology studies, estrogenicity data and an estimation of no-obseved-effect level (1995)

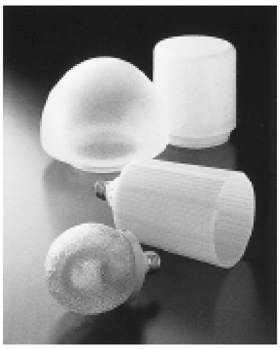
(9) TR-215 Carcinogenisis Bioassay of Bisphenol A (1982)

(10) L.H.Pottenger, et.al, Toxicological Sciences, 54, 3-18 (2000)

High Performance **Polycarbonate Product**

- Lightweight
- Heat Resistant
- Non-Flammable
- Distortion Resistant

Camera ▶



- Transparent
- Lightweight
- Break Resistant
- Heat Resistant

◀ Light Covers

Q3-4

What is the low-dose issue of Bisphenol A?

A

When bisphenol A, in doses far lower than the allowable intake, was repeatedly administered to pregnant mice, prostatic hypertrophy and a low sperm counts were recognized in juvenile mice Thus, a question about the conventional allowable intake was raised by Dr. vom Saal, et al. of Missouri State University.
A number of researchers have carried out experiments with greater numbers of animals and altered dosages; however, no abnormality has been replicated.
The U.S. NTP (National Toxicology Program) reviewed these reports and published their opinions in spring 2001; these effects are not recognized as definitive phenomena that are general or reproducible, and are problems to be studied. There are, however, reliable grounds for suspecting the existence of low-dose effects of bisphenol A.

Based on the results of animal experiments on the reproductive toxicity of bisphenol A as well as on general toxicity, the allowable intake that causes no problems even when taken continuously everyday is specified to be 0.05 mg/kg body weight/day in humans. According to this level, the safety standards for foodstuffs is regulated in Japan, Europe and America. Nonetheless, Dr. vom Saal et. al. of Missouri State University has reported results of experiments in which there are abnormalities such as prostatic hypertrophy and a decrease in the sperm count in juvenile mice after repeated administration of 1/2000 to 1/20,000 of the allowable intake (20 μg/kg bodyweight/day, 2 μ/kg bodyweight/day) to pregnant mice.[1)]
Since the above results differ from conventional toxicological findings, a number of researchers have carried out large-scale experiments as follows.

- Reproduction experiments in mice conducted in MPI research laboratories in the U.S.(SeeQ3-5, (1))
- Two-generation study in rats in welfare scientific studies (See Q3-5, (2))
- Three-generation study in rats conducted by the U.S RTI (Research Triangle Institute) (SeeQ3-5, (3))

Since a variety of investigational results have been reported, the Environmental Protection Agency (EPA) has requested the National Toxicology Program (NTP) affiliated with the National Institute of Environmental Health Science (NIEHS) for specialist advice on the low-dose issue. In response to the above request, the NTP held a Peer Review Panel in October 2000.

Government officials from the U.S., Canada and Japan (35 in total) and about 170 NGO members of the U.S. Consumers' Federation as well as the Chemical Industry Associations, environmental protection organizations (WWF, etc.) of Japan, the U.S. and Europe joined this Peer Review Panel.

1) Nagel, S.C., F.S. vomSaal, et al. (1997), "Relative binding affinity-serum modified access assay predicts the relative in vivo bioactivity of xenoestrogens bisphenol A and octylphenol." Environmental Health Perspective 105 (1): 70–76

The official opinion of the NTP summarizing the results of this Peer Review Panel are as follows.

(Original English-language text in the NTP 2001 “The National Toxicology Program Endocrine Disrupters Low-Dose Peer Review Final Report, August 2001”)

There is credible evidence that low dose of BPA can cause effects on specific endpoints.
However, due to the inability of other credible studies in several different laboratories to observe low dose effects of BPA, and the consistency of these negative studies, the Sub-panel is not persuaded that a low dose effect of BPA has conclusively been established as a general or reproducible finding.
In addition, for those studies in which low dose effects have been observed, the mechanism(s) remains uncertain (i.e., hormone related or otherwise) and the biological relevance is unclear.

High Performance **Polycarbonate Product**

- Transparent
- Lightweight
- Break Resistant
- Heat Resistant

Swimming Pool Ceiling ▶

Q3-5

What are the recent test results on the low-dose toxicity effects of Bisphenol A?

A

The following are the reported results of the studies on the low dose effects that were conducted during a period from 1998 to 2002.
No abnormality due to low doses was recognized in any of the following experiments.

(1) Reproduction tests of the Dr. vom Saal's experimental results by the U.S. MPI
More reliable tests were carried out by increasing the number of mice.
(2) Two-generation proliferative toxicity tests by the Ministry of Health, Labor and Welfare
Proliferative toxicity tests up to the second generation of rats were carried out.
(3) Three-generation tests by Dr. Tyl of the U.S. RTI
Proliferative and general toxicity tests up to the third generation of rats in a wide range of dose were carried out, this gained a reputation for being a highly reliable test.

(1) The results of reproduction experiments conducted by MPI, an U.S. official safety research organization

The U.S Society of the Plastic Industry (SPI) and European Chemical Industry Association (CEFIC) conducted the reproduction tests by consigning to MPI in relation to Dr. vom Saal's experiments. (Table 9-1)

No similar abnormalities were reproduced in the results although the number of mice was increased in the experiments.

The above results were disclosed in the following academic journal:
"Cagen, S.Z., J.M. Waechter, et al. Normal Reproductive Organ Development CF-1 Mice following Prenatal Exposure to Bisphenol A" Toxicological Science 50,36-44 (1999)

From Japan, the Bisphenol-A Safety Committee of Japanese Manufacturers, the Polycarbonate Resin Manufacturers Group of Japan and the Epoxy Resin Manufacturers Association in Japan also participated in the research activities.

(2) The results of the two-generation experiments in the welfare scientific research.

The Ministry of Health, Labor and Welfare (former Ministry of Health and Welfare) consigned the National Institute of Health Sciences to carry out tests on the proliferate toxicity of bisphenol A in two-generations of rats. (Table 9-2)

No definite changes conceivably due to the effects of bisphenol A were recognized using the same low oral dose administered in the experiments carried out by Dr. vom Saal, on the conditions of genital organs, reproductive functions and hormonal dynamics over the two generations.

The results of the above experiments were released in the following academic journal:
Ema M, Fujii S, Furujawa M, Kiguchi M, Harazono A; Rat two-generation reproductive toxicity study of bisphenol A, Reproductive Toxicology, 15(5) 502-523, September-October 2001

(3) The results of the three-generation experiments carried out by Dr. Tyl et. al. of RTI

Bisphenol A in the same low to high doses as in the experiments carried out by Dr. vom Saal were administered from parent to child to grandchild to great-grandchild of animals in an attempt to obtain more details. (Table 9-3)

In addition to ordinary indicators (life or death, body weight, feed intake, general conditions, weights of major organs, eyes examination, parity, proliferative index, etc.), other indicators for investigating hormonal effects (examinations of sexual maturity period, mating season, genital organs, sperm, etc.) were studied, no abnormality due to low doses was recognized, since the amount relating of proliferative toxicity was 50 mg/kg-bodyweight/day and the same of general toxicity was considered to be above 5 mg/kg-bodyweight/day.

The above results are released in the following academic journal:
"Tyl, R.W., C.B. Myers, et al. Three-Generation Reproductive Toxicity Study of Dietary Bisphenol A in CD Sprague-Dawley Rats", Toxicological Science, 68, 121-146 (2002)

(Table 9-1) Low dose Tests on Bisphenol A (MPI Research vs. vom Saal Research)

Assignment to Study and Parameters measured		SPI/CEFIC (MPI Research USA)	vom Saal (Missouri Univ. USA)
Dose Level （μg/Kg/Day）		0/0.2/2/20/200	0/2/20
Gestation Days		11-17	11-17
Number of Mice at each Dose level		28	7
Total Number of Mice		112	14
Number of Pups		100	14
Number of Tested Mice Measurement of Sex Development		309 90 days of age	14 108 days of age
Parameters measured and Results	Body weight	No Effects	—
	Brain	No Effects	—
	Epididymis	No Effects	—
	Right caudal epididymis	No Effects	—
	Kidney	No Effects	—
	Liver	No Effects	—
	Preputial gland Kidney	No Effects	—
	Prostate	No Effects	Effect on weight
	Seminal vesicle	No Effects	—
	Testis	No Effects	—
	Sperm	No Effects	Effect on daily sperm production

(Table 9-2) Low dose Tests on Rat Two Generation Reproductive Toxicity Study of Bisphenol A

Summary of Tests	To determine the low-dose effects of Bisphenol A(BPA) in two-generation (F0/F1/F2) reproduction, BPA were given to male and female rats.
Dose Level Dosing Method Number of Rats	0/0.2/2/20/200μg/Kg/Day dose BPA solved in water once daily by gastric intubations 25 male and 25 female / group
Parameters measured	Parents of F0/F1/F2/F3 Body weigh, Organ weight and Brain, Heart, Lung, Liver. Prostate,Thymus Testis, etc., Gestation, Lactation period, Vaginal opening, Sperm and parameters, General toxicity , etc.
Results	*No changes in epididymal sperm count/montility in Fo/F1 males. *No necropsy findings or effects on organ weight including the reproductive organs in any generation. *No histopathologic evidence in any organs including the reproductive organs of both sexes. *No significant changes/effects indicated in reproductive or developmental parameters at dose of BPA between 0.2 and 200μg/Kg/Day

(Table 9-3) Three Generation Reproductive Toxicity Study of Dietry Bisphenol A in CD Sprague-Dawley Rats

Summary of Tests	To determine the low-dose effects of Bisphenol A(BPA) in two-generation (F0/F1/F2/F3) reproduction, BPA was given to male and female rats.
Dose Level and Dosing Method Number of Rats	0/0/015/0/3/4.5/75/750/7500 ppm (～0.001/0.02/0.3/5/50/500 mg/Kg/day) dose BPA in diet 30 male and 30 female / group
Parameters measured	Parents of F0/F1/F2/F3 Body weigh, Organ weight and Brain, Heart, Lung, Liver, Prostate, Thymus, Testis, etc., Gestation, Lactation period, Vaginal opening, Sperm and parameters, General toxicity , etc.
Results	*at 500 mg/Kg/day(7500ppm) No effects on reproductive organ histopathology and function Reduced body weight and reduced number of off-spring in F1/F2/F3. *at 50 mg/Kg/day(750ppm) Slightly reduced body weight *at 5 mg/Kg/day(75ppm) No effects in any parameters *No adverse Effect level (NOAEL) Adult systemic NOAEL = 5 mg/Kg/day(75ppm) Reproductive and postnatal NOAEL = 50 mg/Kg/day(750ppm)

Q3-6

We understand that the allowable intake level of bisphenol A is being reviewed in Europe; how is it being treated in Japan?

A

We think that the latest data used for reviewing the allowable intake level in Europe are not relevant to the alteration of the allowable intake level (0.05 mg/kg-bodyweight/day) which is the basis of the existing migration standard, specified in the Notification No. 370 issued by the Ministry of Health and Welfare (current Ministry of Health, Labor and Welfare) in Japan.
As for the review by the European SCF (Science Committee on Food), the migration of bisphenol A from a polycarbonate product is far less than the post-review allowable intake level and thus the safety recommendations for the use of tableware, baby bottles and other food-contact containers will remain unchanged.

The following are the European SCF's comparison between post-review allowable intake levels of bisphenol A and the former ones.

Item	SCF's Review	Conventional level
Inactive amount	5 mg/kg-bw/day (an inactive amount obtained in general toxicity tests up to the third generation, conducted by Dr. Tyle)	25 mg/kg-bw/day
Safety ratio (an indefinite coefficient)	500 (10: difference by animal species 10: difference by individuals 5: uncertainty of database)	same as left
Tolerable Daily intake (TDI)	0.01 mg/kg-bw/day (treated as temporary TDI)	0.05 mg/kg-bw/day

For example, suppose the migration standard for individual specifications of polycarbonate stipulated in Notification No. 18 issued by the Ministry of Health and Welfare is used as the basis for revision, the migration standard will become as follows.

0.01 mg/kg-bw/day x 50 kg (human body weight) ÷ 1 kg/day (daily food intake) = 0.5 ppm

In other words, one fifth of 2.5 ppm, which is the existing migration standard

Even when the migration standard becomes 0.5 ppm, there will be no effective reason to change procedures, since the migration amount from a polycarbonate product is far less than this level (ND-0.01ppm).

Q3-7

How does Bisphenol A accumulate?

A

Bisphenol A is not considered to accumulate in vivo, and so does not cause biological concentration through the food-chain.

As for accumulation, 28% of bisphenol A was excreted into urine and 56% into feces, 8 days after a single oral administration of bisphenol A, labeled with ^{14}C, in male rats, while it was reported that no in vivo accumulation was recognized 8 days after administration.[1) 2)] It was also confirmed by the additional tests on the existing chemical substances carried out by the Ministry of Economy, Trade and Industry that the concentration coefficient in the accumulation in aquatic creatures was 5.1 ~ 68. Since the judgment basis as to whether or not the biological concentration exists is 100, it is conceivable that no biological accumulation exists in aquatic creatures as the accumulation level is lower than the above standard.
Even when bisphenol A is taken into vivo, it changes to glucuronides in the liver. In addition, as residual time in vivo is about 6 hours, bisphenol A is easily excreted with urine and feces.

1) Knaak J. B.,; Sullivan L. J., "Metabolism of bisphenol A in the rat, Toxicol. Appl Pharmacol", 8, 175-184, 1966
2) Sangyo Keizai Shimbun, Evening edition dated August 20, 1998

Q3-8

What is the biodegradability of Bisphenol A?

A

Bisphenol A decomposes in acclimated active sludge. It is also decomposed in river water.

It has been confirmed that bisphenol A does not decompose under the test conditions specified by CDIL (Chemical Drug Inspection Law), but decomposes in acclimated active sludge and also in river water. It is also reported that bisphenol A at the concentration of 3 mg/L decomposed within 4 days and remained concentrated below 0.1 mg/L.[1)]

*When active sludge, a mud-like substance that contains microorganisms and protozoa, mixed with factory waste and sewage, is aerated, organic substances are oxidatively decomposed by microorganisms and partially incorporated in microorganisms before the waste is purified. Acclimated active sludge is active sludge that is acclimated with bisphenol A for easier decomposition.

1) "Aromatics," vol. 5, No. 3–4 (1998), p 46–62

High Performance **Polycarbonate Product**

- Transparent
- Lightweight
- Break Resistant
- Heat Resistant

Arcade ▶

Q3-9

The effects of bisphenol A on the cerebral nerve and immune system of fetuses/newborns have recently been reported; are these reports reliable?

A

The results of these studies on bisphenol A have been reported, but since the review of its evaluation methods has just started, we have no confirmation as to whether or not this substance has such effects. The effects may be clarified, however, by future investigations. Polycarbonates have been used in various applications since their inception, as no adverse effects have been reported, they are safe to use.

At the 4th International Symposium on Environmental Endocrine Disrupters, sponsored by the Ministry of Environment and held in December 2001, Mr. Yoichiro Kuroda of Tokyo Metropolitan Institute for Neuroscience made the following comments in Session 1 (Effects on the Brain and Behavioral Development).

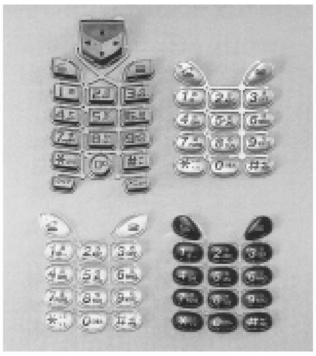
“The data obtainable by the toxicological and epidemiological investigations enabling us to answer such pivotal questions as “what kinds of chemical substances are responsible for which abnormalities of the brain functions in developmental stage” are extremely limited. The research to investigate the behavioral abnormalities of the next generation in experimental animals needs significantly more work and year-unit periods in addition to there being more than several hundred chemical substances yet to be studied. Thus, assay systems for actual screening are required.”

In the experimental results currently being reported, there are a number of case studies under conditions of intake such as injections directly to the brain or joint administration with a narcotic, which are extremely different from actual conditions and actual daily life.

High Performance **Polycarbonate Product**

- Lightweight
- Heat Resistant
- Non-Flammable
- Distortion Resistant

Cellular Phone Keys ▶



Q4-1

Is bisphenol A discharged into the environment during the manufacturing process of polycarbonate resin or the molding process of products?

A

During the manufacturing process of polycarbonate resin, wastewater is allowed to be discharged after bisphenol A has been processed by an activated sludge. Bisphenol A is not discharged during the course of the molding process of polycarbonate products.

It has been confirmed by testing whether or not bisphenol A is discharged into the environment during each manufacturing process of polycarbonate resin.

1) Manufacturing process of polycarbonate

During the manufacturing process of polycarbonate resin using the solvent method, non-reacted bisphenol A is collected for repeated use. The collected waste water is processed with activated sludge, further treated for active carbon adsorption and ozone treatment, etc. before bisphenol A is decomposed and removed for emission.
When the melting method is employed, bisphenol A is not discharged into the environment since polycarbonate resin is manufactured in closed facilities.
Incidentally, the concentration of bisphenol A was below 0.01 ppm, the same as other sea level areas, when it was measured in the sea nearby a polycarbonate resin manufacturing plant.

2) Manufacturing process of pellets for molding materials

An attempt was made to analyze whether or not bisphenol A was contained in the cooling water during the process of cooling the string-shaped resin extruded as shown in an illustration (an outline of a pellet manufacturing apparatus) in Q1-5. No bisphenol A was detected in the cooling water which was collected during the manufacturing process. Thus, bisphenol A is not discharged during the process of manufacturing pellets for molding materials.

3) Process of molding a product

As shown in Fig. 1 (injection molding) referred to in Q1-6, melted polycarbonate resin injected into a mold becomes a product when hardened. Thus, bisphenol A is not discharged into the environment during this process and other molding processes.

Q4-2

Are there any precautions required for the disposal of polycarbonate products?

A

No precautions in particular. You can dispose of polycarbonate products as plastic waste in accordance with the regulations specified by local governments.

The Waste Disposal Law classifies disposal sites into three categories, namely stabilized disposal sites, controlled disposal sites, and secluded disposal sites. Plastic waste including polycarbonate products are burned in an incinerator or disposed of at a stabilized disposal site. “Embers” of incinerated plastic wastes are disposed of at a controlled disposal site.

(Table 10) Kinds of Industrial Waste Disposal Facilities

Disposal Site	Disposal & Management	Disposable Industry Waste
Stabilized Disposal Site	•Industrial waste having no risk of becoming hazardous when covered with rainwater kept for a long period, and no risk of polluting the nearby environment	Plastics, rubbers, metals, glass, ceramics, construction materials, etc.
Controlled Disposal Site	•Employ sealing structure for the bottom of the landfill, using clay, vinyl & rubber sheets, etc. to prevent ground water from being polluted by leaching •Provide gutter on the landfill to prevent entry of rain water. Sewage disposal facilities for drainage from the landfill.	Cinder, sludge, wood, paper, textiles, animal feces and urine, animal corpses, dust/mullock, etc.
Secluded Disposal	•Industrial waste containing hazardous substances over the regulated level	Products which have serious effects on human health and the environment. Hg, Cd, Pb, Organic Phosphate, Cr(VI), As, Se, CN-compounds, PCB, and their compounds

Q4-3

It was reported that bisphenol A was detected in the rivers nearby plastic waste disposal sites; is this attributable to polycarbonate products disposal?

A

We don't think it is attributable to the disposal of polycarbonate, since polycarbonate waste makes up an insignificant amount of total plastic waste, and so the migrated amount of bisphenol A is not significant.

According to the Plastic Waste Management Institute's investigation in 2000, it was assumed that the amount of land filled plastics was 3,070.000 tons out of 10,980,000 tons of all plastics used domestically. (the investigation material in 2000)
Approximately 200,000 tons of polycarbonate was used domestically in 2000. Suppose half the above amount was disposed of, it is only 2% of the total plastics used in land fill. Polycarbonate waste was hardly found in landfill sites. Besides, as the migration amount of bisphenol A from a polycarbonate product is a trace amount, we don't think it is attributable to polycarbonate disposal.

The migration of bisphenol A from plastic wastes and the amount of bisphenol A detected from rivers are described in many reports on the investigations carried out by publicly established research organizations and universities.

Table 11.[1)] and Table 12.[2)] show the results of measurement of migrated bisphenol A from plastic products. It is clear that more migrates from electric cord (PVC), synthetic leather, sheet, etc. than the extremely small amounts that migrate from polycarbonate products (storage containers, CDs).

Investigations carried out by the Kanagawa Environmental Research Center, the Environmental Monitoring Laboratory, etc. found that bisphenol A was detected in high concentrations from leachate from waste plastic disposal sites. [Table 13][3)] However, since it is not conceivable that polycarbonate products in large quantities were disposed of in these disposal sites, polycarbonate is unlikely to be the source of discharge of bisphenol A.

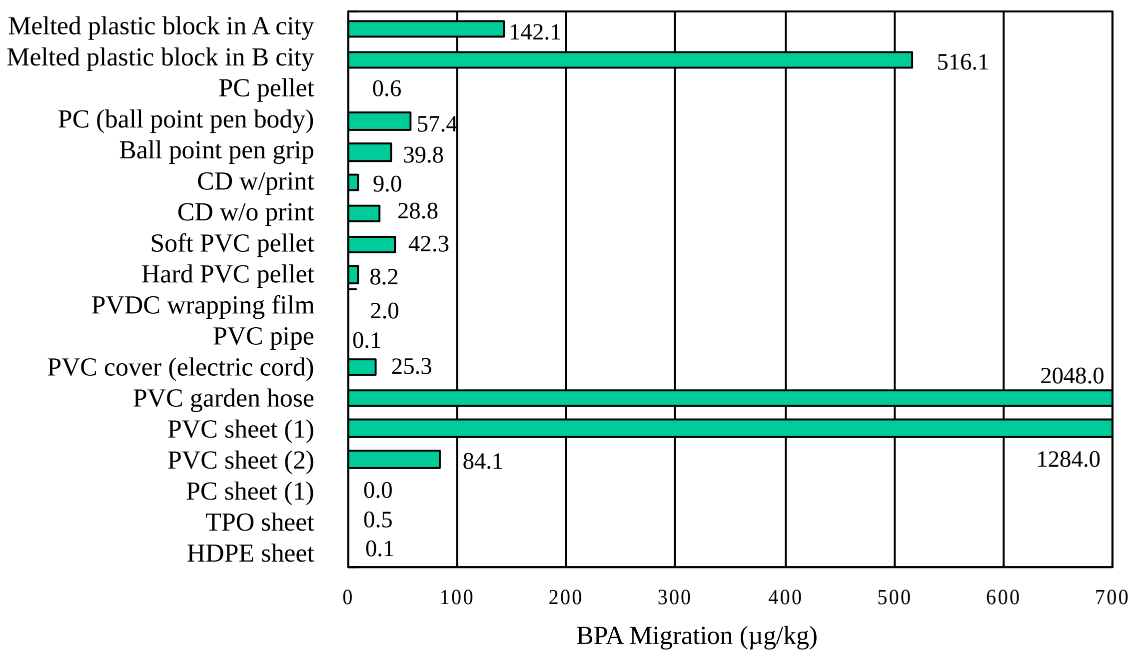
We think the specific sources of discharge and environmental countermeasures for reduction will be developed, as the respective administrative authorities are now carrying out broader investigations on the source of discharge of bisphenol A.

1) Takashi Yamamoto, Akio Yasuhara: Migration of bisphenol A from waste plastics, at the 7th Meeting of Japan Society for Environmental Chemistry. P252-253, 1998
2) Tsutomu Imaoka, Yusou Hotehama: Migration of bisphenol A from waste plastic system materials, at the 2nd study meeting of the Japan Society of Waste Management Experts, P 1011–1013, 2001
3) Hiromi Sakamoto, Hiroshi Fukui, at the study meeting of 11th Japan Society of Waste Management Experts, p1098-1100, 2000

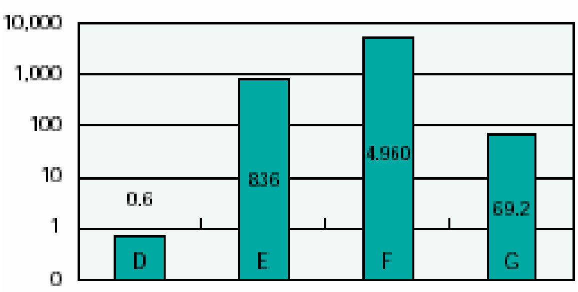
(Table 11)　Plastics supplied for the experiments and the migrated bisphenol A.

	Aspect	Material		Migration Test (water)	
		Name	BPA content (ng/g)	Duration (day)	Migration (μg/L)
1	storage container, transparent	polycarbonate	4.2	12	1.1
2	film, black	not known	9.1	14	1.6
3	wiring plug, gray	not known	3.3	14	1.4
4	electric cord, gray	pvc	1980	14	700
5	sheet, white	not known	N.D.	13	N.D.
6	wiring plug, white	not known	N.D.	13	N.D.
7	synthetic leather, gray	not known	9810	13	2250
8	wiring plug, blue	not known	N.D.	14	N.D.
9	synthetics, gray	not known	N.D.	14	N.D.
10	sheet, translucent	not known	168	14	26
11	film, translucent	not known	N.D.	13	N.D.
12	wiring plug, black	not known	77	13	18
13	synthetic leather, gray	not known	139000	14	12300
14	wiring plug, green	not known	N.D.	14	N.D.
15	IC board	phenol resin	67.7	14	10.1
16	CD	polycarbonate	23.3	14	6.0
17	pipe, gray	pvc	10.7	14	3.0

(Table 12)　The results of migration tests on waste plastics and plastic materials



(Table 13) Migration of bisphenol A from terminal waste disposal sites

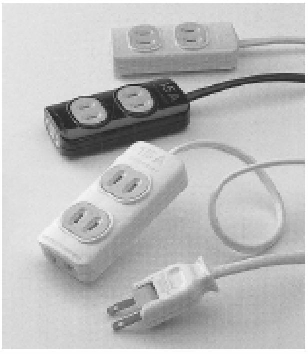


	D Site	E Site	F Site	G Site	H Site
Start of landfill	1st phase 1993~ 2nd phase 1999~	1986~	1st phase 1984~ 2nd phase 1998~	1988~	1997~
What landfilled	Incineration ash	Incineration ash Crushed waste	Incineration ash Crushed waste	Incineration ash Crushed waste	Incineration ash
Waste Landfilled in 1997 (m3)	-	5,211	1,655	8,366	1,018
Landfill Site Capacity (m3)	25,500	155,170	456,000	158,700	200,000
Total Waste Landfilled in 2000 (m3)	11,239	109,412	211,574	143,168	1,222

High Performance **Polycarbonate Product**

- Lightweight
- Heat Resistant
- Non-Flammable
- Distortion Resistant

Plugs & Outlets ▶



Q5-1

Polycarbonate resin has been used for returnable milk bottles and drinking water bottles in Europe and America. What are consumer reactions?

A

Consumers have continued to use these products as before the endocrine issue was raised.

In Europe, polycarbonate resin is used mainly in Germany and Holland for returnable milk bottles and mineral water, etc. In Germany, polycarbonate bottles have been used for 9 years complying with the government basic policy for not increasing "one-way bottles."

A representative German dairy company made the following statement. (Report released in relation with the reuse-model business consigned by the Ministry of Environment in 1997).

1) Milk bottles and other tableware that meet the specifications of the U.S.FDA are used. Dairy products containers made of polycarbonate were investigated in the U.S. in 1990, and as a result, it was announced that they have no adverse effects on the health of babies given dairy products contained in the polycarbonate bottles.
2) Polycarbonate is adopted as it has high heat resistance and does not absorb original food tastes.
3) The same returnable bottle is used roughly 50 times.

Because of the above safety features, polycarbonate bottles are used for returnable milk bottles.
As for drinking water bottles, 20-liter bottles are widely used in both Europe and America. Many people have seen these transparent bottles atop water coolers.
No other material is better than a rigid polycarbonate bottle, which even when filled with 20-liters of mineral water is still light enough to be set on a water cooler. As the bottle is transparent, the remaining amount can be seen at a glance.

High Performance	Polycarbonate Product
• Lightweight • Safe/Hygienic Water Bottles ▶	

Q5-2

What do you think about the safety of polycarbonate tableware and baby bottles?

A

These products are safe to use.
The Food Hygiene Law (Notification No.370 issued by the MHW) set migration levels from polycarbonate products into food below 2.5 ppm (2500ppb). (See Q2-5)
The maximum migration level of bisphenol A detected from tableware and baby bottles used under normal conditions is 50 ppb. (See Q2-7)

50 ppb ÷ 2500 ppb = 0.02 (below 1/50 level under normal conditions)

Polycarbonate resin is a high-performance plastic characterized by its transparency, light weight, durability, impact resistance, strength and heat resistance. Food-contact products such as tableware, baby bottles, water bottles, reusable food containers made of polycarbonate resin are safe to use and have numerous benefits.
According to the Expert Report on Endocrine Disrupting Substances of the Ministry of Welfare (currently the Ministry of Health, Labor and Welfare) 2002, “No reproducible experimental results have been obtained and at this point of time, it is doubtful whether we can conclude that there are endocrine disrupting effects in the low-dose range”
In Japan, Ministries and local government agencies do not prohibit the production and sale food-contact products made of polycarbonate resin. Consequently PC tableware and PC baby bottles are produced and marketed in the Japanese market.

◆ **Polycarbonate Tableware**
Japan Industry Union of Plastic Housewares Manufacturers (JIUPHM) made “The Production Guidelines on Polycarbonate Tableware and The Notes on Use of Polycarbonate Tableware” in 1999.

◆ **Polycarbonate Baby Bottles**
Japan Conference of Baby Bottle Manufacturers (JCBM) made the production guidelines and the notes for safe use (in 2000) in response to the requests of the Bureau of Public Health Tokyo Metropolitan Government as below.

- “The Production Guidelines on Polycarbonate Baby Bottles” describes how to produce hygienic products with less bisphenol A.

- “The Notes on Use of Polycarbonate Baby Bottles for Consumers” and “The Notes on Use of Polycarbonate Baby Bottles for Maternity Hospital and Facilities” describes their safe and hygienic use.

* Production Guidelines for PC baby bottle manufacturers（in Japanese).
http://www.kenkou.metro.tokyo,jp/shokuhin/news/1999/000223-2.html

* Notes on use of PC Baby bottles for consumers and maternity hospitals（in Japanese).
    http://www.kenkou.metro.tokyo,jp/shokuhin/news/1999/000223-3.html
    http://www.kenkou.metro.tokyo,jp/shokuhin/news/1999/000223-4.html

Polycarbonate tableware and baby bottles are manufactured under strict process controls as well as quality controls covering the materials and products. They are safe to use when observing the relevant precautions of the respective products.

* We are supplying safer materials to be used for food-related products including baby bottles through a strict independent control standard, and observance of the specification standard in Notification No. 370 issued by the Ministry of Health, Labor and Welfare in accordance with the Food Hygiene Law.

* As for tableware, we are promoting a safer molding method through compliance with the precautions for handling and the molding process guidelines established by the Japan Industry Union of Plastic House ware Manufactures.

* We are also promoting the safe production of baby bottles through compliance with the precautions for handling and the production guidelines established by the five companies' liaison assembly on baby bottles.

It is important to remember the advantages of polycarbonate tableware and baby bottles, which cannot be equaled by other materials.

*** Polycarbonate tableware has the following advantages.**

- Does not break when dropped or used with other tableware
- Light and easy to carry
- Easy to wash as it sinks in water and is easy to sterilize in boiling water
- Heat resistant
- Can hold and carry hot food such as soup because it insulates heat
- Available in colorful designs

*** Polycarbonate baby bottles have the following advantages.**

- Safe as they don't break like glass products
- Light and easy to carry
- Heat resistant
- Easy to sterilize in boiling water
- Transparent and easy to see remaining contents

Q5-3

How are polycarbonate manufacturers coping with the environmental hormones issue of Bisphenol A in Japan?

A

The manufacturers supplying polycarbonate have organized the Polycarbonate Resin Manufacturers Group to conduct safety-related tests and collect domestic and overseas data /information on safety. The group published Q & A sheets as well as set up a web-site, etc. and thereby keeps on providing the manufacturers and consumers of polycarbonate products with up-to-date information. They are also doing all they can to liaise with relevant organizations to disseminate the most up to date information.

Global efforts to tackle the issue are described in Q5-4, but domestically we are making every possible effort to collect technical information concerning safety through cooperation with the following organizations.

(1) Japan Chemical Industry Association (JCIA)

JCIA is participating in investigation, collection and exchange of information on common chemical substances, as well as taking part in relevant lectures and international conferences, etc. JCIA is also conducting international activities such as LRI (Long-range Research Initiative) and Responsible Care Activities.

(2) BPA/PC/EX Committee

The committee, which consists of the BPA Safety Committee of Japanese Manufacturers, the Polycarbonate Resin Manufacturers Group and the Epoxy Resin Industry Association, is working on common issues.

The BPA Safety Committee of Japanese Manufacturers is organized by the following 4 BPA manufacturing companies and conducts investigation and research activities on the safety of bisphenol A.

- Idemitsu Kosan Co., Ltd.
- Nippon Steel Chemical Co., Ltd.
- Mitsui Chemicals, Inc.
- Mitsubishi Chemical Corporation

The Polycarbonate Resin Manufacturers Group's webside**(P-Magazine)** discloses news on polycarbonate resin, polycarbonate products and bisphenol A as well as technical data and safety information.
Please visit (P-Magazine) http://www.polycarbo.gr.jp/

Q5-4

How are you cooperating with overseas polycarbonate and bisphenol A manufacturers in relation to the environmental hormone issue?

A

We organized the PC/BPA Global Team in cooperation with polycarbonate and bisphenol manufacturers in Europe and America in an attempt to collect/exchange information concerning the environmental hormone issue and to collect /analyze scientific data obtained from various tests. From a common point of view, we are reporting relevant information to polycarbonate manufacturers, consumers and also to each country's government.

It is required for bisphenol A and polycarbonate manufacturers worldwide to fully cooperate with each other to cope with the endocrine disrupter issue, not only in Japan but also in all other countries in the world.

In view of the above concept, in late 2000 the leaders of the business departments of the bisphenol A and polycarbonate manufacturers met together and reached an agreement to globally respond to the issue. Under a "Leadership Team" consisting of the principals, a "Science Team" is working on scientific investigations of the effects on aquatic creatures, animals, human beings, etc. and a "PR/Advocacy Team" is working on collection and disclosure of the required information.

(1) Companies and organizations participating in the PC/BPA Global Team

Japan:
- Polycarbonate Resin Manufacturers Group (polycarbonate resin)
- Bisphenol-A Safety Committee of Japanese Manufacturers (bisphenol A)

Europe and America:
- SABIC Innovative Plastics (polycarbonate resin, bisphenol A)
- Bayer MaterialScience (polycarbonate resin, bisphenol A)
- Dow Chemical (polycarbonate resin, bisphenol A)
- Sunoco (bisphenol A)

(2) Major scientific tests conducted by PC/BPA Global Team

- Bisphenol A low-dose test in mice (Reproduction test by Dr. vom Saal of Missouri State University)
- Bisphenol A low-dose test for multi generation in rats by Dr. Tyl
- Bisphenol A risk assessment test in mice, snails, fishes in response to the request by the European Parliament (on-going)