



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

A WHO Collaborating Centre for
Food Contamination Monitoring



World Health
Organization

December, 2009



Canada

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Published by Authority of the Minister of Health.

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature is available on Internet at the following address:

<http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/index-eng.php>

Également disponible en français sous le titre :

Enquête sur la migration potentielle de bisphénol A dans les préparations liquides en conserve pour nourrissons selon leur durée d'entreposage à la température ambiante

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2009.

Cat.: H164-114/2009E-PDF

ISBN: 978-1-100-14332-3

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

TABLE OF CONTENTS

Background	4
Sampling Plan and Analytical Methodology.....	4
BPA Levels in Canned Liquid Infant Formula Products.....	5
Health Significance of the Survey Results.....	6
Table 1: Concentrations (ng/g) of BPA in canned liquid infant formula products as consumed	7

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Background

Bisphenol A (BPA) is the common name for 2,2-(4,4'-dihydroxydiphenyl)propane, 4,4'-isopropylidenediphenol, or 2,2'-bis(4-hydroxyphenyl)propane. It is used as an intermediate in the production of epoxy resins which are used in the internal coating for food and beverage cans to protect the food from direct contact with metal. Residues of BPA can migrate from these coatings into foods, especially at elevated temperatures (for example, for hot-fill or heat-processed canned foods). BPA is one of the 23000 chemical substances on the CEPA (Canadian Environmental Protection Act) Domestic Substance List (DSL) identified for further evaluation under the Government of Canada's Chemical Management Plan (CMP).

BPA was included in [Batch 2 of the Challenge](#) under CMP carried out by Health Canada and Environment Canada. On October 18, 2008, the Government of Canada released its final assessment report, including the Government's proposed risk management approaches to reduce Canadian exposure to BPA. Health Canada has committed to a research and monitoring agenda in order to further investigate potential human health effects of BPA and improve its understanding of Canadian exposure to this chemical through food sources. The purpose of this investigation was to determine the effect of storage time on BPA migration from can coatings to liquid infant formula at room temperature. The results of this investigation were also submitted for publication in a peer-reviewed scientific journal.

Sampling Plan and Analytical Methodology

The objective of this investigation was to examine possible changes in BPA levels in canned liquid infant formula after extended storage (10 months) at room temperature. This was achieved by analyzing the remaining unopened cans (all within the same lot for each product) of the 21 canned liquid infant formula products that were previously collected and analyzed for the [Survey of Bisphenol A in Canned Liquid Infant Formula](#).

Health Canada continually works to develop more sensitive laboratory methods with detection limits as low as possible for determining the possible presence of chemicals in foods. The method used previously by Health Canada for [determination of BPA in liquid infant formula](#) products was employed for this analysis. The average method detection limit (MDL) was 0.5 ng/g*. For each canned liquid infant formula product, two subsamples from each sample were analysed and the resulting average of the two analyses are shown in [Table 1](#).

* 1 ng/g is equivalent to 0.001 µg/g or 1 part per billion (ppb)

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Notes:

- ❑ The canned liquid infant formula samples were tested as purchased. These [results](#) have been adjusted to account for the product-recommended dilution factor and represent as consumed levels.
- ❑ It should be noted that the absence of any particular brand from this investigation means only that the brand was not included in the [original survey](#). No particular inference should be drawn from the presence or absence of any brand.
- ❑ Samples represent a “snapshot” of the Canadian marketplace at the time of sampling. Product names and availability correspond with the time of the original sampling and may not represent current products on the market. Differences between brands do not necessarily reflect differences in consumer exposure to BPA.
- ❑ The results shown in [Table 1](#) are generated for research purposes and should not be considered as representative of the distribution of BPA in all canned liquid infant formula products or to assist or guide product choices for consumers.

BPA Levels in Canned Liquid Infant Formula Products

The results from the [original October / November 2007 analysis](#) were compared to those obtained in September 2008 (10 months of storage) to determine whether there is a correlation between storage time and the level of BPA in liquid infant formula.

[Table 1](#) summarizes the levels of BPA determined from the 21 samples for both the 2007 and 2008 analyses. BPA was detected in all 21 products in both analyses. In 2007, detected levels of BPA ranged from 1.14 to 5.44 ng/g* with an overall average of 2.88 ng/g*. After storage at room temperature for 10 months, Health Canada detected levels of BPA in these same products from the same lot ranging from 1.39 to 6.18 ng/g* with an overall average of 3.64 ng/g*. All levels of BPA detected in each study are well below the specific migration limit of 600 ng/g* set by the EC Directive for BPA in food or food simulant.

BPA was detected in all 21 products; however when compared to the same products analyzed 10 months earlier, both increases and decreases were noted. Only 9 of 21 products had levels higher than that which could be attributed to variations from within-lot and repeatability of analysis. These findings indicate the possibility of BPA migration from can coatings during the extended storage at room temperature. It should be noted that 16 of 21 products were passed the expiration date by 10 to 206 days when they were analyzed. However, no obvious correlation between the product expiration date and the level of BPA migration was found.

* 1 ng/g is equivalent to 0.001 µg/g or 1 part per billion (ppb)

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Variation of BPA levels in different canned liquid infant formula products could be due to the differences in can coatings (type, amount etc.) or sterilization conditions (temperature and duration) used by different infant formula manufacturers. There is also evidence that can contents can affect migration of BPA.

Health Significance of the Survey Results

In March, 2008, Health Canada's Food Directorate completed a [Health Risk Assessment of BPA from food packaging applications](#)⁺ to determine exposure estimates to BPA. Health Canada's Food Directorate has concluded that:

- ❑ The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and young children.
 - The nutritional benefits of infant formula products far outweigh any possible risk.
- ❑ In view of uncertainties related to datasets on possible neurodevelopmental and behavioural effects that BPA may have in experimental animals, Health Canada's Food Directorate has recommended that precaution be exerted on products consumed by the most sensitive subset of the population; specifically, infants and newborns, by applying the ALARA (as low as reasonably achievable) principle to reduce their exposure to BPA through food packaging applications.

Other international food regulatory agencies – notably in the United States, Europe, the United Kingdom and Australia-New Zealand – have reviewed the "[Health Risk Assessment of Bisphenol A from Food Packaging Applications](#)⁺", prepared by Health Canada's Food Directorate, and have confirmed that the conclusions reached are supported by the current scientific evidence as described in this document.

The results of this survey clearly indicate that exposure to BPA through the consumption of canned liquid infant formula products would be extremely low. The low levels of BPA found in liquid infant formula products confirms Health Canada's previous assessment conclusion that the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the consumer.

⁺ Health Risk Assessment of Bisphenol A from Food Packaging Applications. ISBN: 978-0-662-48686-2

Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature

Table 1: Concentrations (ng/g) of BPA in canned liquid infant formula products as consumed

- It should be noted that the absence of any particular brand from this survey means only that the brand was not included in the original survey. No particular inference should be drawn from the presence or absence of any brand.
- Samples represent a “snapshot” of the market at the time of sampling. Product names and availability correspond to the time of sampling and may not represent current products on the market. Differences between brands do not necessarily reflect differences in consumer exposure to BPA.
- The results shown in the table are exploratory and should not be used to indicate the distribution of BPA in canned liquid infant formula products or to assist or guide product choices for consumers.

Company / Manufacturer	Brand Name	Product Description	Type	Infant age (months)	BPA concentration (ng/g)	
					2007	2008
Abbott Laboratories	Isomil	Isomil Advance Concentrate Soya Infant Formula with Omega-3 and Omega-6	Soya	0 - 12	4.47	4.19
		Isomil Infant Formula with Soya for Allergy and Sensitivity to Milk Protein	Soya	0 - 12	3.18	2.52
	Similac	Similac Advance with Omega-3 Omega-6 Infant Formula with Iron with Eye Q Nutrition System	Milk	0 - 12	4.25	6.18
		Similac Advance Lactose Free Concentrate Infant Formula	Milk	0 - 12	4.89	4.47
		Similac Advance with Omega-3 and Omega-6, Calcium enriched, Iron fortified Infant Formula	Milk	6 - 18	5.12	6.1
		Similac Advance Regular Concentrate Infant Formula	Milk	0 - 12	4.33	5.1
		Similac Advance Concentrate Infant Formula with Iron	Milk	6 - 18	4.08	4.68
PediaSure [∇]	PediaSure Complete Nutrition for Kids	Milk	12 and up	3.91	3.64	
Loblaws Inc.	President's Choice	President's Choice Infant Formula Concentrate with Iron + Omega-3 and Omega-6	Milk	0 - 12	1.87	2.97
		President's Choice Soya Infant Formula Concentrate Plus Omega-3 and Omega-6 with Iron	Soya	0 - 12	2.5	2.38
		President's Choice Infant Formula Concentrate	Milk	0 - 12	1.6	3.38
Mead Johnson Nutritionals	Enfapro	Enfapro Calcium Enriched Concentrate Infant Formula	Milk	6 and up	1.71	4.44
	Enfamil	Enfamil with Iron Fortified Infant Formula	Milk	0 - 12	2.72	2.85
		Enfamil A+ with LIPIL our blend of Omega-3 & Omega-6. Our closest formula to breast milk Infant Formula Iron Fortified	Milk	0 - 12	2.19	2.96
		Enfamil Lower Iron than other Enfamil brands Concentrate Infant Formula	Milk	0 - 12	2.43	2.63
	Enfagrow ⁺	Enfagrow Toddler Nutrition High in Iron and Calcium Nutritional Supplement	Milk	12 and up	5.44	6.03
Nestlé Nutrition	Nestlé	Nestle Alsoy Iron Fortified Soy Infant Formula Lactose Free and Vegetarian Omega-3 Omega-6	Soya	0 - 12	1.35	1.39
		Nestle Follow-Up Transition Iron Fortified Infant Formula Calcium Enriched	Milk	6 - 18	1.14	3.93
		Nestle Good Start 2 Iron Fortified with Added Calcium with Omega-3 Omega-6 Easier to Digest Infant Formula with Whole whey protein partially hydrolyzed by an exclusive process	Milk	6 - 18	1.14	2.34
		Nestle Good Start Iron Fortified with Omega-3 Omega-6 Easier to Digest Infant Formula Whole whey protein partially hydrolyzed by an exclusive process	Milk	0 - 12	1.15	2.21
		Nestle Good Start Iron Fortified Infant Formula with Whole whey protein partially hydrolyzed by an exclusive process	Milk	0 - 12	1.16	2.15

[∇] A nutritional supplement. Although typically consumed less frequently than infant formula, nutritional supplements do contribute to the overall BPA exposure for this sensitive subset of the population (i.e. infants).