Danish Ministry
of the Environment
Environmental
Protection Agency

Migration of bisphenol A from cash register receipts and baby dummies

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The reports are, however, published because the Danish EPA finds that the studies represent a valuable contribution to the debate on environmental policy in Denmark.

Content

Preface

Bisphenol A (BPA) has been classified an endocrine disruptor, but the experts disagree on which concentrations it would take before these effects occur. The substance has great political and public attention especially because BPA is in food packaging and baby bottles. A preliminary ban has been imposed in Denmark against BPA in materials touching food for the 0-3 year-olds and EU has just agreed on a ban against BPA in baby bottles for the 0-1 year-olds.

Exposure of consumers and cashiers from BPA in cash register receipts made of thermal paper has until recently not had much attention and is not included in the EU risk assessment of BPA. Within the last 6 months new information and data have been published causing doubt whether migration of BPA from receipts could have damaging health effects.

This study has been initiated by the Danish Environmental Protection Agency with the aim of:

- illustrating whether migration of bisphenol A from receipts creates a health problem for Danish consumers and

- illustrating whether migration of bisphenol A from the shield of baby dummies on the Danish market constitutes a health risk for the 0-3 year-olds.

The project has been carried out in autumn 2010. During the project period a number of studies have been published reviewing the possible migration of BPA in cash register receipts. Studies which have been available before 12 November 2010 are included in the discussion of the results of this study.

Steering committee
The project has been followed by a steering committee with following members:

Karina L. Vintersborg, Danish Environmental Protection Agency (Chairman)

Shima Dobel, Danish Environmental Protection Agency

Carsten Lassen, COWI

Sonja Hagen Mikkelsen, COWI

Project group
The study was made by a team consisting of Carsten Lassen (project manager), Sonja Hagen Mikkelsen and Ulla Kristine Brandt, COWI A/S. Analysis of BPA in products and release of BPA from the products have been carried out by Danish Technological Institute with Ulla Christensen as contact person.

Summary

Based on an analysis of consumers' exposure to bisphenol A (BPA) emitted from cash register receipts and other receipts of thermal paper, the daily uptake of BPA from these sources has been calculated in a realistic worst case scenario to be approx. 0.24 mg BPA. In this scenario it is assumed that the receipts are touched with humid fingers and that 50% of the quantity left on the skin is absorbed. With this scenario the exposure will be approx. 1/5 of the Derived No Effect Level (DNEL). As a worst case scenario has been used, the actual exposure of the general consumer in most cases will be considerably lower. A realistic worst case scenario for cashiers also shows a calculated uptake below the DNEL value.

Based on analyses of migration of BPA from baby dummies with a shield of polycarbonate, the maximum daily uptake of BPA has been calculated to be far below the level where damaging health effects are expected.

The aim of this study is to illustrate to which extent releases of bisphenol A (BPA) from cash register receipts constitutes a health problem for Danish consumers and to investigate whether the releases of bisphenol A from the shield of baby dummies made of polycarbonate is a health risk for 0-3 year old children.

BPA in cash register receipts ticket
Based on contacts with Danish suppliers of cash register receipts it is assumed that 90% of cash register receipts in Denmark are made of thermal paper. It is also assumed, based on general EU figures, that 70-80% of the receipts are made of thermal paper containing BPA. BPA is used as a developer in the process of colouring the paper when heated.

12 printed cash register receipts have been analysed in this study covering receipts from different types of shops, cash point machines and a library. Apart from this, a test sample of a sticker from weighing vegetables in a supermarket has been analysed. The content of BPA in 7 out of 12 analysed cash register receipts varied from 8,700 to 17,000 mg/kg (see Table 1). There is no correlation between the quantity of BPA in the cash register receipts and the migrating quantity. The concentrations found are in accordance with what has been found in other surveys. Based on Swedish studies and information from suppliers of thermal paper, it is estimated that thermal paper containing BPA is also used for a number of other purposes such as tickets, boarding cards, queue tickets, parking tickets and various printer and recorder papers.

Bisphenol S (BPS) was found in three of the cash register receipts. BPS is typically used instead of BPA in more resistant receipts from cash point machines and shops where it is expected that the receipt could be saved for many years. Two contained neither BPA nor BPS, but the actual substances were not determined. There are several types of thermal paper on the market where the developers are not based on phenol chemicals, but it has not been possible to find out which developers are used instead.

In order to examine to which extent consumers are exposed to BPA from the receipts, analyses were carried out of the migration of BPA to artificial sweat and of the quantity released to fingers when handling the tickets.

Immersion of the cash register receipts in artificial sweat for 5 seconds showed a migration from the receipts of 7-21µg BPA/cm^2, equivalent to 10-37% of the content of BPA in the receipts. There were no relation between the content of BPA in the receipt and the migrated quantity, and none of the cash register receipts were significantly different from the others in regard to releases of BPA from the receipt.

Based on this test, four cash register receipts were selected for at test imitating a realistic handling situation of a receipt. The tests showed significant differences in the migrated quantities depending on whether the fingers were dry (with natural humidity), humid or with lotion. The average quantity of BPA left on the fingers in the three situations was 11, 103 and 28 µg BPA respectively. The values equal results from a Swiss study published in 2010.

Table 1
Content of BPA in cash register receipts, exposure to fingers and artificial sweat

Place of sampling	Content of BPA		BPA exposure to artificial sweat, 5 sec	BPA exposure to fingers, µg		
	mg/kg	µg/cm^2	µg/cm^2 **	Dry fingers	Humid fingers	Fingers with lotion
Petrol station 1 (payment machine)	1.4	0.011	n.a.	n.a.	n.a.	n.a.
Petrol station 2 (payment machine)	b.d. *	b.d.	n.a.	n.a.	n.a.	n.a.
Furniture chain	b.d.*	b.d.	n.a.	n.a.	n.a.	n.a.
Toy shop	8,700	46	13	4.6	21	n.a.
Supermarket chain 1	9,300	61	11	5.4	240	n.a.
Supermarket chain 2	11,000	51	19	30.0	64	26
Discount super market 1	17,000	77	21	5.3	88	30
Discount super market 2	10,000	48	13	n.a.	n.a.	n.a.
Bank (cash machine)	b.d *	b.d	n.a.	n.a.	n.a.	n.a.
Library	9,700	53	13	n.a.	n.a.	n.a.
Discount super market 3	14,000	64	7	n.a.	n.a.	n.a.
Hardware store	37	0.19	n.a.	n.a.	n.a.	n.a.
Supermarket chain, sticker	b.d *	b.d *	n.a.	n.a.	n.a.	n.a.
Average **	11,400	57	14	11	103	28

* Contained BPS, quantity of BPS not determined.

** The two lowest values of 1.4 and 37 mg/kg (0.011 and 0.19 µg/cm^2) are not included when calculating the average.

n.a. Not analysed.

b.d. Below the detection limit for bisphenol A, which in this study is 0.1 mg/kg.

Based on the listed exposed scenarios it was calculated how much BPA a consumer could be exposed to in a realistic worst case scenario. For this scenario the results of migration to humid fingers were used, which in average was 9 times higher than the measured migration to dry fingers. In the scenario it was taken into account that the consumer handles the cash register receipts several times.

The calculated exposure was compared to a so-called DNEL value. The DNEL (Derived No Effect Level) has been determined based on animal tests and illustrates the exposure level, below which no effects are expected. At the comparison it was taken into account that the consumer is also exposed to BPA from other sources.

There is some uncertainty to which extent BPA deposed on the skin is actually absorbed in the body. The EU risk assessment for BPA assumed for its calculations that only 10% is absorbed, whereas later studies indicate that it could be a larger quantity and calculations in this study have been made assuming that 10% and 50%, respectively, is absorbed.

In order to assess whether there could be a risk related to the exposure, a so-called Risk Characterization Ratio (RCR) is made by dividing the calculated internal dose (uptake) with a DNEL value, which designates the level below which no effects are expected to occur. If the RCR is below 1, the exposure is assessed to cause no risk. The RCR for the worst case scenario for consumers, where it is assumed that 50% is absorbed, was calculated to 0.14. If, at the same time, cumulative exposure from dietary intake is included, the total RCR will be 0.19. For cashiers a total RCR of 0.79 was calculated. In the calculations it has not been taken into account that BPA on the fingers probably reduces the amount of BPA left on the skin from the next touch. In a Swiss study where this effect was taken into account and migration data to more dry fingers are also included, a considerably lower absorption was calculated than in the worst case scenarios in this study. As worst case scenarios are used here, and the RCR values are below 1, it is estimated that with the present knowledge on he effects of BPA there will be no significant risk related to the handling of the cash register receipts.

BPA in baby dummies made of polycarbonate

Polycarbonate is made by a polymerization of BPA and the final polycarbonate contains small quantities of BPA which is not polymerized. According to information from suppliers of baby dummies it is estimated that shield and ring in 10-20% of the dummies on the Danish market are made of polycarbonate. The part is diminishing, as other plastic types are used, such as polypropylene or co-polyester.

In analyses of BPA exposure from dummies' shield to artificial sweat and saliva, the migration to both media was below the detection limit for 6 out of 8 examined dummies. For one dummy, migration was above the detection limit to both media, whereas for one dummy only migration to saliva was found.

In an exposure scenario where it is assumed that the baby has the dummy in the mouth 7.75 hours a day and assuming that 50% of the amount migrated to the skin is absorbed, the total RCR value is calculated to 0.0069 which is far below 1. The results confirm a previous result from a large study of 2 year-old's exposure to chemical substances published by the Danish EPA in 2009.

Conclusion

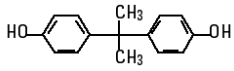
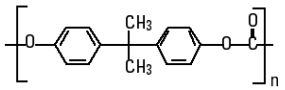
The results of this survey thus signify that there is no immediate health risk related to the use of BPA based cash register receipts and baby dummies. No matter the results it is worth noticing that BPA has been classified as an endocrine system disruptor with the hazard statement "Suspected of damaging fertility". The substance is also listed on the Danish EPA's "List of undesirable substances", a signal list and guidance to companies about problematic substances and use of which should be reduced or terminated in the long term.

Alternatives to cash register receipts are available, but it has not been investigated to which extent the alternative developers are better from an environmental and health perspective and the costs of changing to the alternatives is unknown. The alternatives are probably more expensive today because they are niche products, but this may change with an increased demand for the alternatives. Parts of the Danish retail trades have informed, that the price for paper with the alternative developer bisphenol S is approximately twice as expensive as BPA based paper, while thermal paper without phenol-chemistry is claimed to be four times the price for paper with BPA. At present the health risks of papers with alternative developers is unknown. Alternatives to baby dummies made of polycarbonate today account for a major part of the market.

1 Introduction

1.1 Identification of the substance

This study concerns the following substance:

Chemical name:	4,4'-isopropylidenediphenol
Synonym:	Bisphenol A; BPA
CAS No:	80-05-7
EINECS No:	201-245-8
BPA structure:	
Polycarbonate structure (polymerised BPA):	
Hazard class and category codes:	Repr. 2 STOT SE 3 Eye Dam. 1 Skin Sens. 1
Hazard codes and statements:	H361f: Suspected of damaging fertility H335: May cause respiratory irritation H318: Causes serious eye damage H317: May cause an allergic skin reaction

1.2 BPA in thermal paper

BPA is used for coating of thermal paper where print is developed by the heat impact from a print head. The colour is developed by the reaction between a pigment and a developer which often is BPA, but could also be bisphenol S (BPS) or other substances. The composition of thermal paper is illustrated below by two manufacturers. It should be noted that “print” in the first example is not the print caused by thermal impact, but can be a pre-print e.g. of a ticket where the date is printed subsequently with a thermal printer in the layer indicated as “thermal coat”. Magnetic stripes do not normally appear on thermal paper used for receipts, but for example on certain types of tickets.

The thermo coating containing BPA is only on one side of the paper. The paper can have a topcoat above the thermal BPA-containing layer.

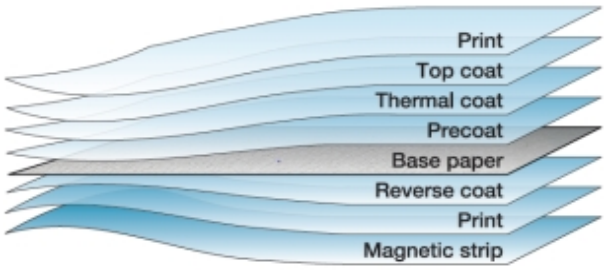


Illustration from thermal paper manufacturer Mitsubishi HiTec Paper Flensburg GmbH

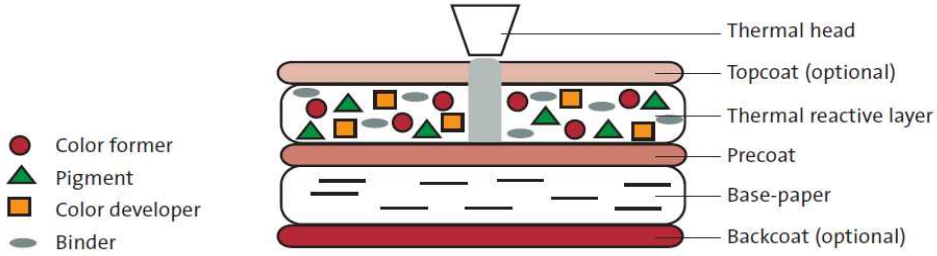


Illustration fra termopapirproducent Papierfabrik August Koehler AG. Gul firkant 'Color developer' illustrerer en phenol-fremkalder, der kan være BPA.

Thermal paper can be used for cash register receipts, paper for certain printers, tickets, lottery tickets, stickers and fax paper. Suppliers of thermal paper point out the following qualities of thermal print: soundless, reliable, low current costs, no use of toner or ink, easy to use, no solvents and compact printer unit. Another quality, often mentioned in connection with e.g. tickets, is that it is practically impossible to change the print without trace.

Manufacturers of thermal paper are organised in the European Thermal Paper Association (ETPA) which in 2003 organised all manufacturers of thermal paper in EU except one. In 2003, ETPA assessed that 70-80% of all thermal paper sold in EU contained BPA (DEFRA, 2003). ETPA was contacted in connection with this study, but the association did not know whether it still applies that 70-80% of the thermal paper on the European market contains BPA (ETPA, 2010).

In the beginning of 2000, approx. 1,400 tons BPA were used for production on 105,000 tons thermal paper (Møller & Helveg, 2004). On average the paper contains approx 13,000 mg BPA/kg. The latest version of EU's risk assessment of BPA states that in 2005/2006 1,890 tons BPA were used for production of 168,000 tons thermal paper (EC, 2010). This is an increase of 35% compared to Møller & Helveg's figures from 2000. Based on these figures the paper contains approx. 11,000 mg/kg on average.

Until recently the primary focus related to BPA in thermal paper was releases by recycling of the paper as discussed in the EU Risk Assessment of BPA (EC, 2010).

1.3 BPA in polycarbonate

BPA is used as monomer for production of e.g. polycarbonate plastic and epoxy. In the production the substance is polymerised and a stable matrix is created. By the polymerisation there will be a small part left of the monomer

which does not polymerise. The release of bisphenol A is mainly due to release of free monomers not bound in the matrix.

1.4 Previous studies

A number of previous studies have been undertaken of the release of BPA from cash register receipts and dummy shields. As the results of these previous studies will be part of the discussion of the results in this study they will be briefly reviewed here.

1.4.1 BPA in thermal paper

Swiss study of release of BPA from cash register receipts
Release of BPA from receipts was recently examined by the food control authorities in the Swiss canton Zürich (Biedermann ***et al.***, 2010). 13 different thermal papers were examined in total and 11 of the samples BPA was found in concentrations of 8,000-17,000 mg BPA/kg, which is in accordance with the EU average for thermal paper as indicated above. 10 of the 13 thermal paper samples were cash register receipts and 9 samples included BPA. BPA was also found in 2 samples of print paper, whereas there was no BPA in a trolley ticket. The receipt samples were collected randomly from shops and tickets for thermal print were identified based on their ability to darken when heated. In the article it is not indicated how many of the collected receipts are made of thermal paper. No information about manufacturers/suppliers of receipts seems to have been collected and it is thus difficult to say how representative the samples are.

The transfer to fingers was examined by holding the paper for 5 seconds with a movement where the thumb touched the backside at the same time as the forefinger and the long finger pressed against the BPA-containing top of the paper. Transfer to the fingers was measured by extracting BPA from the fingers by dipping them in ethanol and move them slightly for 30 sec. The receipt was only touched with one hand to imitate the movement when a cashier takes a receipt out of the printer and gives it to the client. Control tests showed that by extraction with ethanol, approx. 95% of the BPA released to the fingers could be extracted.

It can be seen from the results that the transfer differs very much between the two sides which corresponds with the fact that only one side contains BPA. By touching the front of the paper, 2.2 µg BPA was transferred to the fingers, whereas only 0.2 µg BPA was transferred from the backside. The authors suggest that transfer from the back is due to contamination.

The results show that more than 1.1 µg BPA (interval: 0.2-6 µg) was transferred on average to each of the two fingers if the skin was dry and more than 10 times more if the skin was wet. The result was more or less the same whether the receipt was held for 5 sec. or 60 sec. whereas the release was less if the receipt only was held for 1 sec.

Some of the results, also important for the interpretation of the results of the present study, are shown in the table below.

Table 1.1
Transfer of BPA to two fingers depending on how the receipt is held and time (Biedermann *et al.*, 2010)

Method	BPA transfer to two fingers (µg)	Average (µg)
Holding the receipt for 1 sec.	0.4; 0.3	0.35
Holding the receipt for 5 sec.		
- standard conditions (in the test)	1.2; 0.9; 1.5; 1.1	1.18
- low pressure	0.7; 0.2	0.45
- pulling the receipt through fingers	0.6; 0.7	0.65
Holds the receipt for 60 sec.	1.5; 0.7	1.10

The quantity that could be extracted did not increase significantly if the receipts were handled several times in a row which implies that BPA on the skin prevents additional release from the receipt to the fingers. Based on this, the authors conclude that persons at a cashier desk would have more or less the same quantity on their fingers all the time.

Studies of to which extent BPA was absorbed in the skin showed that BPA applied as a solution in ethanol apparently was absorbed by the skin so that after 90 minutes only 5 and 40% of the applied dose could be extracted depending on the applied concentration. The authors note that the fact that BPA cannot be extracted not necessarily means that it has been absorbed in the body. BPA transferred by handling receipts seems to behave differently, as after 2 hours 88% could still be extracted from the fingers. The results also showed that BPA is not very efficiently removed from fingers by washing them. However, the low number of samples makes this part of the study very uncertain.

The results are discussed further in chapter 5 in relation to the results of the present study.

American studies of BPA in cash register receipts

An American study of BPA in receipts for the Environmental Working Group in 2010 showed that 16 of the 36 collected receipts contained BPA in concentrations from 8,000 to 30,000 ppm mg/kg (Lunder ***et al.***, 2010). The study also showed that 0.7-3.8% of the content of BPA could be wiped off the receipts with a wet paper cloth. The study does not mention to which extent the paper had a top coat. Another study carried out by Warner Babcock Institute for Green Chemistry found concentrations of 3,000 to 17,000 mg/kg in 8 out of 10 receipts made of thermal paper (Mendum ***et al***., 2010).

Swedish study of BPA in thermal paper

In 2010 a study was made in Sweden of BPA in thermal paper used for various purposes. The analysis of cash register receipts were made by different families collecting receipts over a certain period. Pooled samples were taken of the receipts and based on the analysis, it can not be concluded that all receipts contained BPA.

BPA was found in all samples in concentrations varying from 5,000 mg/kg to 32,000 mg/kg with an average of 15,800 mg/kg. It is expected that a similar content of BPA would be found in Denmark in thermal paper for similar uses.

The study also points out that BPA migrates from the thermal paper to e.g. notes and lining in wallets. Up to 2,000 mg/kg was found in the lining of a

wallet and up to 86 mg/kg in 20 kr. notes. It can thus be concluded that there is also a certain exposure of BPA to these secondary sources even though the total exposure for secondary sources must be assumed to be low compared to the exposure to primary sources.

Table 1.2
Test results for BPA in thermal paper (Östberg & Noaksson, 2010).

Description	BPA (mg/kg)	BPA (%]
Receipts - family 1	14,000	1.4
Receipts - family 2	18,000	1.8
Receipts - family 3	14,000	1.4
Receipts - family 4	9,500	0.95
Receipts – wallet 1	19,000	1.9
Receipts – wallet 2	11,000	1.1
Parking tickets	32,000	3.2
Labels	5,000	0.5
Queue tickets	16,000	1.6
Cash point receipts	19,000	1.9
Print from local authority	16,000	1.6
Air tickets	5,800	0.58
Train ticket	14,000	1.4
Bus ticket	23,000	2.3
Game ticket	18,000	1.8
Medico technical paper slip	18,000	1.8

1.4.2 BPA in polycarbonate

As mentioned previously, BPA is only released from polycarbonate by migration of free un-reacted monomers not bound in the matrix.

Norwegian studies of BPA release from baby bottles made of polycarbonate shows that babies' intake of BPA via infant formulae is less than the quantities set by the food authorities as the tolerable daily intake.

BPA in the shield of baby dummies
A previous survey of dummies for the Danish EPA published in 2009 showed that the shield of dummies most often consist of hard plastic made of polycarbonate or polypropylene (Tønning ***et al.***, 2009). More than 30 different dummies were identified in the survey by shop visits and searching on internet shops. Out of the 21 products, for which information about the plastic type in the shield could be achieved, 10 had a shield of polycarbonate whereas the rest had shields of polypropylene. Because of the large number of products and retailers it was not possible to determine the market share for each product and thus not possible to demonstrate whether dummies with shield of polycarbonate also represented approx. 50% of the total sale of dummies.

5 dummies were tested in the study, all with shields made of polycarbonate. The BPA content was by a GC/MS determined at 1,000-1,900 mg/kg whereas quantitative analysis with GC/MS of two of the shields showed a concentration of approx. 106 and 280 mg/kg.

Analysis of BPA migration to artificial sweat and saliva for 7.75 hours from two dummies showed a migration of 7 mg/kg material to one of the media in one of the tests, whereas the migration in the other tests were below the detection value. By using the value of 7 mg/kg it could be calculated that BPA from dummies potentially could contribute with approx. 15% of the child's daily intake of BPA from different sources. When calculating the uptake via the skin it was assumed, in correspondence with the EU's Risk Assessment for BPA, that only 10% of the BPA that is applied to the skin is absorbed in the body.

2 Mapping

2.1 Cash register receipts

There are a number of Danish companies selling paper for cash register receipts. Basically there are two types: thermal paper and paper printed differently. The products are sold as receipt rolls, paper rolls, thermal paper rolls, thermal paper, thermal rolls and cash register rolls.

The aim of the mapping has been to answer two questions:

1 To which extent are receipts used in Denmark based on thermal paper?

2 To which extent do receipts of various types of thermal paper contain BPA?

Selection and provision of test material
The working group has contacted suppliers of receipts. The suppliers have been identified via searching on the Internet and by contacting a few, large grocery chains like Danish Supermarket and FDB as they represent a large part of the total use of receipts.

The two most important suppliers of thermal paper were contacted by phone and asked to give their best estimate to the above questions based on their own deliveries and knowledge of the market.

2.1.1 Information from suppliers and manufacturers

One supplier informed that the company has approx. 50% of the market share of thermal paper in Denmark. The company assesses that today approx. 80% of receipt paper on the Danish market is thermal paper and that the share is increasing. The company also stated that there are different qualities of thermal paper which differs by different types of coating. The company primarily works with three different qualities, but approx. 99% of the paper to the Danish market is sold in a standard quality containing BPA in top coating. A stronger coating can be used if a longer durability of the print is desired, or if you want the receipt to be more resistant to e.g. grease.

The other large supplier says that between 85-95% of the receipts on the Danish market are made of thermal paper. The company also estimates that nearly all thermal paper on the Danish market contains BPA. New products are however coming up where the more expensive bisphenol S (BPS) is used instead of BPA because the producers try to meet an increasing demand for BPA-free products. According to the company there are several different qualities but only few qualities are used in Denmark most is standard quality. Receipts with a 'top coat' are used in cash point machines, at some petrol stations, but also in furniture chains that have a long guarantee on many products and shops where you sell long-lasting consumer goods. The company states that primarily BPS is used in qualities where long durability is required. The technical reason why BPS is used in these qualities has not been investigated.

Both of the leading suppliers import thermal paper which they cut and pack for the retail business or sell to small suppliers. The companies receive the majority of the coated paper from the following four large manufacturers of quality paper; primarily from the two first:

1. Papierfabrik August Koehler AG, Oberkirch, Germany
2. Mitsubishi HiTec Paper, Flensborg, Germany
3. Jujo Thermal Ltd. Kauttua, Finland
4. Kanzan Spezialpapiere GmbH, Dueren, Germany

A large internet supplier of receipt rolls estimates that approx 90% of the receipt rolls on the Danish market are made of thermal paper and that the majority contain BPA. The company estimates there are maximum 10 different qualities of thermal paper on the Danish market.

An examination of the product lists for thermal paper on August Koehler's and Mitsubishis' homepages confirm that there are different qualities of thermal paper for receipts ref. Appendix 1 and 2. The qualities are characterised by their sensitivity (how easy to print) and their durability.

At Koehler they have three different qualities of thermal paper for receipts:

1. Paper with standard sensitivity that can last for minimum 7 years.
2. Paper with high sensitivity that can last for minimum 8 years
3. Paper with medium sensitivity that can last for minimum 5 years

At Mitsubishi they have seven different qualities of thermal paper for receipts:

1. Paper with low sensitivity that can last minimum 10 years
2. Paper with standard sensitivity that can last minimum 5 years
3. Paper with standard sensitivity that can last minimum 7 years
4. Paper with standard sensitivity that can last minimum 25 years
5. Paper with high sensitivity that can last minimum 5 years
6. Paper with high sensitivity that can last minimum 10 years
7. Paper with high sensitivity that can last minimum 12 years

A leading supplier explains that a quality with high sensitivity can be used at a fast printer with a very precise result. The less heat required developing colour on the paper, the more sensitive it is. The contacted companies explain that BPA is important for the sensitivity of the thermal paper, but they are not aware whether the paper with high sensitivity contains more BPA.

A thermal paper quality with high durability has a coating protecting against grease and UV radiance. Thermal paper can be identified from non-thermal paper by scratching a nail tip over the paper. If it is thermal paper the nail will leave a colour line as the heat from the scratch is sufficient to develop the colour.

One of the leading suppliers estimates that the use of thermal paper for receipts in Denmark is 1,000 to 1,200 tons per year. 2/3 is used in daily food chains and the rest in other sectors such as selected goods stores (e.g. furniture stores), restaurants, petrol stations, libraries, hospitals, etc. When testing the receipts it turned out that approx. 60% of the receipts contain BPA (Table 4.1), but the actual percentage is probably larger as it by the collection has aimed at covering many different types of receipts. The questioned suppliers estimate that the majority of receipts made of thermal paper contain BPA. In this study it will be assumed that the Danish market equals the EU average where 70-80% of the thermal paper contains BPA. Based on the estimates and figures of the average content of BPA in thermal paper 11,000 – 13,000 mg/kg (ref. section 1.2,), it is estimated that the total content of BPA in receipts used in Denmark is between 9 and 12 tons BPA a year.

Alternative developers

Analysis of the receipts (section 4.2.1) revealed that some types of thermal paper types do not contain BPA or BPS. Both Jujo Thermal and Kanzan Spezialpapiere deliver thermal paper without the two substances, but it has not been possible to get information about which developers are used.

Jujo Thermal describes the paper types on their website where they inform that phenol-chemicals are not used in the paper, i.e. the paper neither contains BPA nor BPS (Jujo, 2010). An example of the types without phenols, AP62KJ-R, is listed to have 25 years ”image stability” and may be used for receipts, labels, bank receipts, parking tickets and medical purposes.

2.2 Baby dummies

As mentioned in the previous mapping, baby dummies are sold in many types of shops: baby care shops, pharmacies, groceries, daily food stores, internet shops, etc. A mapping of the market for dummies was made in relation to another test in 2008/2009 (ref. section 1.4) and it has thus not been the intention to repeat this mapping.

In order to have an indication of whether there have been major changes in the last years in relation to plastic in the shields, a search was made on the supply of dummies in Danish internet shops. A few key manufacturers/importers of dummies with consumer facts (Danish: varefakta) registered with the Danish Institute for Informative Labelling (Dansk Varefakta Nævn) were contacted. Altogether they are representing more than 30 different labels including ”Apotekets” (from the pharmacies) and Matas.

Phase 2 of the internet search included purchase of dummies with a shield of polycarbonate representing a representative sample of manufacturers of dummies sold by different shops, including internet shops.

2.1.1 Information from manufacturers and retailers

Only two of the three manufacturers of labelled dummies have contributed to the study as the third and smallest supplier have stopped the production and the product will no longer be marketed.

The largest Danish manufacturer estimates that 10-20% of the shields on dummies on the Danish market are made of polycarbonate today and that the share is decreasing. The company assess that this is due to a large pressure and wish from both politicians and consumers to find alternatives to polycarbonate. When contacted, less than 5% of the company's own products were made of polycarbonate and this share is also decreasing. The company is outphasing polycarbonate entirely and plans not to use it at all by the end of 2010. Tritan™ copolyester is used an alternative to polycarbonate, but it is not as suitable as it is more fragile, less heat-resistant and not apt for print.

A Danish distributor of dummies from a leading international manufacturer says that this manufacturer also have used the alternative Tritan™ copolyester since February 2010.

2.2.1 Dummies sold via the Internet

A study of dummies sold on the Internet in view of identifying dummies with shield of polycarbonate for this study showed that in this market segment still is a major part of the dummies have a shield of polycarbonate (ref. appendix 3).

Out of 15 types of dummies where the plastic type of the shield was specifically indicated, 10 were made of polycarbonate. These 10 dummies were produced by 7 different manufacturers in Denmark, Sweden, USA, Germany and Austria. It should, however, be noted that a major part of these are supplied as dummies with the possibility of having the child's name printed on them (MyDummy) and that polycarbonate apparently is very suitable when names should be printed on the dummy.

2.3 Summary

The study shows that the largest Danish suppliers of cash register receipts assess that approx. 90% of cash receipts used in Denmark is based on thermal paper. The usage is increasing and several large stores are about to change from non-thermal paper to thermal paper. Furthermore the study indicates that BPA is used in thermal coating on the major part of receipts. For papers with long durability some manufacturers are now using BPS. In some types of receipts other developers are used, but it has not been possible to find out which substances are used.

In Denmark, use of thermal paper for receipts is estimated to be between 1,000 and 1,200 tons a year. According to the contacted companies, the Danish market is dominated by two large suppliers having a market share of more than 90%.

There are approx. 10 different qualities of receipts on the Danish market, differentiating by different sensibility and durability. The content of BPA is important for a visible print on the receipt.

According to a leading supplier of dummies, dummies of polycarbonate represent 10-20% of the market. The market is actually moving away from dummies made of polycarbonate replaced by dummies of copolyester. An internet search shows that there are still many types of dummies on the market made of polycarbonate. As dummies made of polycarbonate are particularly good for print it is assumed that the sale via the internet not necessarily is representative for the entire market as there are relatively many dummies sold via the internet.

3 Exposure scenarios

3.1 Calculation of consumer exposure

Exposure scenarios are developed in line with the REACH guidance '***Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.15 - Consumer exposure estimation', version 2 from April 2010*** (ECHA, 2010a). Algorithms and formulae for dermal exposure are based on the models shown in section R.15.3.2.2 on dermal exposure and scenarios involving non-volatile substances migrating from an article and R.15.3.3 on oral exposure. The formulae are here modified to include results of analysis of BPA migrating to saliva and sweat simulants. The potential uptake per time unit (internal dose) of BPA from exposure to cash register receipts and dummies is compared to the DNEL (Derived No Effect Level) for BPA.

3.2 Cash register receipts

The exposure calculations involve calculating the amount of substance which will migrate from the surface of a product in contact with skin. As outlined in the guidance document, the essential parameters used for this model are:

- Weight fraction compound: the fraction of the compound in the total product
- Amount of product: the total amount of product applied to the skin
- The surface area of the exposed skin
- The migration rate of the substance absorption
- The contact time of the substance absorption
- Skin contact factor, a factor that can be used to account for the fact that the product is only partially in contact with the skin.

The dermal load is then calculated using the following equation (Equation 3.1):

$$L_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{contact} \cdot T_{contact} \cdot 1000}{A_{skin}}$$

where Q_{prod} is the weight of the receipt. Fc_{prod} is the share of BPA in the receipt and Fc_{migr} is the rate BPA migrates from the receipt to sweat. A_{skin} is the area in contact with the skin in those cases where the skin in only partly in contact with the receipt. The default value for $F_{contact}$ is 1. $T_{contact}$ is the time the skin contacts the receipt.

The used parameters are explained in Table 3.1.

Tier 1 exposure scenario
For a Tier 1 assessment (first rough assessment of potential risks) of the ex-

posure from cash register receipts, the migration of BPA from collected receipts to a sweat simulant was measured and used for the calculation of the dermal load.

By using the migration of BPA (Migr.) to a sweat simulant per surface and time unit the dermal load is calculated based on the following equation:

$$L_{der} = Migr \cdot F_{contact} \cdot T_{contact}$$

where the measured migration to sweat per surface and time unit is considered equivalent to the amount of BPA migrating to the skin:

$$Migr \cong \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr}}{A_{skin}}$$

The Tier 1 model probably result in a considerable overestimation of the exposure as the amount of BPA which can be extracted from the submerged receipt is expected to exceed the amount of BPA which can migrate to the fingers when handling the receipt, even when the fingers are humid.

The external dermal dose (dermal exposure of the skin) in mg per kg bodyweight is then calculated based on migration data to the sweat simulant:

$$D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW}$$

which is equivalent to:

$$D_{der} = \frac{Migr \cdot A_{skin} \cdot T_{contact} \cdot F_{contact} \cdot n}{BW}$$

If you include absorption through skin in the formula, the internal dermal dose (what is absorbed and may be taken in the blood veins) of BPA mg per kilo bodyweight is calculated as:

$$D_{der} = \frac{Migr \cdot A_{skin} \cdot T_{contact} \cdot F_{contact} \cdot F_{abs} \cdot n}{BW}$$

Parameters and symbols used in the formula that here are used for the dermal exposure scenarios are explained in Table 3.1.

Table 3.1
Explanation of symbols used in exposure scenario for skin (based on ECHA, 2010a)

Input parameter	Description	Unit
Q_{prod}	Amount of product used	mg
Fc_{prod}	Weight fraction of substance in product	mg/mg product
Fc_{migr}	Rate (fraction) of substance migrating to skin per time unit	mg/mg/t
Migr.	Amount of substance migrating to skin per skin area and time unit	$mg/cm^2/t$
Extr.	Amount extracted from exposed fingers per area and time unit	$mg/cm^2/t$
$F_{contact}$	Fraction of product in contact with skin (default = 1)	cm^2/cm^2
$T_{contact}$	Contact duration between article and skin	t
A_{skin}	Contact area between product and skin	cm^2
C_{der}	Dermal concentration of substance on skin	mg/cm^3
BW	Body weight	kg
n	No of incidents per day	d-1
F_{abs} *	Dermal absorption	%
Output parameter	Description	Unit
L_{der}	Dermal load on skin due to migration	mg/cm^2
D_{der}	Dermal dose per day and body weight	mg/kg bw/d

* For a Tier 1 estimation, a dermal absorption of 100% is normally used.

Realistic worst case scenario

A more realistic worst case scenario is based on measurements of BPA extracted from a known skin area exposed to receipt for a typical handling time.

In this case the equation for the dermal load is as follows:

$$L_{der} = Extr \cdot F_{contact} \cdot T_{contact} \cdot 1000$$

The external dermal dose in mg per kg bodyweight is then calculated based on data from analysis of the amount of BPA extracted from the fingers using the following equation:

$$D_{der} = \frac{Extr \cdot A_{skin} \cdot T_{contact} \cdot F_{contact} \cdot n}{BW}$$

If you include the absorption through the skin in the formula, the internal dermal dose in mg per kg bodyweight is calculated as:

$$D_{der} = \frac{Extr \cdot A_{skin} \cdot T_{contact} \cdot F_{contact} \cdot F_{abs} \cdot n}{BW}$$

As illustrated exposure will depend on the migration of BPA in the receipt, how long time receipt is in contact with the skin (contact duration), how many times during the day the person is in contact with thermal paper/receipts (frequency) and the area of the fingers in contact with the receipts.

3.2.1 Determination of exposure parameters for consumer exposure

In the exposure scenario for cash register receipts the parameters "duration of contact", "frequency of incidents per day" and "surface of exposed skin" were determined as follows:

Duration of contact
Duration of contact has been set based on observations of consumer behaviour in a large supermarket. 25 random customers were observed and on average they held their receipt for 11 seconds in the shop. Nine of the 25 customers didn't want to take the receipt. The 16 customers who took the receipt on average held their receipts for 17 seconds. For some of the time they held it with two hands; for some of the time they held it in only one hand. Two customers held it for 55 and 66 seconds, respectively, most of the time with one hand. The customers that chose to take the receipt all kept it. They didn't throw it out but put it in their pocket, bag or purse. These customers will most likely be in contact with the receipt one or two times more when it is disposed of and/or archived. We assume that the customers are in contact with the receipt for a shorter period the second time they handle the receipt (e.g. to throw it out).

Based on these observations a standard handling was determined representing both the handling in the shop and the subsequent handling when the receipt is thrown out or archived (and later thrown out). In this scenario the receipt is held with both hands for about 10 sec. where the fingers move over the receipt while it is checked and then folded. When folding the receipt, the BPA-containing side is turned out so all fingers are in contact with this side during folding.

Frequency
The frequency of contact with receipts containing BPA has been estimated by extrapolating data on payment card transactions and the payment methods in a large Danish supermarket chain as described below.

A large Danish supermarket chain has provided information on number of transactions where credit cards are used as payment method. Information about total number of payment card transactions in Denmark is based on information from Nets (previously PBS), data on the Danish population are from Statistics Denmark and the two largest suppliers of receipts have provided an estimate of the percentage of receipts based on thermal paper. The percentage of receipts of thermal paper containing BPA is based on general EU data as it is assumed that these data also apply for the Danish market.

Obviously there can be variations in the pattern of payment methods in different sectors. Customers who shop in stores selling expensive consumer goods more often use credit cards as payment whereas customers in small newspaper stands rather pay cash. Using data from a large supermarket chain is considered to give a good average picture of the payment patterns in Danish stores in the absence of more precise data. Parameters and results from the calculation of how many receipts the consumers handle annually can be seen in Table 3.2.

Based on the above, the total number of receipts with BPA used in Denmark is estimated at 1,220 million a year. Alternatively the number can be estimated based on the total tonnage of thermal paper rolls delivered, estimated by a leading supplier at 1,000-1,200 tonnes per year. In a recent Swedish study of

BPA in thermal paper, the average weight of 47 randomly sampled cash register receipts is reported to be 0.55 gramme (Östberg, T. & E. Noakson , 2010). Using this average weight and assuming that 75% of 1,000-1,200 tons thermal paper contains BPA, the total number of BPA-containing receipts can be estimated at 1,355 – 1,627 million. This alternative estimate indicates that 1,220 million receipts in Table 3.2. are probably not far from the actual number and the uncertainty of this estimate is probably lower than the uncertainty on other parameters used for estimating the total number of handled receipts.

In addition to when the receipts are received, the receipt will be handled again at least once when it is disposed of. It is possible to imagine many different scenarios for the disposal and/or archiving. Some people save all their receipts in a binder, others keep them in their wallet until it is full and then throw most of them out and keep a few. Before the receipts are disposed of, the customer often checks it again and all received receipts will be handled twice. Here it is roughly assumed that those consumers who carefully check the receipts and keep them, on average handles each receipt 2.5 times.

Some consumer groups receive more receipts than the average consumer. Women with children at an age where they do not shop themselves receive considerably more receipts than the average. It is here roughly estimated that these consumers receive twice as many receipts as the average consumer, and they thus handle about 3.6 receipts a day (ref. Table 3.2).

Besides cash register receipts the consumer will also be exposed to BPA in thermal paper used for other applications: library receipts, queue tickets, labels, parking tickets, boarding pass etc. It has not been possible to obtain data on use of thermal paper for all these applications. It has been roughly assumed that the consumer group “women with children” on average handle one of these receipts/ tickets a day.

Table 3.2
Parameters used for calculating the frequency i.e. number of events receipts handled per day

Credit card transactions:	
Danish credit card transactions in 2009 *	828 million
Internet transactions *	45 million
- here of Dankort/Visa Dankort *	38 million
Dankort as % of total	83%
Number of Dankort transactions less internet transactions	790 million
Number of transactions assuming that Dankort transactions represent 83% of total	952 million
Data for supermarket chain:	
- card transactions per year	125 million
- transactions per year	237 million
- card transactions in percent of all transactions	53%
Estimated number of transactions (receipts) in Denmark	1,807 million
Receipts:	
Share of receipts made of thermal paper ****	90%
Share of receipts made of thermal paper containing BPA	75%
Estimated number of receipts with BPA-containing thermal paper	1,220 million
Receipts per inhabitants:	
Population in Denmark above the age of 12 in 2009	4.7 million
BPA-containing receipts per consumer above 12 years, per year	259
BPA-containing receipts per consumer above 12 years per day	0.7
Number of times each receipt is handled	2.5
BPA-containing receipts handled per consumer above 12 years per day	1.8
Factor for consumers handling more than the average	2
BPA-containing receipts handled per consumer per day in the group handling relatively many receipts.	3.6
BPA-containing receipts handled per consumer per day in the group of consumers handling relatively many receipts – including thermal paper used for other purposes	4.6

* Total number of card transactions in Denmark in 2009 was 3,038 million, but according to Nets (personal contact) the main part of these transactions are not payments in shops in Denmark. There are only data for transactions with Dankort.

** Source: NETS, 2010.

*** Source: Statistics Denmark.

**** Source: Leading suppliers of receipts.

Contact area between product and skin

The contact area between the cash register receipt and skin highly depends how the receipt is handled. When checking the receipts the customer will usually touch the receipts several times at different parts of the surface.

Consequently the touched part of the receipts will be larger than the part of the skin touching the receipts. The touched surface has been estimated by letting two persons handle four receipts after their fingers had been blackened with ink. The test was illustrating two different scenarios. In scenario 1, the

customer receives the receipt, looks at it briefly and throws it away. In scenario 2 the customer examines the receipt more closely before folding it and putting it in the purse. Scenario 2 is the scenario used later in connection with studies of how large quantities of BPA migrating from the receipt to the fingers.

As the receipts have BPA on the upper side only, it is of great importance for the exposure whether the receipt is folded with the upper side or the lower side against the finger pads. In scenario 2 the receipt is folded with the upper side turning outside in touch with the finger tips.

In scenario 1 where it primarily was the thumb, which was in contact with the receipt but touched it several places, the blackened part of the upper side was on average 8.3 cm^2. The total surface of thumbs having been in contact with the receipt was smaller. In scenario 2 where the receipt was folded, was on average 46 cm^2 of the blackened upper side. The major part of this area, however, was touched for much less than 5 seconds.

The results of the Swiss study indicate that even though the receipt is handled several times it does not result in a significantly higher amount of BPA on the skin. It is therefore assumed that migration of BPA to the skin is proportional with the skin area being in touch with the receipt. The area of the finger pads being in touch with the receipt is different from person to person, but typically approx. 10 cm^2 of the finger pads (on 8 fingers) will be in contact with receipt when it is checked and folded with the front side turning out.

The parameters used in the two scenarios are shown in Table 3.3.

Scenario for cashier workers

Focus of this study is exposure of the consumers, but as the cashiers are also exposed to BPA in receipts, a variation of the scenario has been made with values that are assessed to be representative for a cashier's handling of the receipts. No studies have been made in order to determine the parameters. A cashier in a supermarket roughly handles approx. 100 receipts a day (equivalent to one transaction each 4.5 min.) and the receipt is handled with one hand for 5 seconds.

Table 3.3
Parameters for the exposure scenarios for exposure of consumers and cashiers to BPA in cash register receipts

Parameters for exposure scenarios		Value	Source
Total migration from receipt to sweat simulant in mg/cm^2 for 5 seconds	$Migr_{Total}$	$0.14*10^{-3}$	Measured value
Migr , mg/cm^2/sec.	Migr.	$2.8*10^{-3}$	Calculated based on measured value
Duration of contact, sec. per incident	$T_{contact}$	Consumers: 10 Cashiers: 5	Consumers - based on observations Cashiers – Rough estimate
Fraction product in contact with skin, cm^2/cm^2	$F_{contact}$	1	Default value
Frequency, number of incident per day	n	Consumers: 4.6 Cashiers: 100	Consumers: worst case based on calculations of total number of receipts per year in Denmark. Cashiers: rough estimate
Surface of finger pads being in contact with the receipts, cm2	A_{skin}	Consumer: 10 Cashier: 5	Consumers: Worst case based on observations. Cashiers: Rough estimate based on assumption that cahiers only handle the receipt with one hand.
Dermal absorption, %	F_{abs}	10 / 50	Dermal absorption of 10% as in the EU risk assessment (EU, 2010) and 50% as indicated in a later study (ref. section 5.1.2, Zalko *et al*, 2011)
Body weight of consumer and cashier, kg	BW	60	Average body weight of a grown woman

3.3 Baby dummies

In the previous study of 2 year-olds' exposure to BPA from dummies with shield of polycarbonate it has been assumed that the child is exposed via sweat and saliva for 7.75 hours a day (Tønning ***et al***, 2009). This value was determined as a worst case based on British and German studies of babies' dummy behaviour. The reason was that children, when they use the dummy, partly will be in contact with the shield when they have the dummy in their mouth, partly will be in contact with shield and ring when they handle the dummy. Often the children touch the dummy when they have it in the mouth. When they have the dummy in the mouth a part of the shield will be in contact with saliva from the mouth and a part of this saliva will be swallowed. There will also be part of the shield that is in contact with the skin around the mouth. The child can use the dummy when it sleeps, during the night and during the day and it can use the dummy for comfort. We assume that, as in the previous study, the baby has oral contact with approx 25% of the surface of the shield (approx. 50% of the part facing the mouth) and has dermal contact with approx. 25% of shield and ring (if the dummy has a ring) but so that the major contact is between face and shield.

3.3.1 Dermal exposure

In this scenario the exposure calculation involves an estimation of the same essential parameters used for the calculation of the dermal exposure from BPA in cash register receipts.

For dummies only the worst case scenario has been made based on migration of BPA from the dummy shield to a simulant sweat.

The exposure will depend on the amount of BPA in the dummy shields and handle, the migrating to sweat, the contact duration, the area of the shield in contact with the skin and the absorption of the substance.

According to the guidance document, the dermal load is calculated as follows:

$$L_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{contact} \cdot T_{contact}}{A_{skin}}$$

with Q_{prod} being the weight of the dummy, Fc_{prod} the fraction of BPA in the shield and Fc_{migr} the rate of BPA migrating from the pacifier to sweat. A_{skin} is the contact area between the skin and the shield (surface of the shield) and $F_{contact}$ is the share of this area in contact with the skin. $T_{contact}$ is the period the skin is in contact with the dummy.

When results of analysis of the migration (Migr.) of BPA per surface unit from the shield to simulant sweat are available for a period equivalent to the contact period, the formula for dermal exposure is as follows:

$$L_{der} = Migr \cdot F_{contact} \cdot T_{contact}$$

where the measured Migr. is equivalent to:

$$Migr \cong \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr}}{A_{skin}}$$

The external dermal dose can then be calculated as:

$$D_{der} = \frac{L_{der} \cdot F_{abs} \cdot A_{skin} \cdot n}{BW}$$

And the absorbed (internal) dermal dose in mg per kg body weight can then be calculated based on the following formula:

$$D_{derint} = \frac{Migr \cdot T_{contact} \cdot F_{contact} \cdot A_{skin} \cdot n \cdot F_{abs}}{BW},$$

Where A_{skin} is the surface of the skin in contact with the dummy's shield, $F_{contact}$ is the part of the shield in contact with the skin, n is number of contacts with the shield per day, F_{abs} is the absorption through the skin and BW is the body weight for the baby using the dummy.

For the exposure assessment two calculations are made where it is assumed that the dermal absorption is 10% in line with the EU risk assessment and 50% based on new studies as mentioned in the section on cash register receipts.

Parameters used in the dermal exposure scenario are shown in Table 3.3 3.4.

Table 3.4
Parameters for dermal exposure scenario for BPA in baby dummies

Parameter		Value	Source
Total amount migrating to sweat per kg or cm^2 over 7.75 hours	$Migr_{Total}$	4.17 µg/27.8 cm^2 shield (0.15)	Based on analysis of migration from a 27.8 cm^2 shield for 7.75 hours
Migration to sweat, µg/cm^2· hour	Migr.	0.019	Based on total migration divided by with 7.75 hours
Contact duration, hours	$T_{contact}$	7.75	(Tønning *et al*,, 2009)
Fraction of contact area for skin, cm^2/cm^2	$F_{contact}$	1	Default – 1 cm^2 skin touches 1 cm^2 of the shield
Surface of exposed skin, cm^2	A_{skin}	6.95	The exposed skin surface is set to equal 25% of the shield. (Tønning *et al,*, 2009)
Dermal absorption, %	F_{abs}	10 / 50	Dermal absorption of 10% as in the EU risk assessment (EU, 2010) and 50% as indicated by a later study (Zalko *et al.*, 2011)
Body weight, kg	BW	4.5	Body weight of a 1-2 month old baby
Incidents per day	n	1	One contact incident lasting 7.75 hours is estimated as worst case (Tønning *et al,*, 2009)

3.3.2 Oral exposure

Oral exposure is the result of swallowing saliva containing BPA migrated from the dummy to the saliva. Oral exposure expressed as the internal dose will depend on the amount of BPA migrating to the saliva and the amount of saliva swallowed during use of the dummy.

The amount of BPA migrating to the saliva will be determined in an analysis where the shield of a pacifier is submerged in a saliva simulant and the amount of BPA migrated to the saliva simulant is measured over a time period of 7.75 hours. It was decided to let the migration tests (for both sweat and saliva simulant) follow the same period of time as used for contact period in the exposure scenario to avoid any uncertainty about changes in the migration rate over time.

It is assumed that BPA can migrate to an exposed area around the mouth corresponding to 25% of the surface of the shield.

It is assumed that the absorption is 100% and that the total amount of BPA migrating to the saliva from 25% of the surface of the shield will be ingested by the child.

When the migration of BPA from the shield to the saliva (Migr.) per surface unit is analysed for a given time period, the formula for the daily internal dose is calculated as follows:

$$D_{oral,int} = \frac{Migr \cdot T_{contact} \cdot S_{shield} \cdot F_{contact} \cdot n \cdot F_{abs}}{BW}$$

For the worst case scenario, the body weight of a 1-2 month old baby of 4.5 kg is chosen.

Table 3.5
Parameters for oral exposure scenario of BPA in baby dummies

Parameter		Value	Source
Surface of shield, cm^2	S_{shield}	27.8	Analysis
Fraction of surface in contact with saliva, cm^2/cm^2	$F_{contact}$	0.25	25% of shield surface (Tønning *et al.*. 2009)
Contact duration, hours	$T_{contact}$	7.75	(Tønning *et al.*. 2009)
Total amount migrating to saliva per cm^2 over 7.75 hours, $\mu g/cm^2$/7.75 time	$Migr_{Total}$	0.049	Calculated based on analysis of migration from 27.8 cm^2 shield for 7.75 hours
Migration rate to saliva, $\mu g/cm^2$/ hour	Migr.	0.0063	Calculated based on total migration (divided by 7.75 hours)
Oral absorption, %	F_{abs}	100	It is assumed that the child swallows all the saliva containing BPA
Body weight, kg	BW	4.5	Body weight of a 1-2 month old baby has been selected for the scenario
Incidents per day	n	1	One contact incident lasting 7.75 hours is estimated as worst case (Tønning *et al.*. 2009)

4 Analyses

4.1 Collection, methods of analyses and test design

4.1.1 Cash register receipts

Collection of cash register receipts
Based on information from the suppliers on where it can be expected to find receipts of different qualities of thermal paper, 12 printed receipts was collected from the following shops or places:

- Shops representing groceries: grocery chains, discount supermarkets and a toy shop.
- Shops that are expected to use receipts with long durability: a furniture chain and a hardware store.
- Machines that are expected to use weather resistant paper qualities (e.g. with top coat): two cash machines at petrol stations and a cash withdrawal machine in a bank.
- A library.

Furthermore, there has been collected one sample of a sticker from the weighing of vegetables in a supermarket.

At the collection is has been envisaged that the receipts were printed with at least 6-10 transaction lines. A total of 7 receipts have been collected from each of the collection points.

Disposable gloves were used at the sample collection to avoid cross contamination of the tests.

Analyses of content
A subsample of each type of receipt was weighed and the surface measured. The subsamples were selected so they represent an average receipt with 6-10 printed lines.

BPA was extracted from the sample by immersing the sample in methanol at 60°C for one night. The extracts were subsequently diluted with methanol, deuterium labeled internal standard BPA-dx was added and analysed by use of reverse phase HPLC.

For each analysis series, two control samples of low and high concentration level were included to verify the calibration.

In order to verify the presence of BPA, the tests were analysed with GC/MS. In this analysis it was also qualitatively determined whether the sample contained BPS, but the BPS concentration was not quantified.

For all samples a double determination was made (applies for all analysis), i.e. for each test two analyses of extraction fluid/contact fluid were carried out.

Analysis of migration to sweat
Based on the results of the analyses of the content all 7 samples containing BPA were selected for migration analysis.

A subsample of each of the 7 types of receipts was weighed and the surface are was measured. As with the analysis of the content the subsamples were taken so they represented an average receipt with 6-10 printed lines. The sample was immersed in 20 ml sweat simulant, pre-heated to 37 °C for 5 seconds. It was ensured that the entire surface was exposed to the contact media. The sample was not shaken during the immersion.

For the migration tests an extraction time of 5 sec. were used which is somehow shorter than what the average time a receipt is handled. The short time was chosen to avoid that the receipt began to dissolve and the migration thus would be unrealistically high.

The used sweat simulant is described in DS/EN ISO 105-E04 and consist of 1-histidine monohydrochloride-1-hydrate, sodium chloride, sodium dihydrogen phosphate and sodium hydroxide for adjustment of pH to pH 5.5. The simulant has previously been used for migration analysis in other of DEPA's consumer projects.

A part sample of the contact media was diluted with methanol added deuterium labelled internal standard of BPA-dx and the sample was analysed by reverse phase HPLC.

Analyses of migration to fingers
It is assumed that the exposure of the consumer primarily will be through finger pads via sweat and tests were made of how much BPA was migrated to the fingers when handling BPA-containing receipts.

The test method follows the method used in the Swiss study (Biedermann ***et al.***, 2010), however the handling of the receipts in the present study corresponded to a consumer's handling of the receipts. In the Swiss study focus was on the cashier's handling of the receipt.

Before the first test and between all the tests the hands were washed with hot water and soap and air-dried. The fingers were then moved for a while to obtain a natural humidity on the surface.

The receipt was held with both hands and handled with hands' thumb, forefinger, long finger and ring finger. The fingers moved down over the receipt for 5 sec. and then the receipt was folded with the front (with BPA) outwards. The folding took 5 more seconds. During the folding where the fingers all the time were in contact with the BPA-containing front there was a light pressure for each folding.

The forefinger, long finger and ring finger were then dipped for 30 seconds in ethanol in a Petri dish to extract the BPA from the fingers. The fingers were moved slowly during the extraction and rinsed afterwards with ethanol collected in the dish. This was repeated with the two thumbs. In the Swiss study various extraction methods were used and the result was that a satisfactory extraction could be achieved by lowering in ethanol for 30 sec. (95% recovery in recovery tests).

One time during the test an extraction was carried out of possible leftovers of BPA on the fingers after being washed by dipping the fingers for 30 sec. in ethanol with subsequent rinse in the same way as after handling the receipts.

When testing with humid fingers the fingers were moistened with sweat simulant. There were no visible drops on the fingers, but they were shiny. The receipts became visibly humid (dark) where they were handled the first time, but after the first handlings there were no longer a visible effect of the handling. The fingers were in the test more humid than normally when sweating on a hot summer day or after a run. As the humidity changed very fast because the liquid was absorbed by the skin there has been made no attempt to quantify the degree of humidity.

When testing fingers with hand lotion, a lotion labelled "Derma Helse, Decuderm u/parfume, hudneutral, specialpleje" was used. A limited amount of lotion was put on, drying in so the fingers were shiny without being very greasy. There were no visible marks on the receipts after touching.

Recovery and analyses of intake to the skin
To test the recovery of BPA, two fingers were dipped in a known amount of BPA diluted in water and the fingers were subsequently dipped in ethanol for 30 sec. for the extraction of BPA. The aim of the test was to show to which extent the amounts that were extracted from the fingers after handling of the receipts correspond to the amounts that actually migrated. Two tests were carried out where 1.9 and 9.5 µg BPA, respectively, were applied to two fingers. As BPA is difficult to dissolve in water a dilution was made in ethanol, which subsequently was diluted with water so that the diluted solution contained 0.3% ethanol. As it was not possible to make a sufficiently high solution of BPA so that the 9.5 µg BPA could be put on once it was necessary to put it on 5 times with the evaporation of water in between the applications.

Before the extraction it was ensured that the water had evaporated which was approx. 1 min. after the application of the 9.5 µg BPA. With this method there is a risk that there has already been an uptake of BPA in the skin. At the tests with handling of the receipts an extraction was made immediately after the handling (which took 10 sec.) and there is thus a possibility that the extraction in the tests with the receipts are better than at the recovery tests.

A similar test was made where extraction of the applied BPA was made after two hours.

4.1.2 Dummy shield

Purchase
8 types of dummies made of polycarbonate were purchased representing 8 different manufacturers. Six of the dummies were bought via the Internet whereas the two others were bought in daily groceries shops.

Analyses of content
There has been made no analyses of the content of the dummies. BPA are free monomers in polycarbonate and it should be expected that the concentration is at same level as found in previous studies. In the study of 2-year-old's exposure to chemical substances (Tønning ***et al.***, 2009) concentrations of 106 and 280 mg BPA/kg, respectively, were found in two dummy shields.

Scalding
Before the analysis all dummies were scalded for 5 min in boiling water and the dummies were left for 7 days before the analyses. By leaving the dummies for a week any potential diffusion of the BPA to the surface of the dummies after the scalding would be taken into account.

Analyses of migration to saliva and sweat
Before the analyses the shield was removed from the dummies, the shield was weighed and the surface area measured. The intact shields were lowered in the contact media of a saliva simulant and a sweat simulant for 7h45 min at 37°C. The contact media were heated to 37°C before the products were immersed.

A single extraction for each dummy shield was made with the selected contact media.

A subsample of the contact media was diluted with methanol with deuterium labelled internal standard of BPA-dx and analysed by reverse phase HPLC.

For each analysis two control tests were included at low and high concentration level for the verification of the calibration. The contact media was added a known concentration of BPA and BPA-dx in order to demonstrate the recovery of BPA.

The used artificial sweat simulant is described in DS/EN ISO 105-E04 and consists of 1-histidinmonohydrochloride-1-hydrate sodium chloride, sodium dihydrogen phosphate and sodium hydroxide for the adjustment of pH to pH 5.5.

For migration analyses with saliva a simulant of artificial saliva was used. The used saliva simulant is described in a JRC rapport (JRC, 2001). The artificial saliva consists of calcium chloride, magnesium chloride, potassium carbonate, potassium chloride, potassium phosphate, sodium chloride and hydrochloric acid for adjustment of pH to pH 6.8. The stimulant has been used before in DEPA's consumer projects.

4.2 Results of analysis

4.2.1 Cash register receipts

Analysis of content of BPA in cash register receipts
The results of the analysis of BPA in receipts and migration to artificial sweat are shown in Table 4.1. The area is indicated as the area of the receipt, i.e. the area is the BPA-containing front.

The analyses of the content show that 9 of the 12 receipts contained BPA, but two of these contained BPA in such small quantities that it probably derives from a cross contamination.

The content of BPA in the 7 receipts with high BPA content varies from 8,700 to 17,000 mg BPA/kg. The two receipts containing most BPA are from to discount supermarkets and contained 17,000 and 14,000 mg BPA/kg respectively. Lower values were found in five receipts from a discount supermarket, two grocery chains, a library and a toy shop. These receipts contained between 8,700 and 11,000 mg BPA/kg. The average value for the 7 receipts were 11,400 which is slightly lower than the average values found in the

Swedish, Swiss and American studies referred to in section 1.4. In these studies the following average values were found: 15,000 mg/kg (Sweden), 12,500 mg/kg (USA) and 13,500 mg/kg (Swiss).

There is no direct connection between the content of BPA in mg/kg and in µg/cm^2. The receipt from the grocery chain 1 has a higher content of BPA per kilo paper than the receipt from daily goods chain 2 whereas the opposite applies when looking at BPA per cm^2. It is thus two different paper qualities.

In three of the 12 receipts the concentration of BPA was below the detection limit of 0.1 mg/kg. A subsequent GC/MS analyses showed the presence of BPS (bisphenol S) in these receipts, but there have been made no quantitative analyses of BPS. These receipts are from a bank (cash withdrawal machine), petrol station (payment machine) and a furniture store. This confirms information from receipt suppliers that thermal paper for these purposes is often coated and contains BPS instead of BPA.

Two of the BPA-containing receipt had a far lower content of BPA of 37 and 0.28 mg BPA/kg, respectively. These receipts are from a hardware store and petrol station. The low content of BPA in the two receipts, and the fact that the GC/MS analyses did not reveal presence of BPS, may be why another developer is used in these receipts. BPS has only been made analysed qualitatively. The quantities of BPA equals the amounts which the Swedish survey showed could be migrated from BPA-containing receipts to notes. By sampling and analyses new clean gloves have been used for each test and cross contamination should consequently not be possible. The receipts give a colour reaction with the test method used to verify whether it is thermal paper or not. The receipts could be cross contaminated from the manufacturers who also manufacture BPA-containing paper. The suppliers have confirmed that the thermal paper originates from the Finnish manufacturer Jujo and the German-Japanese manufacturer Kanzan. Jujo states at their website that in certain types of the company's thermal paper phenol based developers are not used.

As expected based on information from suppliers, the receipts with long durability from payment and cash withdrawal machines or from a furniture chain and hardware store did not contain BPA. The fact that 5 out of 12 samples did not contain BPA cannot be used to conclude that there will only be BPA in 60% of receipts made of thermal paper on the Danish market. By selecting the receipts it has been deliberately tried to get a large coverage and cover most of the applications where special thermal paper is used. The major part of the tonnage is for receipts for groceries and these receipts all contained BPA. As there is no information indicating that the Danish market differs considerably from the EU market it has been assumed that 70-80% of the receipts of thermal paper used in Denmark contain BPA equivalent to the latest known EU average.

Analyses of migration of BPA from cash register receipts to artificial sweat

Analyses of migration of BPA from receipts to artificial sweat showed that 18 to 37% of the total content of BPA was migrated to the contact media within 5 seconds. Migration varied from 7 to 21 µg/cm^2 with an average of 14 µg/cm^2. There was no linear correlation between the content of BPA in the receipts and the migration rate. None of the receipts differed from the others with a considerably lower migration rate indicating a topcoat on top of the BPA-containing surface. This is in correspondence with information from the suppliers that thermal paper with top-coat typically contains BPS as a developer.

If it is assumed that approx. 10 cm^2 of the receipt is handled for 5 seconds it can be calculated that approx. 140 µg BPA are migrated by each event.

In the Swiss study, 41 µg BPA on average was migrated to fingers when the receipts were handled for 5 seconds with wet fingers. If, as in the present study, it is assumed that the receipt is handled with 8 fingers it corresponds to a migration of 164 µg BPA.

The measured migration was thus of the same size as found in the Swiss study when the receipts were handled with entirely wet fingers. As it is not usual to handle the receipts with wet fingers, 4 of the receipts were selected for further analyses in a more realistic exposure situation.

Table 4.1
Test results of BPA content in cash register receipts and migration to artificial sweat

Place of sample	Id-nr.	BPA content		BPA migration to artificial sweat	Migration in % of content **
		mg/kg	µg/cm^2 **	µg/cm^2/5 sec **	
Petrol station 1 (payment machine)	B1	1.4	0.011	n.a.	n.a.
Petrol station 2 (payment machine)	B2	< d.l.*	< d.l.	n.a.	n.a.
Furniture chain	B3	< d.l.*	< d.l.	n.a.	n.a.
Toy shop	B4	8,700	46	13	28
Grocery chain 1	B5	9,300	61	11	18
Grocery chain 2	B6	11,000	51	19	37
Discount supermarket 1	B7	17,000	77	21	27
Discount supermarket 2	B8	10,000	48	13	27
Bank (cash withdrawal machine)	B9	< d.l.*	< d.l.	n.a.	n.a.
Library	B10	9,700	53	13	25
Discount supermarket 3	B11	14,000	64	7	10
Hardware store	B12	37	0.19	n.a.	n.a.
Grocery chain, sticker	K1	< d.l.	< d.l.	n.a.	n.a.
Average ***		11,400	57	14	25

* Contained BPS. BPS content is not quantified.

** Area of one side of the receipt.

*** The two lowest values of 1.4 and 37 mg/kg (0.011 and 0.19 µg/cm^2) are not included when calculating the average.

"< d.l." The concentration is below detection limit of 0.1 mg/kg per receipt.

n.a. Not analysed.

Analyses of migration of BPA from cash receipts to fingers

Based on the analyses of migration to sweat the following receipts were selected for further analyses of migration of BPA to fingers: B4, B5, B6 and B7. Receipts B6 had the highest migration to artificial sweat – the two others were randomly chosen.

The test results of BPA migration to fingers are shown in Table 4.2. The average amount migrated to dry fingers (with some natural humidity) were measured to be 11.3 µg BPA to 8 fingers. There was a considerable variation a one of the figures was approx. 5 times higher than the others. In the Swiss

study there was an average migration of 1.13 µg BPA (variation from 0.2 to 6 µg BPA) per finger under standard conditions (slightly oily fingers). If it is assumed that the receipt is handled by 8 fingers (as in the handling situation, used in the present study) 9.04 µg BPA would migrate to the skin if the Swiss results were used.

The results for dry fingers in this study consequently correspond quite well with the results under standard conditions in the Swiss study.

Migration was approx. 9 times higher when the fingers were humid. On average 103 µg BPA migrated to 8 humid fingers. There was a considerable variation with a factor 10 between the lowest and the highest value. The high variation may partly be due to different degree of humidity on the fingers. As considerable variations in the measurement for dry fingers and sweat simulant were seen as well there seems to be a considerable degree of mere chance. The calculated average is consequently encumbered with a considerable uncertainty. The 90% confidence interval on the average can be calculated to be 25-181 µg BPA.

In the Swiss study the migration to wet fingers was about 35 times higher than the migration to dry fingers (standard conditions) and the migration to humid fingers about 15 times higher. The differences compared to the results of the present study could very well be due to differences in moistness, but also be a coincidence due to the low number of samples in both studies.

The migration to fingers with hand lotion was approx. 2.5 times the migration to dry fingers. The Swiss study found that the migration was 9 times higher to fingers with lotion than at standard conditions. The lower effect of the lotion seen in the present study could very well be an effect of the fact that fingers were covered with less lotion than in the Swiss study.

The extraction of BPA from fingers before start of the experiment showed in the first two tests that 0.07 µg BPA and 0.16 µg BPA could be extracted from fingers after they have been washed. After the wash upon handling the cash register receipts with wet fingers 0.27 µg BPA could be extracted. The results indicate that BPA is absorbed in the skin and is not washed off. The 0.27 µg BPA equals 5% of the lowest value measured after handling of the receipts and 0.3% of the average value for migration of BPA from receipts to humid fingers which is used in the exposure calculations. This illustrates that even after thorough washing of fingers with soap there will still be some BPA left on the skin and also that there have been a risk of transfer a smaller amount of BPA from one test to the next. The test sequence was dry fingers, humid fingers and fingers with hand lotion so it was not possible to transfer BPA from the tests with high migration rates of BPA to tests with small migration rates.

Table 4.2
Test results of migration of BPA from cash register receipt to 8 fingers after handling the receipt

Place of sample	Id-no.	Migration after handling receipt µg BPA *		
		Dry fingers	Humid fingers	Fingers with lotion
Toy shop	B4	4.6	21	n.a.
Grocery chain 1	B5	5.4	240	n.a.
Grocery chain 2	B6	30.0	64	26
Discount super market 1	B7	5.3	88	30
Average		11	103	28

n.a. Not analysed.
* At the handling the receipt was touched for 10 sec. and was in contact with approx. 10 cm^2 of the skin.

Recovery and absorption in the skin

The results of the recovery tests showed that after adding a known amount of BPA 80% and 45% of the applied quantity, respectively, could be extracted. The low value of 45% of the applied quantity is from the test where 9.7 µg BPA was applied to 2 fingers. In order to add a sufficient large amount, BPA was applied as 5 drops where each drop could dry before the next drop was applied. It took approx. 6 minutes from test start till BPA was extracted from the fingers. There will be a larger possibility that BPA can be absorbed in the skin in this test than in the tests with the receipts where the extraction started 10 sec. after the first handling of the cash register receipts. It is thus estimated that the test where 1.5 µg BPA was applied as one droplet and extracted after approx. 1 min. gives a more realistic picture of how much of the BPA migrated from the receipts will be extracted. In the test with 1.5 µg BPA there was a recovery of 80%. In the Swiss study with a similar extraction of 30 sec. in ethanol, 95% of the applied BPA was retrieved immediate after it had been applied, 83% after 5 min. and approx 40% after 20 min. and there were no major change during the period from 20 min. to 2 hours. In those tests the applied BPA were diluted in ethanol. Tests where the BPA was applied diluted in ethanol gave in the present study only a recovery of approx. 50% immediate after the ethanol had vaporized (data not shown) and the test was therefore repeated with BPA diluted in water which is more like the actual exposure situation.

After 2 hours, 32% and 20%, respectively, of the applied amount could be extracted. It is far less than found in the Swiss study where 88% of the applied amount could still be extracted from fingers after 2 hours upon handling a receipt. When BPA had been applied diluted in ethanol, 40% and 5% could be extracted depending on the used concentration. The differences may be due to the fact that in the present test, the fingers were relatively dry without lotion or oil, whereas the fingers in the Swiss study were slightly oily, but additional studies would be necessary to clarify the reason for the difference.

The recovery tests indicates that the measured migration of BPA from the receipts are less than the actual migration, but considering the relatively large uncertainty on the average values, and the uncertainty as a consequence of differences in time between adding BPA and extraction, this difference will not be adjusted. The tests demonstrate that the applied BPA relatively fast is absorbed in the skin, so it cannot be extracted with ethanol. After 2 hours, 68% and 80%, respectively, of the applied quantity of BPA could not be ex-

tracted. To what extent the BPA, which is absorbed by the skin will be taken into the body will be discussed as part of the health assessment in Section 5.2.

Table 4.3
Result of recovery tests

Applied BPA to 2 fingers, µg	Extraction after addition		Extraction after 2 hours	
	Extracted BPA, µg	Extracted in % of applied BPA	Extracted quantity, µg BPA	Extracted in % of applied BPA
1.9	1.5	80%	0.6	32%
9.7	4.4 *	45%	1.9	20%

* As BPA had to be applied 5 times, there were approx. 5 min. from start to the fingers were immersed in ethanol for extraction.

4.2.2 Shield on baby dummies

The results of BPA migration from the shield of dummies to artificial sweat and saliva are shown in Table 4.4.

Migration of BPA above the detection limit was found to both saliva and sweat from one of the shields whereas from another shield only migration to saliva was found. In both cases the concentration in the artificial saliva was only slightly above the detection limit of 0.1 mg/kg, whereas it was approx. 5 times the detection limit in the artificial sweat.

The only dummy (S5) for which migration to sweat was measured was designed without a ring.

At a previous analysis of migration of BPA from 2 dummies, carried out as a part of a large study of 2-year-olds' exposure to chemical substances migration above the detection limit was only found in one test (Tønning ***et al.***, 2009). In this test the migration was 7 mg/kg material to sweat from one of the dummies which is approx. 50 times higher than the values found in this study. In the previous study migration to saliva above the detection limit was not demonstrated in any of the tests.

Table 4.4
Test results of BPA migration from dummies' shield to sweat and saliva

Id-nr.	Weight of shield g	Surface of shield cm^2	Migration of BPA to sweat			Migration of BPA to saliva		
			mg BPA /kg shield	µg BPA /cm^2 shield	Total migration µg BPA	mg BPA /kg shield	µg BPA /cm^2 shield	Total migration µg BPA
S2	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.
S3	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.
S4	7.36	32.0	< d.l.	< d.l.	< d.l.	0.12	0.028	0.89
S5	8.53	27.8	0.49	0.15	4.17	0.16	0.049	1.36
S6	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.
S7	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.
S8	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.
S9	-	-	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.	< d.l.

"< d.l." means below detection limit which is 0.1 mg/kg shield.

5 Health assessment

5.1 Basis of the toxicological assessment

5.1.1 Effect levels and DNEL

Basically the risk assessment is made by comparing the calculated exposure in a realistic worst case scenario with the Derived No Effect Level (DNEL) which indicates the exposure level below which no damaging health effects are expected.

The risk assessment in this project is based on NOAEL (No Observed Adverse Effect Level) derived from the critical effect. REACH applies a DNEL value calculated based on NOAEL (or similar) and relevant assessment factors (AF – a kind of correction factors) for calculating the risk.

The DNEL value is derived for bisphenol A (BPA) based on NOAEL adjusted by a number of different assessment factors. The assessment factors to be used depend on which study NOAEL is based on (ECHA, 2010b).

The endpoint-specific DNEL (the value is determined in relation to certain organs where effects are seen) is based on the following equation:

$$Endpoint-specific\ DNEL = \frac{NOAEL_{corr}}{AF_1 \times AF_2 \times \ldots AF_n} = \frac{NOAEL_{corr}}{Overall\ AF}$$

$NOAEL_{corr}$ is the corrected NOAEL value, i.e. the carefully selected NOAEL-value which the DNEL value is calculated from (ECHA, 2010b).

The assessment factors applied are listed in the table below. The assessment factors have been established on the basis of the principles in the REACH guidelines.

Table 5.1
Assessment factors applied for determination of DNEL

Parameter	Value	Assessment factor
Interspecies	Allometric scaling. Corrections for differences in metabolic rate per kg body weight.	AS: 4 for rats 7 for mice
Interspecies	Remaining differences between different species	2.5
Intraspecies	Individual differences	10
Dose-response	LOAEL to NOAEL if LOAEL is applied because NOAEL is not established	3

A NOAEL of 5 mg/kg bw/day is based on studies of two generations of rodents where the critical effects were changes in body weight and organ weight (in breed and adult rats) and liver effects (in mice) (Tyl et al., 2001, Tyl et al., 2006) as recommended in the updated Scientific Opinion of bisphenol A from 2010 (EFSA Journal 2010; 8(9):1829).

The total assessment factor is 175 based on a factor of 2.5 for general interspecies differences, 7 for allometric scaling between mice and humans and 10

for intra species differences. The assessment factor for rats has not been used as it is not considered relevant here.

DNEL for bisphenol A is thus 0.029 mg/kg bw/day (NOAEL/AF).

This DNEL will be used for comparison with the estimated dermal and oral exposure. EFSA has also taken into account the results of later toxicity studies showing low-dose effects in rodents, e.g. a neurotoxicity study indicating an effect on learning in male rat offspring in a test following OECD TG 426, and concluded that these tests did not give reasons to reconsider the NOAEL used for establishing the TDI. In general, the opinion of EFSA is that the BPA-related low-dose effects in rats have not been demonstrated in a robust and reproducible way and thus do not allow a conclusion regarding the toxicological relevance for humans. This is also due to the fact that toxic kinetics differs among the species (how the substances are taken into the body and what happens to them) and that BPA is less bio-available in humans compared to rodents.

5.1.2 Absorption of BPA after dermal exposure

In the EU risk assessment of BPA (EC, 2010) it is assumed that only 10% of the dose applied to the skin is absorbed in the body liquids. The percentage is based on an unpublished draft report (In Vitro Technologies, 2001), where 5 and 50 mg BPA/cm^3 were applied to skin samples, respectively. It should be noted that the applied quantities are approx. 1000 times larger than the amounts applied to the skin when handling cash register receipts.

A recent survey of BPA's ability to penetrate the skin gave a similar result (Kaddar et. al, 2008). In the study the penetration to pig skin was examined using a so-called "Franz cell". Skin that had been frozen was used in the study. After 2, 5 and 10 hours of exposure the intake of BPA to the skin was 3, 6.9 and 11.4% of the applied dose, respectively. The BPA that penetrated the skin surface mainly accumulated in the dermis. After 10 hours 65% of the applied BPA was still on the skin surface. The test lasted 10 hours because this is the maximum period the workers handle BPA in their working environment. The authors assume that hereafter BPA is removed from the skin.

In a new French study, diffusion and metabolism of BPA have been examined using skin cultures and viable human skin explants and short-term cultures of skin from pig ears (Zalko ***et al.***, 2011). BPA was effectively absorbed in both skin model with 68% absorbed in pig ears skin and 46% in the viable human explants. BPA was extensively metabolised in both models whereas the same did not apply if the samples had been made non-viable by freezing. The most important metabolites was BPA mono glucuronide and BPA mono sulphate which totals 73% and 27% in skin from pig ears and the human explants, respectively. The authors note that some of the metabolites have less estrogenic activity than BPA so that the metabolism to some extent may be considered as detoxification. At the same time it is also possible that the BPA conjugates are transformed to BPA before or when they reach the target organs. The authors conclude that the study demonstrates that BPA is readily absorbed and is metabolized in the skin and that contact with the free monomer contributes to the human exposure to BPA. The trans-dermal absorption (absorption trough skin) was not determined in this test.

Based on this information it is assumed that dermal absorption may account for 50% of the applied amount and not only 10% as considered in the EU risk assessment. Both absorption factors are used in the calculations.

5.2 Cash register receipts

5.2.1 Exposure

Exposure of consumers

In order to calculate the internal dermal exposure of consumers (the amount absorbed in the body via the skin) values for total migration to the skin per unit area and time are used as well as exposed skin surface and exposure time per event, number of events and a factor for the dermal absorption.

For the Tier 1 scenario the average measured migration for 5 seconds was 0.014 mg/cm^2 corresponding to a migration rate of 0.0028 mg/cm^2/sec. The calculation, based on studies of migration to sweat, is a first rough assessment of the potential exposure which is refined with the realistic worst case scenario.

In the realistic worst case scenario used in this study, the average migration to humid fingers based on analysis were 103 µg/kg for an exposure of 10 cm^2 (8 fingers) for 10 seconds corresponding to a migration rate of 0.00103 mg/cm^2/sec.

Parameters and results of the dermal exposure scenarios are shown in Table 5.2. The maximum internal dose $D_{der, int,}$ in the worst case scenario for consumers has been calculated to be 0.004 mg/kg bw/d equivalent to a dose of 0.24 mg/d for a 60 g person. The formula for calculation of $D_{der, int,}$ is shown in section 3.2.

Table 5.2
Input and output parameters for dermal exposure scenarios for cash register receipts

Input parameter	Tier 1 scenario based on migration to sweat simulant	Realistic worst case scenario based on measured migration to humid fingers	Realistic worst case scenario for cashiers based on measured migration to humid fingers	Unit
Migr.	0.0028	0.00103	0.00103	mg/cm^2/s
$F_{contact}$ (default)	1	1	1	cm^2/cm^2
$T_{contact}$	10	10	5	s
A_{skin}	10	10	5	cm^2
BW	60	60	60	kgbw
N	4.6	4.6	100	d^{-1}
F_{abs} *	10/50	10/50	10/50	%
Output parameter				Unit
L_{der}	0.028	0.028	0.0103	mg/cm^2
D_{der}	0.021	0.021	0.0079	mg/kgbw/d
$D_{der, int}$ *	0.0021/0.0107	0.0021 / 0.0107	0.0008 / 0.004	mg/kgbw/d

* $D_{der, int}$ is calculated based on 10% uptake and 50% uptake.

When calculating the dermal exposure of cashiers based on a very conservative scenario as shown in Table 5.2, assuming that the person have humid fingers all day and 100 individual contact events where the receipt is touched for 5 seconds with a contact surface of 5 cm^2. Based on these assumptions the internal dermal load is calculated at 0.0043 mg/kg bw/day and 0.0215 mg/kg bw/day for 10% and 50% uptake respectively.

In relation to the exposure of the consumer it is reasonable to assume that each event is independent on the previous event, but this do not seem to be the case for cashiers handling a large number of receipts daily. The key question is whether BPA on the skin surface limits additional intake of BPA to skin from the receipts that are handled after each other. This will be discussed further in the health risk assessment.

5.2.2 Health risk assessment

Consumers

The risk characterisation ratio, RCR, shows the relation between the calculated absorption of the substance (the internal dose) and the DNEL which is the exposure level below which no damaging health effects are expected.

When RCR is below 1, the exposure is considered not to cause any risk. In order to consider other sources for exposure and that the RCR should be calculated based on the total exposure to BPA, an estimate have been made of other contributions to the BPA-load.

In the EU risk assessment report (EC, 2010) is presented some conservative estimates of the average consumer exposure in the EU via the diet. The estimates are shown in Table 5.3. The daily intake of BPA with food is estimated at 1.5 µg/kg bw/day). For a person of 60 kg this corresponds to 90 µg BPA/day. An oral intake rate of 100% has been used.

Table 5.3
Conservative estimate of total dietary exposure of adults to BPA (EU risk assessment).

Age of consumer	Source of exposure	Dietary exposure to BPA based on conservative migration value in µg/kg bw/day
Adult	3 kg canned foods/beverages	1.25
Adult	Migration from polycarbonate tableware and storage containers	0.25
Adult	Potential dietary exposure from all sources	1.5
Risk characterisation		
RCR_{diet}	DNEL: 0.029 mg/kg bw/day	0.052

RCR is calculated for the two consumer exposure scenarios based on a dermal absorption rate of 10% and 50% respectively and the results are shown in Table 5.4. The Tier 1 estimation for consumer exposure is shown as well.

It can be seen from Table 5.4, that the RCR for exposure of receipt is well below 1 for both the Tier 1 estimate and the two consumer exposure scenarios where the exposure is based on very conservative assumptions.

When calculating RCR from exposure to both food and cash register receipts (RCR_{total}) for the two worst case consumer scenarios, RCR is still below 1 (0.08 and 0.19, respectively) and based on these assumptions the exposure of BPA to receipts is not considered to constitute a risk.

Furthermore, it can be seen from Table 5.4 that the RCR_{dermal} in the worst case scenario is of the same magnitude as the RCR_{diet} based on conservative assumptions of the average consumer exposure of BPA in food in the EU. The results show that the exposure to cash register receipts potentially may result in absorption of the same magnitude as intake with food. Based on new studies of the relation between absorption of BPA and BPA-concentration in blood serum in mice and monkeys, American scientists conclude that a level of non conjugated BPA (i.e. BPA not bound to other substances) in blood serum of approx. 2 ng/ml serum, which has been found in several studies of humans, indicates that the total exposure of BPA from different sources are considerably higher than previously assumed (Taylor ***et al.***, 2010). BPA in receipts may potentially be one of the sources which previously have been underestimated.

Table 5.4
Calculation of RCR for BPA exposure to consumers in receipts and food

Output parameter	Tier 1 scenario estimate based on migration to sweat simulant	Realistic worst case scenario based on measured migration to wet fingers	Unit
L_{der}	0.028	0.0103	mg/cm^2
D_{der}	0.021	0.0079	mg/kgbw/d
$D_{der, int}$	0.0021 / 0.0107	0.0008 / 0.004	mg/kgbw/d
DNEL	0.029	0.029	mg/kgbw/d
RCR_{dermal}	0.07 / 0.37	0.03 / 0.14	-
RCR_{diet}	0.052	0.052	-
RCR_{total}	0.13 / 0.42	0.08 / 0.19	-

Other sources of exposure relevant for consumers are considered in the EU risk assessment report, e.g. dermal exposure to epoxy resin based adhesives, oral exposure to dental fissure sealants, and exposure to humans via the environment. For all endpoints (i.e. specific organs where effects are seen) assessed in the EU risk assessment the conclusion was that exposure from these sources are very low.

Cashiers

The dermal RCR is calculated for two very conservative cashier scenarios based on a dermal uptake of 10% and 50% respectively and the results are shown in Table 5.5. As in the consumer scenarios, the contribution from dietary exposure is added and the combined RCR has been calculated.

Table 5.5
Calculation of the risk characterisation ratio for BPA exposure to cashiers

Output parameter	worst case scenario for cashiers	Unit
L_{der}	0.0052	mg/cm^2
D_{der}	0.043	mg/kgbw/d
$D_{der, int}$	0.0043 / 0.0215	mg/kgbw/d
DNEL	0.029	mg/kgbw/d
RCR (D_{der} / DNEL)	0.15 / 0.74	-
RCR_{diet}	0.052	-
RCR_{total}	0.2 / 0.79	-

As it can be seen from the table, RCR_{total} is less than 1 for both the scenario with 10% and the scenario with 50% dermal absorption rate.

As mentioned previously, it is a key question for the exposure of the cashiers to what extent BPA on the skin surface limits the uptake of BPA from cash register receipts that are handled subsequently. The Swiss study shows that the amount of BPA on the skin does not increase by contact with additional receipts. In a test with standard conditions the average amount of BPA transferred to the skin of one finger was 1.2 µg BPA. After touching 10 receipts the average quantity transferred was 1.0 µg BPA. There was no effect of touching a receipt for 60 sec. instead of 5 sec. On this basis the authors conclude that the cashiers somehow maintain a constant amount of BPA on the fingers. A test showed that 2 hours after touching the thermal paper the amount extracted was 88% of the quantity that could be extracted immediately after touching the receipt. This could indicate that the absorption via the skin is not a fast process but as only one test was made, the result is considered to be very uncertain. Based on the results the authors assume that there will constantly be approx. 3 µg BPA per finger and that 27% of this is taken up in 2 hours, i.e. a constant absorption rate of 0.41µg BPA per finger. During a working day of 10 hours where the receipts are touched with 10 fingers the total BPA uptake is estimated at 41 µg BPA. If the hands are not washed before going home additionally 30 µg BPA will be left on the fingers which could also be resorbed. The total uptake under standard conditions (moisturized skin) has been estimated at 71 µg BPA/day. This amount is considerably lower than the amount calculated in the present study (up to 1,290 µg BPA/day) which is partly due to the fact that the present study considers a worst case situation where the receipts are touched with humid hands and each event are considered independent of the previous event.

Whether BPA is absorbed further in the body is uncertain, but the results of the Swiss study shows that BPA after a while can no longer be washed off which gives the substance plenty of time to be absorbed via the skin or metabolized. This is also in accordance with the results of this study showing that only a small amount of the applied BPA can be extracted from fingers after 2 hours.

A new American study of BPA concentration in urine from 389 pregnant women found the highest average values for different occupational groups in a group of cashiers (Braun ***et al.***, in press). The average value (geometric mean) for 17 cashier workers were 2.8 µg BPA/g creatine whereas the value for workers in the health sector and office workers was 2.1 µg BPA/g creatine. Due to the large variation the differences were not at a 95% significant level

even when data were adjusted for socio-economic factors. The authors also mention that the results should be interpreted cautiously. Apart from cashier work a high content of BPA in urine was positively associated with the intake of canned vegetables, exposure to tobacco smoke and to high molecular weight phthalates.

There is no doubt that cashiers potentially have a higher exposure to BPA than consumers as they are in contact with a significantly more cash register receipts during a day. However, it is not clear to what extent the number of contact events influence the total uptake of BPA as there is some indication that the skin is saturated at a certain point, but there is no available information about the actual uptake via the skin over time.

Although the combined RCR in this scenario is closer to the DNEL than in the consumer scenarios the conclusion, based on this very conservative estimate, is that the exposure does not cause any concerns with regard to the risk for cashiers.

5.3 Dummies

5.3.1 Exposure

In order to calculate the worst case internal dermal and oral exposure of children between 0 and 3 years, the total dermal and oral load per handling event are calculated based on migration per unit area of the shield and time. The body weight of a 1-2 month old baby of 4.5 kg is used for calculation.

The migration to sweat was measured at 0.15 μg/cm^2 per 7.75 hour corresponding to 0.019 μg/cm^2/h (shield S5).

The maximum migration to saliva was measured at 0.049 μg/cm^2 per 7.75 hour corresponding to 0.0063 μg/cm^2/h (shield S5).

The input and output parameters for dermal scenario are shown in Table 5.6.

Table 5.6
Input and output parameters for dermal exposure scenario for dummies

Input parameter		worst case scenario for dermal exposure based on migration to sweat simulant	Unit
Migration to sweat	Migr.	0.019	$\mu g/cm^2/h$
Fraction of contact with saliva	$F_{contact}$	0.25	cm^2/cm^2
Contact duration	$T_{contact}$	7.75	h
Surface of shield*	S_{shield}	27.8	cm^2
Dermal absorption factor	F_{abs}	10 / 50	%
Body weight of a 1-2 month old baby	BW	4.5	Kg
Events per day, n	Events per day, n	1	d^{-1}
Output parameter			Unit
Dermal load	L_{der}	0.00015	mg/cm^2
Dermal dose**	D_{der}	0.00023	mg/kgbw/d
Internal dermal dose	$D_{der, int}$	0.000023 / 0.00012	mg/kgbw/d

* For most dummies the surface would also include a ring, but this dummy was designed without a ring, but the shield had a relatively large surface that could be in contact with skin.

** $D_{der, int}$ is calculated based on 10% uptake and 50% uptake.

The input and output parameters for the oral scenario are shown in Table 5.7.

Table 5.7
Input and output parameters for the oral exposure scenario for dummies

Input parameter		worst case scenario for oral exposure based on migration to saliva simulant	Unit
Migration to saliva	Migr.	0.0063	$\mu g/cm^2/h$
Fraction of contact area for saliva	$F_{contact}$	0.25	cm^2/cm^2
Contact duration	$T_{contact}$	7.75	Hour
Surface of shield	S_{shield}	27.8	cm^2
Oral absorption	F_{abs}	100	%
Body weight of a 1-2 month old baby	BW	4.5	Kg
Events per day	n	1	d^{-1}
Output parameter			Unit
Oral load	L_{oral}	0.000049	mg/cm^2
Oral dose**	D_{oral}	0.00008 / 0.00003	mg/kgbw/d
Internal oral dose	$D_{oral, int}$	0.00008 / 0.00003	mg/kgbw/d

5.3.2 Health risk assessment

In the EU Risk Assessment Report (EC, 2010) the daily oral intake of BPA with food is estimated at 8 µg/kg bw/day) for a 1-2 month old baby of 4.5 kg corresponding to 35 µg BPA/day. RCR_{diet} is based on intake of BPA from baby bottles made of polycarbonate.

The calculated RCR_{diet} is shown in Table 5.8 and this is added to the total dermal and oral RCR for dummies to provide a more complete picture of the potential exposure and risk.

The risk characterisation ratio is calculated for the two scenarios based on migration of BPA to sweat and saliva simulant. A calculation of the total exposure has also been made considering other sources. The internal dermal exposure is calculated based on a dermal uptake of 10% and 50% respectively and the results are shown in Table 5.9.

Table 5.8
Conservative estimate of total dietary exposure of a 1-2 month old baby to BPA

Age of consumer	Source of exposure	Dietary exposure to BPA based on conservative migration value in µg/kg bw/day
1-2 month old baby	Infant feeding bottles	8
Risk characterisation		
RCR(diet)	DNEL: o.o29 mg/kg bw/day	0.276

It can be seen in Table 5.9 that RCR for both dermal and oral exposure and the combined RCR is considerably below 1 based on a conservative estimate. In comparison, the estimated oral intake with food, in this case from polycarbonate baby bottles, is considerably higher.

When RCR for intake with food, which is much higher than the RCR calculated based on exposure to BPA in dummies, is added the total RCR is 0.28 no matter which absorption factor is used.

Table 5.9
Calculation of the risk characterization ratio for BPA exposure to children

Output parameter	worst case scenario for dermal exposure based on migration to sweat simulant	worst case scenario for oral exposure based on migration to saliva simulant	Unit
L_{der}	0.00015	0.000049	mg/cm^2
D_{der}	0.00023	0.00008	mg/kgbw/d
$D_{der, int}$	0.000023 / 0.00012	0.00008	mg/kgbw/d
DNEL	0.029	0.029	mg/kgbw/d
RCR_{dermal} (sweat)	0.0008 / 0.002	-	
RCR_{oral} (saliva)	-	0.0026	
$RCR_{oral+dermal}$	0.0034/0.0046		
RCR_{diet}	0.276		
RCR_{total}	0.279 / 0.281		

5.4 Summary and conclusion

The results of this study show that there is no immediate health risk related to use of BPA-containing cash register receipt and baby dummies.

For exposure to BPA in receipts, RCR is far below 1 for worst case scenario exposure of consumers and according to the REACH guidelines for consumer exposure there is thus no relevant risk related to the exposure.

Exposure to cashier workers the highest RCR is still below 1. However, small changes in the assumptions will make it above 1. The calculated exposure with worst case scenario is by far higher than the exposure found in an earlier Swiss study where the exposure was not estimated for a worst case situation, but rather a typical situation and where it is also taken into account that the skin at a certain time is saturated so smaller amounts of BPA migrate to the skin. When RCR is still below 1 with the used worst case scenario it should then be concluded that there seems to be no health risk for cashier workers.

The calculated exposure to BPA in dummies is far below the exposure to BPA in baby bottles and the calculated RCR for exposure to BPA in dummies only contributes insignificantly to the total RCR when other sources are included.

The health assessment is based on a NOAEL value based on existing knowledge, but lately there have been results questioning whether health effects may occur at smaller doses than previously considered. The European Food Safety Authority, EFSA has concluded that new studies of low-dose effects of BPA do not give sufficient documentation that exposure from these doses could cause effect at humans and concluded that the no-observed-adverse-effect level (NOAEL) of 5 milligram/kg body weight/day identified in the previous evaluation in 2002, remains. At the moment the suspicion of effects from small doses of BPA cannot be rejected, but in this study NOAL is set as recommended by EFSA.

No matter the results of this study it is worth to note that BPA has been classified as an endocrine system disruptor with the hazard classification Repr.2, H361f: ”Suspected of damaging fertility“. The substance is also on the Danish EPA’s “List of undesired substances”, a signal list and guidance to companies about problematic substances and use which should be reduced or terminated in the long term. Alternatives to cash register receipts are available, but it has not been investigated to what extent the alternative developers are better than BPA from an environmental and health perspective and the costs of changing to the alternatives is unknown. Parts of the Danish retail trades have informed, that the price for paper with the alternative developer bisphenol S is approximately twice as expensive as BPA based paper, while thermal paper without phenol-chemistry is claimed to be four times the price for paper with BPA. At present the health risks of papers with alternative developers is unknown. Alternatives to baby dummies made of polycarbonate today account for the major part of the market.

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Appendix 1 Koehler's assortment of thermal paper

POS = point of scale

Koehler
THERMAL PAPERS

Product Range

Grade	Basis weight (gsm)	Application	Caliper (micron)	Sensitivity (dynamic)	Storage life*
KT 48 F20	48	POS	53	Standard	7 years
KT 55 F20	55	POS, fax	60	Standard	7 years
KT 58 F20	58	POS, fax	66	Standard	7 years
KT 54 2ST Two-sided coated	54	POS	57	Standard	7 years
KT 55 HS	55	POS, fax	60	High	8 years
KT 70 HS	70	POS, fax, medical charts	75	High	8 years
KT 80 HS	78	Tickets, medical charts	87	High	8 years
KT 55 P white, blue, yellow, green, pink	55	POS, weigh scale receipts	60	Medium	5 years
KT 100 P	100	Tickets, coupons	107	Medium	5 years
KT 80 EC	75	Labels, betting tickets	82	Medium	5 years

* in accordance with our storage and handling instructions

Appendix 2 Mitsubishi's assortment of thermal paper

thermoscript	Category	Grade	Substance (g/m²)	Caliper (micron)	Smoothness (Bekk. Sec.)	Sensitivity (dynamic)	Max. Speed (inch/mm pro Sec.)	Durability (years**)	Typical Applications
Fax and POS	Standard	F 5041	55	60	> 350	standard	8/200	5	POS, Fax
	High sensitivity	F 5051	56	60	> 400	high	12/300	5	POS, Fax, Medical
	Heat resistant	P 5027	55	58	> 300	low	4/100	10	POS, Transport
	Offset printable	P 5033	56	61	> 300	standard	8/200	7	POS, Banking
		P 5040	55	60	> 360	standard	8/200	7	POS
		P 5050	56	60	> 360	high	12/300	10	POS
	Resistant	P 5045	55	60	> 350	standard	8/200	7	POS, Medical
		P 5055	56	60	> 350	high	12/300	10	POS, Medical
	Resistant, Offset printable	P 5037	56	59	> 350	standard	8/200	25	POS, Medical
Ticket	High sensitivity	T 7051*	72	76	> 250	high	12/300	5	Transport, Medical, Label, POS
		T 8051*	80	85	> 220	high	12/300	5	Transport, Medical, Label
	Resistant	T 8045*	78	85	> 220	standard	8/200	7	Label, Transport, POS
		T 8055	80	85	> 220	high	12/300	10	Label, Transport, POS
	Offset printable	T 7033*	72	76	> 250	standard	8/200	7	Transport, Label
		T 8033*	80	84	> 230	standard	8/200	7	Transport, Label
		T 8040	78	85	> 230	standard	8/200	7	Transport, Label
		T 8050	80	85	> 230	high	12/300	10	Transport, Label
		T 1033	104	110	> 150	standard	8/200	7	Label
		T 1233	125	135	> 120	standard	8/200	7	Entertainment, Transport, Label
		T 1433	139	145	> 110	standard	8/200	7	Entertainment, Transport, Label
		T 1733	177	185	> 80	standard	8/200	7	Entertainment, Transport, Label
		T 2133	215	235	> 80	standard	8/200	7	Entertainment, Label
	Resistant, Offset printable	T 7037*	72	74	> 300	standard	8/200	25	Transport, Label
		T 8037*	81	84	> 250	standard	8/200	25	Transport, Label
		T 2437	234	265	> 50	standard	8/200	25	Entertainment, Transport, Label
	Heat resistant	T 7027	71	76	> 250	low	4/100	10	Transport
	Pigmented reverse side coating	TE 1633	173	175	> 90	standard	8/200	7	Entertainment, Transport
Topcoat POS	Good resistance	PF 5067	58	60	> 600	high	12/300	12	Medical, Label, POS
		PF 6067	67	68	> 600	high	12/300	12	Label, Gaming, POS
	Very good resistance	PG 6036	66	67	> 1000	low	6/150	25	Label
	Maximum sensitivity	PG 5075	60	61	> 1000	maximum	16/400	12	Gaming, POS
Topcoat matt	Good resistance	TF 7067*	74	74	> 600	high	12/300	12	Gaming, Label
		TF 8067*	82	84	> 600	high	12/300	12	Banking, Label
		TF 1067	107	110	> 600	high	12/300	12	Transport, Entertainment, Label
		TF 1267	127	128	> 600	high	12/300	12	Entertainment, Transport
		TF 1467	140	143	> 600	high	12/300	12	Entertainment, Gaming
		TF 1767	175	183	> 450	high	12/300	12	Transport, Entertainment
		TF 2467	232	255	> 400	high	12/300	12	Transport, Label, Entertainment
	Maximum sensitivity	TF 8075	85	85	> 700	maximum	16/400	12	Banking, Transport
		TF 1775	177	185	> 600	maximum	16/400	12	Transport, Entertainment
		TF 1875	187	200	> 600	maximum	16/400	12	Entertainment
		TF 2475	234	255	> 400	maximum	16/400	12	Transport, Entertainment
	Back barrier	LN 8067	84	84	> 600	high	12/300	12	Label
	Pigmented reverse side coating	TM 1875	188	194	> 600	maximum	16/400	12	Entertainment
Topcoat glossy	Very good resistance	TS 8057*	83	86	> 300	high	12/300	12	Gaming/Security, Label
		TS 2457	231	255	> 300	high	12/300	12	Transport, Label, Entertainment

* Also available as label application.

In addition to the above grades we offer our customers further individual solutions. Talk to our sales department for more information.

** If the storage and handling principles are followed.

Please see our technical datasheets for detailed information on characteristic and physical properties, as well as climatic and chemical stability.

Subject to changes January 2008

ECO • ECO • ECO • ECO • ECO • ECO

Topcoat • Topcoat • Topcoat

Appendix 3 Dummies sold in Danish internet shops

As part of Phase 1 in this project a search was carried out for Danish internet shops (or internet departments of other shops) selling dummies. This search was made in the beginning of September 2010. It is not a thorough mapping as the intention of the mapping was mainly to identify a sufficient number of labels with a shield of poly carbonate.

The following internet suppliers and range of dummies were found at the search:

Light grey background: Shield material not listed.

Dark grey background: Shield of poly carbonate.

White background: Entire dummy made of latex or shield of polypropylene

Net shop	Product name	Material	Web address	Comment/ Labelling
www.vismaa.dk/group.asp?group=6	Hevea Sut	Latex (the whole dummy)	http://www.vismaa.dk/group.asp?group=6	European standard EN 1400
www.superbest.dk	NUK (Germany), anatomic dummy, Classic	shield: ?, nipple: latex	http://www.superbest.dk/produkt/nuk-classic-sovesut-06-md	European standard EN 1400
www.superbest.dk	BIBS dummy with valve	shield: polypropyl-ene, nipple: latex	http://www.superbest.dk/produkt/rund-sut-str2-dreng-pastel	European standard EN 1400
www.bambino-mam.se/dk	NAM (Austria) Mini	shield: polypropyl-ene, nipple: latex	http://www.bambino-mam.se/dk/bambinomam/show.php?id=25245	BPA free
www.bambino-mam.se/dk	NAM (Austria) Classic	shield: polypropyl-ene, nipple: latex	http://www.bambino-mam.se/dk/bambinomam/show.php?id=25247	
www.bambino-mam.se/dk	NAM (Austria) Air og Air Maxi Sut	shield: polycarbon-ate, nipple: latex or silk teat	http://www.bambino-mam.se/dk/bambinomam/show.php?id=25249	
www.babyshoppen.com	Nûby™ (USA)	shield: ?, nipple: silicone	http://www.babyshoppen.com/shop/2-stk-anatomisk-	EU product safety directive 2001/95/EC, has CE label, PVC and

Net shop	Product name	Material	Web address	Comment/ Labelling
			347p.html	phthalate free
www.babyshoppen.com	Tolico (Denmark)	shield: polycarbonate, nipple: latex	http://www.babyshoppen.com/shop/3-stk-anatomisk-350p.html	EU Standard EN 1400, PVC and phthalate free
www.dreamchild.dk	Chicco	Latex (the whole dummy)	http://www.dreamchild.dk/default.asp?numr=9016&vari=Mini%200	Contains no allergens nor carcinogens
www.dreamchild.dk	AVENT (Phillips) Sensitive	shield: ?, nipple: silicone	http://www.dreamchild.dk/default.asp?numr=9016&vari=Mini%200	BPA free
www.dreamchild.dk	Pussycat	shield: polypropylene, nipple: latex	http://www.dreamchild.dk/default.asp?numr=9016&vari=Mini%200	Dansk Varefakta (Danish informative labelling)
www.helsebixen.dk	BornFree™	shield: ?, nipple: silicone	http://www.helsebixen.dk/shop/sutter-flasker-m-m-337c1.html	100% free of bisphenol A, PVC and phthalates
www.navnesutten.dk	Deluxe name dummy	shield: polycarbonate, nipple: latex	http://www.navnesutten.dk/Products.aspx?SalesArticleID=2072	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	NIP (Germany)	shield: polycarbonate, nipple: latex	http://www.navnesutten.dk/Products.aspx?SalesArticleID=7072	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	AVENT (Phillips) Freeflow	shield: polycarbonate, nipple: silicone	http://www.navnesutten.dk/Products.aspx?SalesArticleID=4073	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	Esska (Sweden), Anatomisk .	shield: polycarbonate, nipple: latex	http://www.navnesutten.dk/Products.aspx?SalesArticleID=5016	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	Esska (Sweden), Ellipse, flat	shield: polycarbonate, nipple: latex	http://www.navnesutten.dk/Products.aspx?SalesArticleID=83	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	Esska (Sweden), Happy, flat	shield: polycarbonate, nipple: latex	http://www.navnesutten.dk/Products.aspx?SalesArticleID=93	EU Standard EN 1400, free of PVC and phthalate
www.navnesutten.dk	Nûby (USA), Air, flat	shield: polycarbonate, nipple: silicone	http://www.navnesutten.dk/Products.aspx?SalesArticleID=86	EU Standard EN 1400, free of PVC and phthalate

Net shop	Product name	Material	Web address	Comment/ Labelling
paradisvej.com	Elodie Details (Sverige)	shield: ?, nipple: silicone	http://paradisvej.com/product.asp?product=3801	EU standard EN-1400
www.detbedstetilbaby.dk	Apotekets Sut	shield: ?, nipple: latex	http://www.detbedstetil-baby.dk/sider/apotekets-narresut_97.aspx	Dansk Varefakta (Danish informative labelling), EU standard 1400
www.babysam.dk	MEDA narresut	?	http://www.babysam.dk/meda-narresut-i-love-mom.aspx	
www.babysam.dk	Disney narresut	shield: ?, nipple: silicone	http://www.babysam.dk/disney-narresut-silikone.aspx	
www.babysam.dk	Round dummies	shield: ?, nipple: silicone	http://www.babysam.dk/basic-sutter.aspx	
baby-vest.dk	Avent Naturally	shield: ?, nipple: silicone	http://baby-vest.dk/diverse-tilbehoer-100/flasker-og-sutter-131/avent-narresut-0-3-mdr-430.html	Dansk Varefakta (Danish informative labelling)
www.matas.dk	Narresut	shield: ?, nipple: latex	http://www.matas.dk/graviditet+boern/baby-+smaaboernstilbehoer/sutter/narresut+2+stk+til+drenge.aspx?categoryid=635&productid=3452	Dansk Varefakta (Danish informative labelling)