MIGRATION OF BISPHENOL A AND PLASTICIZERS FROM PLASTIC FEEDING UTENSILS FOR BABIES

- Migration of bisphenol A (BPA) from baby bottles made of polycarbonate
- Migration of plasticizers from (soft) plastic baby cutlery (and drinking equipment)

Report no. ND05o410

Food and Consumer Product Safety Authority

June 2005

INDEX

SUMMARY and KEYWORDS

During their early years of life, children come into contact with plastic feeding utensils. These plastic materials may contain low amounts of chemical substances (such as monomers or additives). Normally they convert into non-noxious plastics or compounds. It is possible that starting substances or reaction products migrate from plastics into foodstuffs under certain conditions such as time, temperature, acidity or ultraviolet (UV) light. For infants the exposure to food, which has been in contact with plastic feeding utensils, is higher as compared to adults (per body weight, at similar conditions) due to their low body weight. Therefore, the chemical safety of these childcare articles is very important. In 2001, the chemical and mechanical safety of teats and soothers was already investigated. All teats and soothers, that were investigated, were safe for use.

In the present survey the safety of two other groups of feeding utensils for babies were investigated: i.e. baby bottles and (soft) plastic feeding utensils. In the Netherlands feeding utensils such as baby bottles, cutlery and drinking cups have to comply with the Packaging and Food utensils Regulation (Food and Commodities Act). In February 2005 a total of 22 new baby bottles and 22 (soft) plastic feeding utensils were sampled from the Dutch consumer market, both representing 14 different brands. In addition, 20 baby bottles were collected, representing 11 different brands, which had been used for 3 up to 36 months in households. All used baby bottles had been put in dishwashers or microwaves for cleaning, sterilisation or the preparing of food.

Baby bottles are often made of polycarbonate (PC). Bisphenol A (BPA) is one of the starting substances of PC and is suspected to have estrogenic (hormone disrupting) properties. Therefore, strict migration limits have been set for BPA. All new and used baby bottles were analysed for the migration of BPA according to European standard EN 14350-2. In nearly all tested baby bottles no migration of BPA was detected in either food simulant A and B (i.e. distilled water and 3% acetic acid). From only 4 used baby bottles traces of migration of BPA were detected in distilled water (below 0.0050 mg/L). These migrations are far below the Dutch specific migration limit (SML) of BPA: 3 mg/kg and 0.6 mg/kg in the near future. They are also tenfold lower than the SML of the European standard: 0.03 mg/kg. Influences of brand, period of use, frequency of boiling and use in microwave or dishwasher on the migration of BPA cannot be shown from this survey.

Soft plastic feeding utensils are commonly used for babies, because they reduce the risks of wounding during daily use. To soften plastics often so-called plasticizers are added during processing, which are sometimes (suspected) estrogenic compounds. All (soft) plastic feeding utensils (i.e. baby cutlery, spouts from drinking cups and sticks for ice-lollies) were screened on material composition. Polyolefines (PP and PE) were mainly found (80%), followed by silicones (PDMS) (8%). Plastics such as PC, PET, acrylonitrile butadiene styrene (ABS) and styrene block copolymer (SBC) were applied to a much smaller extent. PVC was not detected.
All (soft) plastic feeding utensils were also analysed for the migration of plasticizers and other substances. Only one (common) plasticizer was detected: di-2-ethylhexylphtalate (DEHP). A SML of 40 mg/kg applies for this plasticizer. Also antioxidants, photo-initiators, UV-stabilizers, lubricants, solvents (for printing inks), fatty acids, hydrocarbons and monomers/oligomers were detected. All detected migrants are listed in the positive list of the Dutch Packaging and Food-utensils Regulation. Also no restriction or specific migration limits apply for the migrants of 0.05 mg/kg up to 30 mg/kg. For several substances with a low SML official compliance tests were performed. The plasticizers and migrants did not exceed the legal specific migration limit.

All tested baby bottles and feeding utensils complied with the Dutch legislation and cannot be considered as unsafe for daily use. Therefore no enforcement measures were taken.

Keywords: baby bottles, feeding utensils, migration, bisphenol A, plasticizers, plastics, identification, screening.

SAMENVATTING en TREFWOORDEN

In hun eerste levensjaren komen baby's in contact met kunststoffen gebruiksartikelen. Kunststoffen kunnen lage hoeveelheden aan chemische stoffen bevatten, zoals monomeren en additieven. Deze worden normaliter omgezet in niet-schadelijke (kunst)stoffen. De uitgangsstoffen of reactieproducten kunnen uit kunststof migreren in zuigelingenvoeding door omstandigheden als tijd, temperatuur, zuurgraad of ultraviolet (UV) licht. Door hun lage lichaamsgewicht is de blootstelling aan voedsel, dat in contact is geweest met kunststof, hoger voor baby's vergeleken met volwassen (per lichaamsgewicht, onder dezelfde omstandigheden). De chemische veiligheid van kunststoffen kindergebruiksartikelen is daarom erg belangrijk. In 2001 is de chemische en mechanische veiligheid van (fop)spenen al onderzocht. Alle onderzochte (fop)spenen waren veilig voor gebruik.

In dit onderzoek is een tweetal andere kunststoffen babygebruiksartikelen onderzocht: babyflesjes en zachte babygebruiksartikelen. In Nederland moeten deze gebruiksartikelen voldoen aan het Verpakkingen en gebruiksartikelenbesluit (VGB), Warenwet. In februari 2005 zijn 22 nieuwe babyflesjes en 22 zachte kunststoffen gebruiksartikelen bemonsterd op de Nederlandse consumentenmarkt. Ook zijn er 20 gebruikte babyflesjes onderzocht, welke al in gebruik zijn (geweest) gedurende 3 tot 36 maanden. Alle flesjes zijn in de vaatwasser of magnetron gebruikt.

Babyflesjes worden vaak gemaakt van het kunststof polycarbonaat (PC). Bisfenol-A (BPA) is één van de grondstoffen voor deze kunststof. Deze stof heeft oestrogene (oftewel hormoonverstorend) eigenschappen. De migratie van BPA is daarom streng geregeld in wetgeving. Alle babyflesjes worden onderzocht op migratie van BPA zoals beschreven is in de Europese standaard EN 14350-2. Uit bijna alle babyflesjes migreerde er geen BPA in de twee voedselsimulanten A en B (gedestilleerd water en 3% azijnzuur). Alleen uit 4 gebruikte babyflesjes migreerden sporen van BPA in gedestilleerd water (minder dan 0.0050 mg/L). Deze gehaltes overschrijden niet de huidige Nederlandse specifieke migratie limiet (SML) van 3 mg/kg en evenmin de toekomstige limiet van 0.6 mg/kg. De gevonden concentraties liggen zelfs nog tien keer lager dan de SML van 0.03 mg/kg die genoemd wordt in de Europese standaard. Invloeden van merk, gebruiksperiode, frequentie van uitkoken en respectievelijk gebruik in magnetron of vaatwasser op de migratie van BPA, kunnen niet worden bepaald uit dit onderzoek.

Zachte kunststoffen worden vaak toegepast voor babygebruiksartikelen, omdat deze het risico verkleinen op verwonding tijdens gebruik. Er worden zogenaamde weekmakers aan de kunststoffen toegevoegd om ze soepel en zacht te maken. Alle babygebruiksartikelen (bestek, drinktuiten van antilek bekers en een ijslollyset) zijn op de samenstelling onderzocht. Polyolefines (PP en PE) zijn het meest toegepast (80%), gevolgd door silicone (8%). Kunststoffen als PC, PET, acrylonitril butadiëen styreen (ABS) en styreen block copolymeer (SBC) worden in mindere mate toegepast. De kunststof PVC werd niet aangetroffen.
Alle babygebruiksartikelen zijn ook gescreend op de migratie van weekmakers en andere componenten. Er migreerde slechts één (veel toegepaste) weekmaker: di-2-ethylhexylftalaat (DEHP). Voor DEHP is een SML van 40 mg/kg opgelegd in de VGB. Daarnaast migreerden er ook antioxidanten, foto-initiatoren, UV-absorbers, glijmiddelen, oplosmiddelen, vetzuren, koolwaterstoffen en mono/oligomeren. Al deze stoffen zijn toegelaten volgens het VGB: er is geen restrictie of er is een SML opgelegd van 0.05 tot 30 mg/kg. Voor stoffen met een lage SML zijn officiële migratietesten uitgevoerd. De SML's voor de weekmakers en andere migranten werden hierbij niet overschreden.

Alle onderzochte babyflesjes en babygebruiksartikelen zullen naar verwachting voldoen aan de Nederlandse wetgeving en zijn daarom niet onveilig voor gebruik. Er zijn dan ook geen maatregelen als een schriftelijke waarschuwing of boeterapport opgelegd.

Trefwoorden: babyflesjes, (baby)gebruiksartikelen, migratie, levensmiddelen, bisfenol A, weekmakers, kunststof, identificatie, screening.

1. INTRODUCTION

During their early years of life, children come into contact with plastic feeding utensils. These plastic materials may contain low amounts of chemical substances (such as monomers or additives). Normally they convert into non-noxious plastics or compounds. It is possible that starting substances or reaction products migrate from plastics into foodstuffs. For infants the exposure to food, which has been in contact with plastic feeding utensils, is higher compared to adults (per body weight, at similar conditions) due to their low bodyweight. Therefore in general there is more concern about the safety of childcare products like feeding utensils. The Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit, VWA) frequently receives questions and complaints from consumers regarding the safety of childcare articles. In 2001 the chemical and mechanical safety of teats and soothers was already investigated [1]. All teats and soothers, that were investigated, were considered to be safe for use. During this survey the safety of two other groups of childcare products were investigated: baby bottles and (soft) plastic cutlery and drinking equipment.

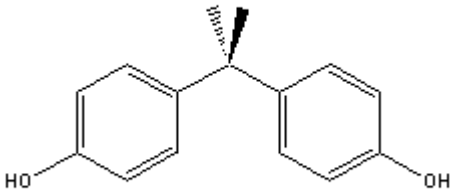
2. THE BACKGROUND OF PLASTIC FEEDING UTENSILS FOR BABIES

Nowadays plastic is a commonly used material for feeding utensils, because plastic has many advantages: it is cheap, light, durable and easy to manufacture in all kinds of forms. Most baby bottles are made of polycarbonate (PC). Baby cutlery and spouts on baby (non-leakage) drinking cups are often made of soft or unrifled plastics, to minimize the risk of injury.

2.1 Polycarbonate baby bottles and bisphenol A

Polycarbonate (PC) is a suitable plastic for baby bottles, because it is clear, heat resistant, rigid, unalterable, impact-resistant and has a high electric capacity for insulating. PC is formed from the reaction of bisphenol A (BPA) and carbonyl chloride. Normally all BPA is reacted to form PC during the polymerisation process. Nevertheless it is possible that small residues of BPA are present that may migrate into the food under certain conditions such as time, temperature, acidity or ultraviolet light (UV).

Figure I: Structural formula of bisphenol A



BPA is estrogenic in animal species above a threshold level (in other words: it disturbs the hormonal regulation). The compound should also be considered as carcinogenic according to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) [2]. BPA has therefore received a lot of negative attention. The exposure of infants to food from baby bottles is high; therefore it is important that these baby bottles are safe for use. In previous studies on migration of BPA from baby bottles only traces of BPA were found [3,4,5,6]. Degradation of the polymer chain may result in a higher release of BPA. The Norwegian Food Control found that the migration of BPA increased when products of PC have been used in a dishwasher or microwave [7]. Therefore in this survey new as well as used baby bottles were analysed for the migration of BPA.

The Scientific Committee on Food (SCF) established a tolerable daily intake (TDI) for BPA of 0.01 mg/kg per bodyweight [8]. This TDI is set using a cautious approach and a high safety factor. From the TDI a specific migration limit (SML) of 0.6 mg/kg for plastic food contact materials was established. In the Netherlands the migration of BPA from consumer and childcare articles must comply with the Packaging and Food utensils Regulation (Food and Commodities Act) [9]. This legislation is based on positive lists of substances that may be used to produce food contact materials [10]. In this regulation a SML of 3 mg BPA per kg food is set. In the short-term this SML will be reduced to the new European limit of 0.6 mg BPA per kg food product [11].

In August 2004 the European normalisation institute CEN published a standard containing a requirement for migration of BPA of 0.03 µg/mL: *'Child use and care articles – Drinking equipment – part 2: Chemical requirements and tests'* (EN 14350-2). By this CEN standard the migration limit for baby bottles is set 20 times more stringent than the current limit (0.03 mg BPA per kg or litre food) [12]. However this new SML has not been implemented in the Dutch legislation yet.

2.2 Plastic feeding utensils and plasticizers

Soft or unrifled plastics are commonly used for childcare articles such as cutlery and drinking tips of cups, because they reduce the risk of wounding during daily use. To soften plastics often so-called plasticizers are added during processing. Often high concentrations of plasticizers are applied (up to 50 weight %); therefore the migration of plasticizers can be substantial.

In general plasticizers are small molecules, mostly phthalate, adipate or citrate esters. On a European level only a limited number of plasticizers are authorised in Commission Directive 2002/72/EC [13]. Based on their toxicological properties, specific migration limits are set. In the Netherlands this directive is incorporated in the Packaging and Food utensils Regulation [9]. This regulation contains, in addition to the European directive, also a positive list of additives that are authorised at a national Dutch level. Childcare artic les, intended for food contact, must comply with the European as well as national legislation.

For consumer articles intended to be placed in the mouth by children under three years of age (like cutlery and drinking tips of cups), also the European Decision 1999/815/EG applies [14]. According to this decision it is prohibited to place these articles on the market made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP). This decision is transferred into the Dutch Food and Commodities Act on phtalates in toys and childcare articles [15]. EN standard 14350-2 has been published for drinking equipment for children. For cutlery and feeding utensils also an EN standard is present: EN14372 [16]. These standards contain chemical requirements for certain elements, phtalates and BPA.

3. EXPERIMENTAL

3.1 Sampling

In February 2005 a total of 22 new baby bottles was sampled on the Dutch consumer market, representing 14 different brands. One sample consisted of 3 identical bottles. In addition 20 baby bottles were collected, representing 11 different brands, which hade been used for 3 up to 36 months in households. All used baby bottles have been used in a dishwasher or microwave for cleaning, sterilisation or food preparation. In annex II an overview of the new as well as used baby bottles is presented. All baby bottles were analysed for the migration of BPA.

Simultaneously 22 (soft) plastic baby cutlery, spouts from drinking cups and sticks for ice-lollies were sampled on the Dutch consumer market, also representing 14 different brands. One sample consisted of 3 identical articles. An overview of these (soft) plastic feeding utensils is presented in annex III. All (soft) plastic feeding utensils were analysed of materials and migration of plasticizers and other migrants.

3.2 Survey for migration of bisphenol A from baby bottles

Each baby bottle was analysed for the migration of BPA according to the European standard EN 14350-2 [12]. Food simulant A (distilled water) and B (3% acetic acid) were used for this method, representing milk and syrup respectively. For each simulant another new bottle was used. Before testing the new baby bottles were immersed in boiling water for 10 minutes (according to the instructions for use). The baby bottles were filled with 100 ml of simulant and put aside for 24 hours at 40°C. The simulant extract was analysed for BPA using HPLC (High Performance Liquid Chromatography) with fluorescence detection (FLD). The limits of detection for distilled water and 3% acetic acid were 0.0025 mg/L and 0.0039 mg/L respectively. The recovery meets the limit as laid down in the European standard.

3.3 Survey for material identification and migration of plasticizers from soft feeding utensils

The material of the childcare articles was identified using Fourier Transformed Infra Red (FTIR). A flat sample was cut out of the utensils. A FTIR reflection spectrum was recorded using a Perkin Elmer apparatus. Four scans from 4000 to 450 cm^{-1} were recorded with a resolution of 4.0 cm^{-1}. This method is described in a standard operation procedure [17].

Another standard operation procedure was used to identify potential migrants from the feeding utensils [18]. Approximately 300 mg of the sample is cut into small pieces and put in a vial. Subsequently 2 ml of diethylether was added, containing n-dodecane (15 mg/L) as internal standard. The sample was extracted in an ultrasound bath for 30 minutes. This extract was analysed for plasticizers and other migrants using Gas Chromatography followed by a Mass Spectrometric detector (GC-MS).

The plasticizers and other migrants were compared to the positive lists of the Packaging and Food-utensils Regulation. When it was suspected that a migration limit was exceeded, an official compliance testing was performed [9]. The feeding utensils were immersed in or filled with distilled water for one hour at 40°C. This process is repeated for 3 times. The outcome of the third consecutive compliance test shall meet the migration limit. Furthermore the identity of the migrant was confirmed by addition of the standard.

4. RESULTS and DISCUSSION

4.1 Migration of bisphenol A from baby bottles

All new and used baby bottles were analysed for the migration of BPA in distilled water and 3% acetic acid. In annex IIa and IIb an overview is presented of these baby bottles and their test results. For all 22 new baby bottles no BPA migration was detected in both food simulants. Also for all 20 used baby bottles no BPA migration was detected in 3% acetic acid.

In only 4 used baby bottles traces of BPA migration were detected in distilled water. These traces are below the limit of quantification of 0.0050 mg/L, which are far below the Dutch SML of BPA (3 mg/kg and 0.6 mg/kg in the future). They are also tenfold lower than the SML of the European standard (0.03 mg/kg).

The migration of BPA was quantitative; therefore influences of brand, period of use, frequency of boiling and use in microwave or dishwasher on the migration of BPA cannot be shown from this survey.

4.2 Identification of soft feeding utensils for babies

Some feeding utensils consisted of several different parts or materials; in this case all parts and materials are identified and tested on migration of plasticizers and other migrants. In total 50 sub-samples were identified using FTIR. In annex III an overview is presented of the sub-samples and the results of identification. In table I the results of the identification and their frequency are presented.

Table I: Identification of used materials for (soft) feeding utensils for babies

Frequency	Material	
21	PP	polypropylene
9	PP-PE	polypropylene-polyethylene copolymer
7	PE	polyethylene
4	PDMS	polydimethylsiloxane (or silicones)
3	TPE	thermoplastic elastomer
2	PC	polycarbonate
2	PET	polyethylene terephthalate
1	ABS	acrylonitrile butadiene styrene
1	SBC	styrene block copolymer

Polyolefin's such as PP, PE, TPE and their copolymers are found 40 times, which represent 80% of all sub-samples. These materials also formed the majority in previous surveys for packaging materials and plastic (cooking) utensils [19,20]. Polyolefin is a commonly used plastic, because it has good mechanical and chemical properties, it is easy to manufacture and it is cheap.

PDMS or silicones are also applied several times (representing 8%). Use of this material for consumer articles is booming, because it has advantageous properties. It is heat-resistant, it stays flexible (even at low temperatures) and is water and fat-proof. Materials like PC, PET, ABS and SBC are applied to a smaller extent. PVC was not detected. The starting substances for the identified plastics are listed in the Packaging and Food-utensils Regulation.

4.3 Migration of plasticizers and other compounds from feeding utensils for babies

All sub-samples were screened on migrants, such as plasticizers and other additives. In table III an overview of the migrants is presented. Besides plasticizers eight different groups of migrants were detected.

Plasticizers

Plasticizers are added to plastics to soften them. Only one common plasticizer was detected: di-2-ethylhexylphtalate (DEHP). This plasticizer is listed in the Packaging and Food-utensils Regulation. For DEHP a specific migration limit of 40 mg/kg is set.
Also o- and p-toluenesulphonamide were detected. Only small amounts were found in the extract. These compounds are possibly used as plasticizers, but considering the low content it seems more likely that these compounds are degradation products of the catalysts o- and p-toluenesulphonic acid. o- and p-toluenesulphonic acid are listed in the Packaging and Food-utensils Regulation without any restriction, so the overall migration limit of 60 mg/kg applies. However for all (degradation) compounds it is required that these compounds should not cause a change in organoleptic properties (i.e. smell and taste) and colour of the food product or cause risks for public health (Packaging and Food-utensils Regulation, article 2, first part under c).

Antioxidants

Antioxidants are organic compounds, which are added to plastics to prevent oxidation of plastics and to extend their shelf life. Antioxidant 2,6-BHT and its degradation products 2,6-DTBQ, 2,4-DTBP, 2,6-BHT-quinone methide and BHT-CHO were found [21,22,23]. There is no restriction for this antioxidant, so the overall migration limit of 60 mg/kg applies. For degradation compounds it is required that these compounds may not cause a change in organoleptic properties and colour of the food product or cause risks for public health. Also the antioxidant dodecylsulphide was detected. A specific migration limit of 0.05 mg/kg applies for dodecylsulphide.

Photo-initiators

Photo-initiators convert absorbed light energy, UV or visible light, into chemical energy to advance the processing of plastics and certain printing inks. (Degradation products of) photo-initiators were found: benzophenone, acetophenone and p-methylbenzophenone [24]. For benzophenone a specific migration limit of 0.6 mg/kg applies, for the last two compounds there is no restriction.

UV-stabilizers

Most plastics degrade if they are exposed to ultra violet (UV) light. Therefore UV-stabilizers are applied in polymers. UV-stabilizer 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole is detected. A total specific migration limit of 30 mg/kg is set for this UV-stabilizer, together with other benzotriazole derivatives (2-(2'-hydroxy-3',5'-di-tert-butylphenyl)-5-chlorobenzotriazole and 2-(2-hydroxy-5-methylphenyl)-chlorobenzotriazole).

Lubricants

Lubricants simplify the processing of plastics, such as blending and moulding. Lubricants oleamide and parafine-like compounds were detected. Both lubricants have no restriction, so again the overall migration limit of 60 mg/kg applies.

Solvents (for printing inks)

To process monomers, (printing) inks and colorants, they can be dissolved in solvents. During this survey the solvent ethyl-4-ethoxybenzoate was detected. A specific migration limit of 3.6 mg/kg applies for this solvent.

Fatty acids
As plastics are normally hydrophobic surfactants such as fatty acids can be added. In addition fatty acids are also being used as lubricant. Fatty acids methylmyristate, methylpalmitate, methylstearate, palmitic acid and stearic acid were detected. There is no restriction for these fatty acids, so the overall migration limit of 60 mg/kg applies.

Hydrocarbons
Hydrocarbons often are derived from wax but may also be reaction products of plastics. Dodecylmercaptane, alkanes and isomers of alkanes were detected. There is no restriction for these hydrocarbons. It is required that these compounds may not cause a change in organoleptic properties and colour of the food product or cause risks for public health.

Monomers and oligomers
During the processing it is possible that monomers (starting substances) are not completely converted into plastics (polymers). Therefore small amounts of monomers and oligomers can be present in the plastics. During this survey tetradecylacrylate, ABS oligomer, polypropylene oligomer, siloxanes, dodecylacrylate and BPA were detected. There is no restriction for the first four monomers/oligomers. For dodecylacrylate and BPA a specific migration limit of 0.05 mg/kg and 3 mg/kg respectively applies.

Compliance testing
Of all identified migrants the content in the extract was semi-quantitatively estimated, by comparing the peak area to the internal standard (15 mg/L). Subsequently this estimation was compared to the SML. It is very likely that the SML for DEHP and 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorbenztriazole were not exceeded. For several substances with a low SML (i.e. benzophenone, 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole, ethyl-4-ethoxybenzoate, BPA and dodecylacrylate) it was suspected that the SML may be exceeded and therefore official compliance tests in stimulant A were performed. However all these substances complied with the SML. The results of the first compliance tests are presented in table II.

Table II: Results compliance tests in distilled water for substances with a low SML

Substance	SML [mg/kg]	Migration first compliance test [mg/L]
benzophenone	0.6	0.06 - 0.1
2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole	30	not detected
ethyl-4-ethoxybenzoate	3.6	not detected
bisphenol A	3	0.005 - 0.5
dodecylacrylate	0.05	not detected

As the migration normally decreases with each migration test, only the extract of the first migration test was analysed. As these migration values are far below the SML, no second and third migration tests were performed.

There was no standard available of dodecylsulphide. Therefore no compliance test was performed for this substance. However it is very likely that dodecylsulphide will not migrate into water, as it is very hydrophobic. It is therefore expected that the SML will not be exceeded.

Table III: (Type of) migrants from feeding utensils for babies

Type of migrant	CAS-number	Status RVG	Detected in:	Freq.
Plasticizers				
di-2-ethylhexylphtalate (DEHP)	117-81-7	SML = 40 mg/kg	PP	1
o-toluenesulphonamide	88-19-7	no restriction*	SBC	1
p-tolueensulphonamide	70-55-3	no restriction*	SBC	1
(Degradation product of) antioxidants				
2,6-di-tert-butylquinone (2,6-DTBQ)	719-22-2	no restriction	PP-PE	1
2,4-di-tert-butylphenol (2,4-DTBP)	96-76-4	no restriction	PP-PE	4
			PP	2
			PDMS	1
			TPE	1
2,6-di-tert.butyl-4-methylphenol (2,6-BHT)	128-37-0	no restriction	PP	7
			PP-PE	5
			TPE	3
			PE	2
			SBC	1
2,6-di-tert.butyl-4-methylphenol-quinone-methide (2,6-BHT-quinone-methide)	2607-52-5	no restriction	PP-PE	2
			PP	1
			PE	1
dodecylsulphide	2469-45-6	SML = 0.05 mg/kg	PP	1
3,5-di-tert-butyl-4-hydroxybenzaldehyde (BHT-CHO)	1620-98-0	no restriction	PP-PE	1
Degradation product of photo-initators				
acetophenone	98-86-2	no restriction	PET	1
benzophenone	119-61-9	SML = 0.6 mg/kg	PP-PE	1
			PP	1
p-methylbenzophenone	134-84-9	no restriction	PP	1
UV-stabilizer				
2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole	3864-11-5	SML(T) = 30 mg/kg with other benzotriazole derivatives	PP	1
			PP-PE	1
			TPE	1
Lubricant				
oleamide	301-02-0	no restriction	PE	2
paraffine-like compounds	-	no restriction	PP-PE	7
			TPE	3
			PET	1
			SBC	1
Solvents (for printing ink)				
ethyl-4-ethoxybenzoate	23676-09-7	SML = 3.6 mg/kg	PP	1
Fatty acids				
methylmyristate	124-10-7	no restriction	ABS	1
methylpalmitate	112-39-0	no restriction	ABS	1
methylstearate	112-61-8	no restriction	ABS	1
palmitic acid	57-10-3	no restriction	PP-PE	1
			ABS	1
stearic acid	57-11-4	no restriction	ABS	1
Hydrocarbons				
dodecylmercaptane	112-55-0	no restriction	ABS	1
(isomers of) alkanes	-	no restriction	PP	12
			PE	6
			PP-PE	4
			PDMS	1
			PET	1
Monomers and oligomers				
bisphenol A (BPA)	80-05-7	SML = 3 mg/kg	PP	1
			PP-PE	1
dodecylacrylate	2156-97-0	SML = 0.05 mg/kg	PP-PE	3
			PP	1
tetradecylacrylate	21643-42-5	no restriction	PP	1
ABS oligomer	-	no restriction	ABS	1
PP oligomer	-	no restriction	PP	2
siloxanes	-	no restriction	PDMS	3

* Only restricted for dry food products, according to §1.2.2 of paper and paperboard (chapter 2 of Packaging and Food-utensils Regulation).

5. CONCLUSIONS

All new and used baby bottles were investigated on the migration of BPA in distilled water and 3% acetic acid. For all new and nearly all used baby bottles no migration of BPA was detectable in distilled water as well as in 3% acetic acid. In 4 used bottles traces migration of BPA were detected in distilled water. The migration of BPA from these baby bottles was far below the present and future specific migration limit. The migration was also tenfold lower than the SML of the European standard EN 14350-2.

All (soft) plastic feeding utensils were tested on material composition and also screened for plasticizers and other potential migrants. Polyolefines (PP and PE) were applied most (80%), followed by silicones (PDMS) (8%). Plastics such as PC, PET, ABS and SBC were applied to a much smaller extent. PVC was not detected.
Only one common plasticizer was detected: di-2-ethylhexylphtalate (DEHP). A specific migration limit of 40 mg/kg applies for this plasticizer. Also antioxidants, photo-initiators, UV-filters, lubricants, solvents (for printing inks), fatty acids, hydrocarbons and monomers/oligomers were detected. For several substances with a low SML compliance tests were performed. It was found that the specific migration remained far below the SML. The plasticizers and migrants did not exceed the legal specific migration limit.

With regard to the parameters that were measured in this study, all tested baby bottles and feeding utensils comply with the Dutch legislation. Therefore no enforcement measures such as an official warning or report of offence were taken.

6. LITERATURE

1. Bouma K. & Nab F.M., 2002, *Teats and soothers: migration of nitrosamines, nitrosatable substances and 2-mercaptobenzthiazol, screening of other migrants and mechanical safety of soothers,* Report number NDTOY003/01, Inspectorate for Health Protection and Veterinary public Health.
2. European Commission, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 2002, *Opinion on the results of the Risk Assessment of Bisphenol A, Human Health Part*.
3. Biles J.E., McNeal T.P., Begley T.H. & Hollifield H.C., 1997, *Determination of Bisphenol-A in Reusable Poycarbonate Food-Contact Plastic and Migration to Food-Simulating Liquids*, Journal of Agriculture and Food Chemicals vol. 45: 3541-3544.
4. Susan R., Howe & Lester Borodinsky, 1998, *Potential exposure to bisphenol A from food-contact use of polycarbonate resins*, Food Additives and Contaminants vol. 15 (3): 370-375.
5. Mountfort K.A., Kelly J., Jickells S.M. & Castle L., 1997, *Investigations into the potential degradation of polycarbonate baby bottles during sterilization with consequent release of bisphenol A*, Food Additives and Contaminants vol. 14 (6-7): 737-740.
6. Simoneau C., Roeder G., Anklam E., 2004, *Migration of bisphenol A from baby bottles: effect of experimental conditions and european survey,* European Commision, Joint research centre.
7. Brede C., Fjeldal P., Skjevrak I. & Herikstad H., 2003, *Increased migration levels of bisphenol A from polycarbonate baby bottles after dishwashing, boiling and brushing*, Food Additives and Contaminants vol. 20 (7): 684-689.
8. European Commission, Scientific Committee on Food (CSF), 2002, *Opinion on Scientific Committee on Food on Bisphenol A*.
9. Verpakkingen en gebruiksartikelenbesluit (Warenwet), 1 October 1979, Stb. 558.
10. Regelingen verpakkingen en gebruiksartikelen (Warenwet), 20 November 1979, Stcrt 1980, 18.
11. Commission Directive 2004/19/EC, 2004, *Amending Directive 2002/72/EC relating to plastic materials and articles intended to come in contact with foodstuffs*, Official Journal of the European Union: 0008 - 0021.
12. European standard 14350-2, 2004, *Child use and care articles – Drinking equipment – part 2: Chemical requirements and tests*: 14-16.
13. Commission Directive 2002/72/EC, 2002, *relating to plastic materials and articles intended to come into contact with foodstuffs*, Official Journal of the European Union: 0018 - 0058
14. Commission Decision 1999/815/EC, 1999, *adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP) (notified under document number C(1999) 4436)*, Official Journal of the European Union: 0046 - 0049.
15. Warenwetregeling ftalaten in speelgoed en kinderverzorgingsartikelen, March 13, 2003, Stcrt 2003, 53.
16. European standard 14327, 2004, *Child use and care articles – Cutlery and feeding utensils – Safety requirements and tests*.
17. Kwaliteitshandboek Keuringsdienst van Waren Noord, Standard Operation Procedure CHE01-WV426.
18. Kwaliteitshandboek Keuringsdienst van Waren Noord, Standard Operation Procedure SIG01-ND425.
19. Otter den M.J., Bouma K., Nab F.M. & Peursem van A.J.J., 2005, *Controle van kunststof verpakkingen en gebruiksartikelen voor levensmiddelen*, Report number ND04o042/01, Inspectorate for Health Protection and Veterinary public Health.
20. Vondel van M.P.Y. & Anakotta R., 2005, *Controle van kunststoffen en papieren kook- en magnetronverpakkingen en gebruiksartikelen voor levensmiddelen*, Report number ND04o046, Inspectorate for Health Protection and Veterinary public Health.
21. Nagai F, Ushiyama K. & Kano I, 1993, *DNA cleavage by metabolites of butylated hydroxytoluene*, Archives of Toxicology vol. 67(8): 552-557.

22. Anil Wali, Jagannath Das, S. Muthukumaru Pillai & M. Ravindranathan, 2002, *Disproportion, isomerization and de-tert-butylation of 2,6-di-tert-butylphenol catalyzed by H-MCM-41*, Green Chemistry vol. 4: 587-591.
23. Skjevrak I., Due A., Gjerstad K.O. & Herikstad H., 2003, *Volatile organic components migration from plastic pipes (HDPE, PEX and PVC) into drinking water*, Water Research vol. 37: 1912-1920.
24. Dr. F. Sauer (Borchers GmbH, R&D), *Unsaturated polyesters – an overview.*

Annex I: Symbols and abbreviations

ABS	acrylonitrile butadiene styrene
BBP	butylbenzyl phthalate
2,6-BHT	2,6-di-tert.butyl-4-methylphenol
BHT-CHO	3,5-di-tert-butyl-4-hydroxybenzaldehyde
BPA	bisphenol A
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
2,6-DTBQ	2,6-di-tert-butylquinone
2,4-DTBP	2,4-di-tert-butylphenol
DBP	dibutyl phthalate
DEHP	di(2-ethylhexyl) phthalate
DIDP	di-iso-decyl phthalate
DINP	di-iso-nonyl phthalate
DNOP	di-n-octyl phthalate
GC-MS	Gas Chromatography followed by a Mass Spectrometric detector
FLD	fluorescence detection
FTIR	Fourier Transformed Infra Red
HPLC	High Performance Liquid Chromatography
PC	polycarbonate
PDMS	polydimethylsulfonide
PE	polyethylene
PET	polyethylene terephthalate
PP	polypropylene
PVC	polyvinylchloride
RVG	Packaging and Food-utensils Regulation, Food and Commodities Act (*Regeling Verpakkingen en Gebruiksartikelen, Warenwet*)
SBC	styrene block copolymer
SCF	Scientific Committee on Food
SML	specific migration limit
TDI	tolerable daily intake
TPE	thermoplastic polyethylene
UV	ultra violet
VGB	Packaging and Food-utensils Decision, Food and Commodities Act (*Verpakkingen- en Gebruiksartikelenbesluit, Warenwet)*
VWA	The Food and Consumer Product Safety Authority (*Voedsel en Waren Autoriteit*)

Annex IIa: Overview of new baby bottles

Sample number	Content	Material indication on bottle	BPA migration distilled water [mg/kg]	Recovery distilled water [%]	BPA migration 3% acetic acid [mg/kg]	Recovery 3% acetic acid [%]
44187418	250 ml	-	n.d.		n.d.	100.3
45306135	250 ml	-	n.d.		n.d.	102.8
57154519	250 ml	-	n.d.	103.4	n.d.	
44187434	150 ml	-	n.d.	79.2	n.d.	
45306143	250 ml	-	n.d.		n.d.	106.4
45306259	250 ml	PC	n.d.	98.7	n.d.	
45306232	250 ml	PC	n.d.		n.d.	93.1
46395832	125 ml	PC	n.d.		n.d.	89.7
46395867	250 ml	PC	n.d.		n.d.	71.2
57156678	250 ml	PC	n.d.	95.3	n.d.	
57156686	320 ml	PC	n.d.	96.1	n.d.	
44187396	250 ml	PC	n.d.	109.2	n.d.	
57156694	125 ml	-	n.d.	103.8	n.d.	
44187426	250 ml	-	n.d.		n.d.	100.4
44187442	250 ml	-	n.d.	100.5	n.d.	
46423186	200 ml	-	n.d.	79.8	n.d.	
46423143	120 ml	-	n.d.	98.4	n.d.	98.0
46423178	250 ml	-	n.d.		n.d.	96.7
48477054	125 ml	-	n.d.	76.6	n.d.	75.9
48477003	125 ml	-	n.d.	99.7	n.d.	
48476996	260 ml	-	n.d.	110.7	n.d.	
48477321	250 ml	-	n.d.		n.d.	102.3

n.d. = Not detectable. Limit of detection for distilled water and 3% acetic acid were 0.0025 and 0.0039 mg/L.

Annex IIb: Overview of used baby bottles

Sample number	Content	Material indication on bottle	Period of use [months]	Boiled before use	Used in dishwasher	Used in microwave	BPA migration distilled water [mg/kg]	BPA migration 3% acetic acid [mg/kg]
44110377	150 ml	PC	9	Every time		x	n.d.	n.d.
44110385	250 ml	-	10	Once per 2 times	x	x	n.d.	n.d.
44110393	320 ml	PC	18	Once a week		x	n.d.	n.d.
44110407	150 ml	-	15	Every day	x	x	n.d.	n.d.
44110415	250 ml	-	24	Every day		x	trace	n.d.
44110423	250 ml	-	3	Once per 3 times	x		n.d.	n.d.
44110431	125 ml	-	24	Every day		x	trace	n.d.
44110458	-	-	12	Once per 3 times	x		n.d.	n.d.
44110466	250 ml	-	12	Every day		x	n.d.	n.d.
44110474	250 ml	-	24	Every day		x	trace	n.d.
44110482	125 ml	-	6	Once per 2 days	x	x	n.d.	n.d.
44110504	250 ml	-	36	Once per 5 times	x		n.d.	n.d.
44110512	250 ml	PC	24	Every day		x	trace	n.d.
44110539	250 ml	-	3	Once per 3 times	x		n.d.	n.d.
44110547	250 ml	-	12	Once a week		x	n.d.	n.d.
44110555	125 ml	-	24-36	Once per 3 times	x	x	n.d.	n.d.
44110571	250 ml	-	24	Every day	x	x	n.d.	n.d.
44110563	250 ml	-	18	Every day	x	x	n.d.	n.d.
44110598	250 ml	-	30	3 times a week		x	n.d.	n.d.
44110601	125 ml	-	3	Once per 6 times		x	n.d.	n.d.

n.d. = Not detectable. Limit of detection for distilled water and 3% acetic acid were 0.0025 and 0.0039 mg/L.
trace = Below limit of quantification for distilled water of 0.0050 mg/L.

Annex III; Overview of identification of materials and migrants of (soft) plastic feeding utensils for babies.

Sample no.	Description		Material (FTIR)	Migrant (GC-MS)
45306267	spoon	soft part	PP-PE	alkanes benzophenone 2,4-DTBP paraffine-like compounds
		stiff part	PP	benzophenone 2,4-DTBP p-methylbenzophenone PP oligomers
46395859	drinking cup	cup	PP	alkanes 2,4-DTBP PP oligomers
		straw	PE	alkanes 2,6-BHT 2,6-BHT-quinone-methide oleamide
		lower part straw	PE	alkanes 2,6-BHT oleamide
46395824	drinking cup	cup	PC	-
		lid	PP	isomers of alkanes
44187469	spoon	soft part	PP-PE	BPA 2,4-DTBP 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazol paraffine-like compounds
		stiff part	PP	alkanes 2,6-BHT
44187353	bin	lid	PE	alkanes
		bin	PET	-
57154535	spoon	spoon	PDMS	alkanes siloxanes
		grip	PP	-
44187477	spoon	soft part	PP-PE	dodecylacrylate isomers of alkanes paraffine-like compounds
		stiff part	PP	BPA dodecylsulphide 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazol
44187361	ice lolly	stick	PE	isomers of alkanes
		bin	PE	isomers of alkanes
		lid	PE	isomers of alkanes
57154543	spoon	stiff part	PP	2,6-BHT tetradecylacrylate
		soft part	PP-PE	2,6-BHT BHT-CHO 2,6-BHT-quinone-methide 2,6-DTBQ isomers of alkanes paraffine-like compounds
57154578	spoon	stiff part	PP	2,6-BHT
		soft part	PP-PE	2,6-BHT dodecylacrylate paraffine-like compounds
46423194	spoon	stiff part	PP	alkanes
		soft part	SBC	2,6-BHT paraffine-like compounds o-toluenesulphonamide p-toluenesulphonamide

Annex III; Overview of identification of materials and migrants of (soft) plastic childcare articles (continuation).

Sample no.	Description		Material (FT-IR)	Migrant (GC-MS)
57154551	drinking cup	drinking tip	PP-PE	2,6-BHT 2,4-DTBP
		soft part spout	PMDS	2,4-DTBP siloxanes
		stiff part spout	PC	-
45306224	spoon	stiff part	PP	2,6-BHT
		soft part	TPE	2,6-BHT 2,4-DTBP 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazol paraffine-like compounds
		bin	PP	alkanes DEHP
44187388	drinking cup	lid	PDMS	siloxanes
		cup	PP	isomers of alkanens
57154527	spoon	stiff part	PP	2,6-BHT 2,6-BHT-quinone-methide dodecylacrylate alkanes
		soft part	PP-PE	2,6-BHT 2,6-BHT-quinone-methide dodecylacrylate 2,4-DTBP palmitic acid paraffine-like compounds
45309789	spoon	stiff part	PP	2,6-BHT
		soft part	TPE	2,6-BHT paraffine-like compounds
48477089	spoon	stiff part	PP	2,6-BHT
		soft part	TPE	2,6-BHT paraffine-like compounds
48477097	spoon	stiff part	PP	-
48477046	spoon	soft part	PP-PE	2,6-BHT isomers of alkanes paraffine-like compounds
		stiff part	PP	isomers of alkanes
45306151	drinking cup	lid	PE	-
		cup	ABS	ABS oligomers dodecylmercaptane methylmyristate methylpalmitate methylstearate palmitic acid stearic acid
		drinking tip	PP-PE	-
		lower part tip	PDMS	-
48477038	drinking cup	lid/cup	PP	alkanes ethyl-4-ethoxybenzoate
48477062	drinking cup	lid	PP	alkanes
		cup	PP	alkanes
		spout	PP	alkanes
		inside spout	PET	acetophenone alkanes paraffine-like compounds