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Survey of selected endocrine disruptors

Survey of chemical substances in consumer products No. 183

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Editors: Pia Brunn Poulsen,
Susan Geschke,
Christiane Borregaard and
Charlotte Merlin,
FORCE Technology

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Foreword

Survey of selected endocrine disruptors and/or suspected endocrine disruptors

This project is a survey and screening project which investigated the market for products targeting children and pregnant women with regard to their content of selected endocrine disruptors and suspected endocrine disruptors. 78 consumer products were investigated in greater detail using screening analyses to detect the presence of some or all of the sub-stances D4, BHA, BHT, BPA, butylparaben and propylparaben, depending on the product in question.

The results of the survey and screening analyses are presented in this report.

This project was conducted by FORCE Technology with Danish Technological Institute and Medico Kemiske Laboratorium ApS (Medical Chemical Laboratory ApS) as subcontractors for certain of the screening analyses.

The participants in this project were:

- Pia Brunn Poulsen, FORCE Technology (project manager)
- Susan Geschke, FORCE Technology (chemical analyses)
- Christiane Borregaard, FORCE Technology
- Charlotte Merlin, FORCE Technology (quality assurance)

The project was overseen by an advisory group composed of
- Sehbar Khalaf, Danish Environmental Protection Agency (chairman)
- Nadine Heidi Brueckmann, Danish Environmental Protection Agency
- Julie Marie Kruse Anton, Danish Environmental Protection Agency
- Mette Holm, Danish Veterinary and Food Administration
- Mette Christiansen, Danish Veterinary and Food Administration
- Annette Grossmann, Danish Veterinary and Food Administration
- Pia Brunn Poulsen, FORCE Technology (secretariat)

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The project was conducted during the period from April to September 2020.

Abbreviations

4-MBC	4-methylbenzylidene camphor (CAS no. 36861-47-9)
ABS	Plastic consisting of the monomers acrylonitrile, 1,3-butadiene, and styrene
BHA	Butylated hydroxyl-anisole (CAS no. 25013-16-5)
BHT	Butylated hydroxytoluene (CAS no. 128-37-0)
BPA	Bisphenol A (CAS no. 80-05-7)
BPAF	Bisphenol AF (CAS no. 1478-61-1)
BPF	Bisphenol F
BPS	Bisphenol S (CAS no. 80-09-1)
CeHoS	Danish Centre for Endocrine Disruptors [Danish: *Center for Hormonforstyrrende stoffer*]
D4	Octamethylcyclotetrasiloxane (CAS no. 556-67-2)
DFL	Danish Colourant and Adhesive Industry Association
DGEBA	An epoxy plastic also abbreviated as BADGE (bisphenol A diglycidyl ether)
DLS	Danish Pharmaceutical Standards [Danish: *Danske Lægemiddelstandarder*]
EFSA	European Food Safety Authority
EPDM	Ethylene propylene diene monomer rubber
EVA	Ethylene vinyl acetate (plastic)
FCM	Food contact materials
FVST	The Danish Veterinary and Food Administration [Danish: *Fødevarestyrelsen*]
HDPE	High-density polyethylene (plastic)
HIPS	High-impact polystyrene (plastic)
LDPE	Low-density polyethylene (plastic)
LMST	The Danish Medicines Agency [Danish: *Lægemiddelstyrelsen*]
PC	Polycarbonate (plastic)
PMP	Polymethylpentene
PP	Polypropylene (plastic)
PS	Polystyrene
PU	Polyurethane (plastic)
VKH	Danish Cleaning, Cosmetic, and Household Product Industry Association [Danish: *Dansk Vask-, Kosmetik- og Husholdningsindustri*]

Summary and conclusion

Survey of selected endocrine disruptors and/or suspected endocrine disruptors

Endocrine disruptors can affect the body's own hormonal systems in various ways. The activity of some substances resembles (but may be more pronounced than that of normal hormones), while others block or impede the activity of natural hormones. Endocrine disruptors are suspected of contributing to the increasing prevalence of a number of conditions and illnesses, such as malformed genitalia and affecting brain development. Fetuses and children are most vulnerable to exposure, particularly during their development as their organs are not fully developed and thus can be affected. Endocrine disruptors may result in serious effects that do not appear until later in life or in subsequent generations.

The exposure of children and pregnant women (and thereby unborn children) to substances that may affect the natural balance of hormones is problematic and can be a critical issue since hormone-regulated processes by which organs develop are particularly sensitive. For this reason, the exposure of children and pregnant women to problematic chemicals (including endocrine disruptors) should be limited.

Purpose and scope
The purpose of this project was to investigate the use of selected endocrine disruptors and/or suspected endocrine disruptors in products which children and pregnant women use. The project has the additional purpose of performing certain screening analyses on consumer products. Consumer products have been selected such that 1/3 come from physical and online shops within Denmark, 1/3 come from online shops within the EU, and 1/3 come from online shops outside of the EU, in order to investigate whether differences exist in the content of selected endocrine disruptors and/or suspected endocrine disruptors depending on where the purchased products originate from.

The scope of the project was limited to a screening investigation of the selected substances as described by the Danish EPA in its introduction to the project (see the fact box below).

The project is limited to the following selected substances:

Bisphenol AF (BPAF), bisphenol A (BPA) and bisphenol S (BPS)

4-methylbenzylidene camphor (4-MBC)

Butylparaben and propylparaben

BHA and BHT

D4

The project was additionally limited to focusing on products that children and pregnant women use or are exposed to. Furthermore, the screening phase was restricted to analysing only consumer products.

In addition to the listed selected substances, a survey was also conducted of nitromethane. However, as the use of nitromethane was limited to two niche applications not used by the target group (children and pregnant women), nitromethane was not further addressed in the report.

Potential endocrine disruptors
The endocrine-disruptive effects of the selected substances were not evaluated in this project. Instead, hazard assessments were referenced, primarily those performed by DTU (the Technical University of Denmark) and/or CeHoS (the Danish Centre for Endocrine Disruptors).

These hazard assessments show clear evidence of endocrine-disruptive effects for BPAF, BPA, 4-MBC, butylparaben, BHA, and D4 as well as suspected endocrine-disruptive effects (due to some or weak evidence) for propylparaben. Based on read-across from similar substances, BPS and BHT are suspected endocrine disruptors, and the substances have therefore been raised for assessment, but a final assessment is not yet available.

Survey
In general, knowledge about the use of the selected substances was investigated in consumer products, cosmetic products, food products, and food contact materials as well as in medicinal products.

The following activities were carried out to investigate the use of the selected substances:
- Contact with various relevant industries via industry organisations and authorities
- Searches in various databases
- Literature review / internet searches

A search was made in various databases e.g. material databases and ECHA's database of registered substances and plastics database. The Danish Consumer Council "Tænk" was also contacted to have a search made of the use of the selected substances in their database ("Kemiluppen") of ingredients in cosmetic products on the Danish market. Finally, a literature search was performed for information on the use of the selected substances.

The result of the survey
In general, the result of the survey was that bisphenols are used either as monomers in certain types of plastics or as antioxidants for other types of plastics. In addition, the bisphenols are used for coating of metal cans for food products and have been observed used in some cosmetic products in small amounts (impurities). Bisphenols are not used in medicinal products. Primarily BPA has been observed in consumer products, but also BPAF in some cases. In a recent survey, BPA has been identified in children's cotton socks.

For 4-MBC, the survey showed that the use of the substance has been phased out in cosmetic products in Denmark and in the EU. In addition, it is prohibited to use 4-MBC in the USA and Japan, but it is allowed to use a concentration of up to 4% in cosmetic products in e.g. China (in line with the EU legislation). Whether it is actually used in Chinese products is unknown. No uses of 4-MBC were identified other than a previous use in cosmetic products.

Parabens are generally used in a number of cosmetic products, toys, and medicinal products. In general, both butylparaben and propylparaben are used less than other parabens (e.g. methylparaben). Both butylparaben and propylparaben are used in cosmetic products on the Danish market today, but the use of butylparaben is limited, whereas the use of propylparaben is more widespread. Information received from the industry indicates that butylparaben and propylparaben are also used outside the EU. The use of butylparaben in medicinal products is limited, whereas the use of propylparaben in medicinal products is widespread. Propylparaben

is approved as an additive in food contact materials, while butylparaben is not. In a recent survey, propylparaben was also identified in children's cotton socks.

BHA is used as an antioxidant (especially in plastics) but is not as widespread as BHT. BHA is used in few types of cosmetic products today, in Denmark too. BHA is used in medicinal products and e.g. vitamin pills but is not as prevalent as BHT. BHA is allowed as a food additive, but the use is limited and is primarily identified in e.g. chewing gum.

BHT is like BHA an antioxidant that is used in a wide range of plastic types. BHT is used in many different cosmetic products (especially in fragrances) – also in Denmark today. In addition, BHT is used in a variety of medicinal products and in vitamin pills. BHT is allowed as food additive, but according to available analyses its use is limited. BHT is identified in e.g. chewing gum. According to the industry, BHT is, however, primarily used in foods.

D4 is used as a building block for the production of silicone polymers. Thus, D4 can be present as small (unreacted) residuals in all products that contain silicone. D4 is therefore identified in various products that contain silicone e.g. food contact materials, silicone dummies for babies, wax, polishes and car care products. D4 is also identified in PU foam products (e.g. mattresses, baby mattresses and squishy toys). D4 is not allowed in foods and is not identified used in medicinal products. D4 was previously allowed in cosmetic products but is today prohibited via a restriction adopted in 2019. In addition, a proposal has been made for restriction on D4 (as well as D5 and D6) in different consumer products, but this proposed restriction is not dealt with by the Commission yet, and is not expected to be adopted until the end of 2020 or the beginning of 2021.

Prioritisation of substances and product types

On the basis of the survey and in co-operation with the Danish Environmental Protection Agency, the below-mentioned product areas and following substances were prioritised, and it was decided to conduct screening analyses on those substances. The reason for this prioritisation is partly to investigate areas where there is a lack of knowledge and partly to investigate the substances that are expected to be used in these product areas. Last but not least these consumer products were prioritised as they have the largest expected exposure of the target group.

- D4, BHT and BHA in silicone products, including:
  - Silicone teething rings/teething animals
  - Silicone iPad and tablet covers
  - Dummies with silicone nipple
- BHA, BHT and D4 in plastic products, including:
  - Plastic mobile covers
  - Plastic toys focusing on rattles, teething rings or toys for very young children, i.e. products that are expected to be placed in the mouth
  - Dummies with plastic shields
- BPA, butylparaben and propylparaben in textiles, including:
  - Cottons socks for both children and adults
  - Underpants or special cotton maternity briefs
- Butylparaben and propylparaben in chemical mixtures, including:
  - Finger paints
  - Soap bubble liquid

Results of the screening analyses

The result of the screening analyses was that BHA was not identified in any of the examined products. BHT was identified in four out of the 18 examined plastic products and primarily in

plastic toys and in one mobile cover. None of the dummies for babies (plastic shield) contained BHT.

In addition, the screening analyses showed that butylparaben was not identified in textiles – only propylparaben and BPA (and only in socks – not in underpants). Butylparaben and propylparaben were both identified in two of the examined soap bubble liquids, but not in any of the examined finger paints.

D4 was the substance that was identified in most of the examined products (in eight out of the 18 examined silicone products). The occurrence of D4 was most frequent in teething rings/teething animals and in silicone iPad and tablet covers. None of the examined silicone dummies for babies contained D4 above the limit of detection. Furthermore, D4 was identified in one plastic mobile cover.

In general, the prioritised substances (other than BHA) were identified in some of the examined products (in between 5 and 38% of the products). That means that the substances occur in the examined products, but there are also products on the market in which the substances do not occur (at least not above the limit of detection).

Suggestions for further work

Based on this screening investigation it does not make sense in a possible follow-up project to focus on neither BHA in plastic and silicone products nor on butylparaben and propylparaben in finger paints as those substances do not appear to be present in the examined product types. For the other substances and product types, it would be relevant in a possible follow-up project to carry out quantitative analyses of the content of these substances followed by migration analyses to carry out a risk assessment of whether the quantities present in the products may constitute a health risk of endocrine disruptive effects.

There were a number of product areas, which were not selected for the screening investigations in this project. It might also be relevant to investigate those product areas further in a possible follow-up project, for example:

- BHT and propylparaben in cosmetics (the use of butylparaben is low)
- BPA and possibly BPAF in metal containers for cosmetics
- D4 in other silicone consumer products
- BHT in other plastic consumer products
- BHT, BHA and propylparaben in pharmaceuticals

In any case, it would be relevant in a possible follow-up project to focus on the total risk from several products at once and from several products with the same endocrine disrupting effect (same endpoint).

1. Introduction

Endocrine disruptors are substances that can affect the endocrine system of the body in various ways. The activity of some substances resembles (but may be more pronounced than) that of natural hormones, while others block or impede the activity of natural hormones (CeHoS, 2020). These activities include reducing the production of or blocking the activity of male sex hormones (antiandrogens), altering the balance of female sex hormones (oestrogens), and/or disrupting the effect of thyroid hormones (Andersen et al., 2012). Endocrine disruptors are suspected of contributing to the increasing prevalence of a number of conditions and illnesses, such as malformed genitalia, reduced fertility, and the development of obesity and diabetes, in addition to affecting the development of the brain. Foetuses and children are most vulnerable to exposure, particularly during their development. Endocrine disruptors may provoke serious effects that do not appear until later in life or in subsequent generations (WHO, 2013; Danish EPA, 2020a).

1.1 Background

The exposure of children and pregnant women (and thus unborn children) to substances that may affect the natural balance of hormones is problematic. This can be a critical issue, since the hormone-regulated processes by which organs develop are particularly sensitive. For this reason, the exposure of children and pregnant women to problematic chemicals (including endocrine disruptors) should be limited.

1.2 Purpose

The purpose of this project is to survey the use of selected endocrine disruptors and/or suspected endocrine disruptors in products which children and pregnant women use. The project has the additional purpose of performing certain screening analyses on consumer products. Consumer products have been selected such that 1/3 come from physical and online shops within Denmark, 1/3 come from online shops within the EU, and 1/3 come from online shops outside of the EU, in order to investigate whether differences exist in the content of selected endocrine disruptors and/or suspected endocrine disruptors depending on the origins of the purchased products.

1.3 Definitions

It should be noted that not all substances investigated in this project are documented endocrine disruptors. However, some substances have been designated as endocrine disruptors based on currently available data. In preparation for this project, the Danish EPA selected a number of substances that are either endocrine disruptors or suspected endocrine disruptors. Within this report, these substances are referred to collectively as the *"selected substances"* in order to avoid using the longer phrase, "endocrine disruptors and/or suspected endocrine disruptors", too frequently in the report.

The WHO defines endocrine disruptors as follows: *"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."* The endocrine disruptor expert group under REACH has concluded that a substance may be considered an endocrine disruptor when it has adverse effects, when it has a mechanism of action

characterised by endocrine disruption, and when there is a likely correlation between the two (adverse effect resulting from hormonal mechanism of action), (Danish EPA, 2020c).

1.4 Scope

The scope of this project is limited to a screening investigation of the selected substances as described by the Danish EPA in its preparations for the project. These are as follows:

- BPAF Bispenol AF, CAS no. 1478-61-1
- Possibly other bisphenols; the primary focus chosen here is on BPA (bisphenol A) CAS no. 80-05-7, and BPS (bisphenol S) CAS no. 80-09-1
- 4-MBC (4-methylbenzylidene camphor), CAS no. 36861-47-9
- Butylparaben, CAS no. 94-26-8
- Possibly other parabens; the focus chosen here is on propylparaben (CAS no. 94-13-3)[1]
- BHA (Butylated hydroxyl-anisole), CAS no. 25013-16-5
- BHT (Butylated hydroxytoluene), CAS no. 128-37-0
- D4 (Octamethylcyclo-tetrasiloxane), CAS no. 556-67-2
- Nitromethane, CAS no. 75-52-5

The project is additionally limited to focusing on products that children and pregnant women use or are exposed to. Furthermore, the screening phase was restricted to analysing only consumer products.

The survey shows that for nitromethane, the use of the substance is highly limited and exclusively for purposes that are not relevant to the target group. For this reason, nitromethane was generally not reviewed in the survey, though all information regarding nitromethane is given in Appendix 1, which contains an overview of the extracts and searches for information conducted on the substance.

[1]The reason for this focus is that the evidence for endocrine-disruptive effects in humans is weaker for methyl- and ethylparaben, and because no data is available on the endocrine-disruptive effects for isopropylparaben or isobutylparaben. According to CeHoS (the Danish Centre for Endocrine Disruptors), there is an indication of endocrine-disruptive properties for methyl- and ethylparaben, but not to the degree that they are "suspected" endocrine disruptors (CeHoS, 2012b).

2. Health effects

This chapter gives a short description of the health effects of the selected substances. The description focuses solely on the endocrine-disruptive effects of the substances and the endpoints considered to be of relevance for the individual substances.

The endocrine-disruptive effects of the selected substances were not evaluated in this project. Instead, hazard assessments were referenced[2], primarily those performed by DTU (the Technical University of Denmark) and/or CeHoS (the Danish Centre for Endocrine Disruptors). The hazard assessment of the substances is summarised in TABLE 1 below. It should be noted that a thorough assessment of endocrine-disruptive properties and effects is not available for every substance. BPS and BHT were raised for discussion due to suspicions of endocrine-disruptive effects, but a thorough assessment of the endocrine-disruptive properties of the substances is not yet available. During the spring/summer of 2020 a new review of literature has been carried out on BHT[3], This review does not result in a final conclusion of the endocrine-disruptive properties of BHT, but the data is presented in TABLE 1 below. BPS was reviewed in this survey because it is used as an alternative to bisphenol A (BPA) in some cases. The Danish EPA included nitromethane as a prioritised substance in this project because of a suspicion of endocrine-disruptive properties, but no final investigations or assessments of the endocrine-disruptive properties of the substance are yet available. Therefore, this substance is not discussed further in this report.

TABLE 1. Summary of endpoints and endocrine-disruptive effects for the selected substances

Substance name	Relevant endpoint(s)	Effects	Conclusion	References
Bisphenol AF (BPAF)	Female endocrine system (oestrogenic activity) Male endocrine system	Strong evidence for oestrogenic and anti-oestrogenic activity both *in vitro* and *in vivo*. Delayed onset of puberty in males. Early onset of puberty in females and effects on fertility.	Meets WHO's definition of an endocrine disruptor per CeHoS.	CeHoS, 2018
Bisphenol A (BPA)	*Not evaluated by CeHoS* Female hormonal cycle (oestrogenic activity)	*Not evaluated by CeHoS* Substance is classified as Repr. 1B, H360F (may damage fertility).	Indicated as a suspected endocrine disruptor with oestrogenic effects. Identified as particularly problematic under REACH regulations; is an SVHC (Substance of Very High Concern) and	Andersen et al., 2012 ECHA, 2017a ECHA, 2017b

[2]A hazard assessment encompasses only the intrinsic properties of a substance, meaning that usage and exposure are not considered as they would be for a risk assessment.

[3] While conducting this project, DTU (Danish Technlogical University) carried out an updated assessment of available literature for BHT with respect to its possible endocrine-disruptive properties.

Substance name	Relevant end-point(s)	Effects	Conclusion	References
		Effects involve changes in the menstrual cycle.	assessed to be an endocrine disruptor. The substance was added to the candidate list and restrictions on certain uses were imposed[4].	
Bisphenol S (BPS)	*Not evaluated by CeHoS*	*No information*	Raised for discussion in the ECHA's ED Expert Group (i.e., the expert group on endocrine disruptors). No evaluation available[5]. That is, the substance is a suspected endocrine disruptor.	ECHA
4-MBC	Female endocrine system (oestrogenic activity) Thyroid	Both oestrogenic effects and thyroid effects *(in vitro).* Thus, affects both men and women.	Meets WHO's definition of an endocrine disruptor per CeHoS. CeHoS assessment: Clear evidence of endocrine-disruptive effects.	DTU CeHoS, 2012a
Butylparaben	Female endocrine system (oestrogenic activity)	Strong evidence for oestrogenic activity *in vitro* and *in vivo.* Effect on sperm count and sperm quality, but conflicting data.	CeHoS assessment: Clear evidence of oestrogenic activity. As of 18 June 2020, the ECHA recognises the substance as an SVHC because it has endocrine-disruptive properties in humans.	CeHoS, 2012a ECHA, 2020a ECHA, 2020c
Propylparaben	Female endocrine system (oestrogenic activity) Male endocrine system	Strong evidence for oestrogenic activity *in vitro.* Anti-androgenic effects also observed *in vitro.*	CeHoS assessment: Some evidence exists for endocrine-disruptive effects, but the quality of some data has been questioned.	CeHoS, 2012a
BHA	Female endocrine system (oestrogenic activity) Male endocrine system Thyroid	Weak evidence for oestrogenic activity *in vitro.* Indications of anti-oestrogenic activity *in vivo.* Effects involve changes to the menstrual cycle, altered sperm morphology, and sperm count reduction.	CeHoS assessment: Clear evidence of oestrogenic activity. The potential endocrine-disruptive properties of the substance are being evaluated in the EU per REACH regulations, and they have not yet been determined.[6]	CeHoS, 2012a ECHA

[4] ECHA's candidate list (https://echa.europa.eu/da/candidate-list-table/-/dislist/details/0b0236e180e22414)

[5] https://echa.europa.eu/da/ed-assessment/-/dislist/details/0b0236e180764fc5

[6] https://echa.europa.eu/da/ed-assessment/-/dislist/details/0b0236e180765d2b

Substance name	Relevant end-point(s)	Effects	Conclusion	References
		Reduced levels of thyroid hormones and testosterone.		
BHT	Thyroid	Effects on thyroid hormones and the reproductive system	The potential endocrine-disruptive properties of the substance are being evaluated in the EU per REACH regulations, and they have not yet been determined.[7] Assessment of newer studies does not provide any clear conclusion about the endocrine-disruptive properties. The substance is a suspected endocrine disruptor.	ECHA DTU, 2020
D4	Female endocrine system (oestrogenic activity).	Strong evidence for oestrogenic activity both *in vitro* and *in vivo*. Weak evidence for thyroid effects. Effects involving reduced fertility and decreased ovulation.	Meets WHO's definition of an endocrine disruptor per CeHoS. CeHoS assessment: Clear evidence of oestrogenic activity.	CeHoS, 2018

This means that assessments have found clear evidence for endocrine-disruptive properties (based on the assessments listed in TABLE 1):

- Bisphenol AF
- Bisphenol A
- 4-MBC
- Butylparaben
- BHA
- D4

Endocrine-disruptive effects are suspected for the following substances, based on moderate or weak evidence:

- Propylparaben

Based on e.g. read-across from similar substances, the following substances are suspected endocrine disruptors. They have been raised for assessment, but a final assessment is not yet available.

- BPS
- BHT

[7] https://echa.europa.eu/da/ed-assessment/-/dislist/details/0b0236e180773a48

3. Survey

This chapter describes the approach taken in examining the selected substances in this survey and screening project, as well as the results of the survey. The following activities were carried out:

- Contact with various relevant industries via industry organisations and authorities
- Searches in various databases
- Literature review / internet searches

In general, the approach taken to the survey was to broadly investigate the types of products in which the selected substances are used. Subsequently, an assessment of the consumer products that are most relevant to the target group (i.e., children and pregnant women) appears in chapter 4 "Prioritisation of substances and product types".

The survey was performed over approximately one month, due to the relatively short timeline of the project. It was performed during the period in which Denmark and large portions of Europe were shut down due to COVID-19. For this reason, many of the industries contacted had other priorities, and the information received from industry organisation members has thus been limited.

3.1 Contact with relevant industry organisations and authorities

An initial investigation of the selected substances showed that the substances are primarily used in cosmetic products and in plastics. Additionally, certain substances are used as additives in food products and medicinal products. Beyond these contexts, instances of use in washing and cleaning products, paints, and joint fillers were found for certain substances, as well as limited use in chemical toys. For these reasons, the following industry organisations and authorities were contacted in the initial stage of the project:

- The Danish Plastics Federation [Danish: *Plastindustrien*]
- The Danish Cosmetics and Hygiene Industry Association [Danish: *Kosmetik- og hygiejnebranchen*]
- VKH: the Danish Cleaning, Cosmetic, and Household Product Industry Association [Danish: *Dansk Vask-, Kosmetik- og Husholdningsindustri*]
- DFL: the Danish Colourant and Adhesive Industry Association
- The Danish Association of the Pharmaceutical Industry [Danish: *Lægemiddelindustriforeningen*]
- The Danish Medicines Agency [Danish: *Lægemiddelstyrelsen*]
- The Danish Veterinary and Food Administration (via their participation in the advisory group of this project) [Danish: *Fødevarestyrelsen*]
- TIE (Toy Industries of Europe)
- The Danish registry of products (Danish Working Environment Authority) [Danish: *Produktregisteret, Arbejdstilsynet*]
- The Swedish registry of products

The purpose of contacting these industry organisations was to acquire more specific knowledge regarding the use of the selected substances in products today. Some of the industry organisations agreed to send a questionnaire to their members, while others contributed with general expert knowledge and references to relevant literature and studies.

Contact with the Danish and Swedish registries of products was orchestrated through the Danish EPA. The results of searches in the two product registries are described in section 3.2.9 "Data extracted from the Danish registry of products" and section 3.2.10 "Data extracted from the Swedish registry of products".

It was not possible to obtain information from Toy Industries of Europe (TIE) about the use of the selected substances during the period in which the survey was conducted. There are thus no further details on this matter.

3.1.1 The Danish Plastics Federation

The Danish Plastics Federation[8] stated that out of the substances listed, the bisphenols and BHT are the substances of primary relevance for plastics.

BPA is used as a building block (monomer) in the production of polycarbonate (PC) and epoxy resins. A reaction occurs involving the majority of the BPA when the plastics are produced, but a small residual amount of BPA can be found in these types of plastic. BPA has been the subject of much discussion, and there has been a particular focus on plastic products for children and products that are heated during use, such as feeding bottles. Breakdown can occur when the plastic is boiled or heated in a microwave oven. Today, BPA is prohibited in plastics for feeding bottles and sippy cups (EU regulation 10/2011) and must not migrate from coatings and surface treatments used on materials or articles in contact with foods for infants, such as formula milk and baby food (EU Regulation no. 213, 2018).

Small residual amounts of free BPA remain in plastics produced using BPA. The amount that actually migrates out of the plastic is even smaller and has been studied to some extent previously, particularly in the case of polycarbonate.

BPA is also used in coatings for metallic cans, as such a coating on the inside of a can used for food products improves shelf life.

According to the Danish Plastics Federation, bisphenol A (BPA) is the most widely used of these substances. There has been a focus on finding alternatives, but these are typically other bisphenols whose health effects may be unknown. Bisphenol F is used, perhaps to a lesser extent.

BHT does not appear to be widely used. According to the Danish Plastics Federation, BHT is primarily used to produce wrapping films, where it is used as an additive (antioxidant).

3.1.2 The Danish Cosmetics and Hygiene Industry Association

The Danish Cosmetics and Hygiene Industry Association sent a short questionnaire to all of its 80 members and forwarded the responses to the project group. A total of 17 out of 80 members, or 21%, responded with information. According to the Danish Cosmetics and Hygiene Industry Association, responses were received from all types of businesses; that is, large/small, Danish/international, and manufacturers of both cosmetic products and cleansers.

The responses from the 17 businesses are presented below in TABLE 2. It should be noted that inquiries regarding bisphenols were not made to this industry, since these substances are not used as additives in cosmetic products. All respondents indicated that the substances listed below were not used in their products:

- 4-MBC

[8]Personal correspondence with Christina Busk and Rasmus Grusgaard, Danish Plastics Federation, April 2020

- Butylparaben
- D4
- Nitromethane

Beyond the information below, six questionnaires indicated that none of the listed substances was used in the respondent's products, and one respondent indicated that they were closely following developments without offering any information on their use of the listed substances.

TABLE 2. Overview of information received from members of the Danish Cosmetics and Hygiene Industry Association. Each row represents a response from a manufacturer/importer. Only responses indicating use of the substances are shown.

Substance name	Used in	Use frequency	Typical concentration	Difference in use: EU/non-EU
Propylparaben	Cosmetic products (professional)	In two out of approx. 400 products	< 0.1%	Same usage
	Skin cleanser	Approx. 5% of products	0.0005%	Product sold only in the UK
	Moisturising lotion	In one out of six products, representing approx. 15% of Danish sales	As indicated in the regulation on cosmetic products	-
	Yes, used in cosmetic products	No data for Danish market	No data for Danish market	No difference between EU and non-EU products
BHA	Only for non-EU products under contract	< 1 kg/year	0.02 - 0.04%	Unknown. Not used in EU
BHT	Soap (cosmetic)*	50 kg ingredients per year at 0.1% BHT (i.e., 50 g/year)	0.00008% in finished product	Unknown. Not used in EU
	Ointment (one product)	Very low	0.004%	Unknown
	Mascara (M) Liquid eyeliner (LE) Eye shadow (ES) Lip products (LP)	Rare, less than 10% of each product group	M < 0.0003% LE < 0.03% ES < 0.0001% LP < 0.003%	-
	Yes, used in cosmetic products	No data for Danish market	No data for Danish market	No difference between EU and non-EU products
	In micro-crystalline wax, for hair wax*. Possibly also in perfume from limonene, but no specific information	Found in two different hair waxes. In far less than 1% of all products, but corresponding to perhaps 10% of all hair wax produced	0.00011%	The two products containing the substance are an EU product and a product sold in Norway
	In two rinse-off products*	Few	-	-
	In four different product types, as an antioxidant	-	0.008 – 0.1%	-

* This business has decided to phase out its use of BHT in the future.
- indicates no response to the question

3.1.3 The Danish Cleaning, Cosmetic, and Household Product Industry Association

The Danish Cleaning, Cosmetic, and Household Product Industry Association (VKH) sent a short questionnaire out to its expert network, comprising 41 individuals from its ten member businesses. The responses were forwarded to the project group. The results of this inquiry are presented below in TABLE 3, and they show that six out of ten member businesses responded. All respondents indicated that out of the selected substances, only BHT and propylparaben are used in cosmetic products or cleansers. For both substances, only two of the six businesses use these substances in some of their products. The concentrations of BHT and propylparaben used in the finished products can be found below in TABLE 3. In general, these substances are used at low concentrations.

VKH was asked the same questions as those asked of members of the Cosmetics and Hygiene Industry Association, above. Three members responded that they used neither BHT nor propylparaben in any of their products. These responses were not included in TABLE 3 below.

TABLE 3. Overview of information received from VKH members. Each row represents a response from a manufacturer/distributor. Only responses indicating use of the substances are shown.

Substance name	Used in	Use frequency	Typical concentration	Difference in use: EU/non-EU
BHT	Facial crèmes Eye crèmes Exfoliating masks Hair wax	Two products One product One product Two hair waxes Comprises a very small part of sales	0.06 and 0.075% 0.01494% 0.000014% 0.013303 and 0.01399%	Unknown
	Found in a large number of perfumes and scented products	Used in more than 80% of perfumes included	*Not specified*	Unknown
	Found in many perfumes*	*Not specified*	Approximately 10 ppm in ingredients; 0.5 to 3% used in finished product	Unknown
Propylparaben	Body lotion Shower gel	One product One product	0.015% 0.015%	Unknown
	Not used	-	-	Still used to some extent as a preservative in leave-on products, but not in Nordic countries
	Wax	One product	0.0219%	Unknown

* One business indicated that BHT can be found in essentially all scented products. The fragrance ingredient they purchase contains BHT as an antioxidant. This is likely the reason that BHT is allowed (albeit in limited quantities) in products bearing the Nordic swan mark, despite the fact that it is a suspected endocrine disruptor.
- indicates no response

3.1.4 The Danish Colourant and Adhesive Industry Association

The Danish Colourant and Adhesive Industry Association (DFL)[9] indicated that both bisphenols and D4 are used in the production of raw materials used in the industry. Only very small residual amounts of these substances are present in the finished products. According to DFL, the colourant and adhesive industry's use of BPA and D4 is likely minimal, relative to other uses of these substances. In the colourant and adhesive industry, BPA is used in epoxy products made primarily for industrial and professional use. However, while not widespread, they are also present in e.g. flooring products that consumers may purchase. According to DFL, the products of the sector are not targeted pregnant and children.

D4 is a substance used in the production of silicone polymers, among other uses. Silicone polymers are used in many industries but can also appear in products (including consumer products) in the colourant and adhesive industry. Silicone polymers are used in some types of paints, but they occur more frequently in certain types of joint filler. Other uses include yacht paints (as an alternative to traditional anti-fouling paints) and some paints for buildings. In recent years, vendors have attempted to reduce the quantities of D4 residue in unfinished silicone materials, such that they comprise less than 0.1% of the product in many cases. D4 can also occur in some defoaming agents.

Parabens are not approved as active ingredients in paints/adhesives/joint fillers — the so-called PT6 "in-can preservatives" — so they are not used in the industry.

3.1.5 The Danish Association of the Pharmaceutical Industry and the Danish Medicines Agency

The Danish Association of the Pharmaceutical Industry suggested searching various available databases, including:

- DLS (Danish Pharmaceutical Standards) 2020.1, which is a list of approved ingredients for medicinal products
- The Danish Medicines Agency's list of medicinal products permitted in Denmark
- The Danish Medicines Agency's product summaries for medicinal products in Denmark.

The lists and reference works named above were thus used as the main sources of information regarding the use of the selected substances in medicinal products. Danish Pharmaceutical Standard DLS 2020.1 (DLS, 2020) is a long list of the names that must be used when describing ingredients for medicinal products. In addition to the listed chemical names, plant names may also be used. A search for the selected substances was performed in pharmaceutical standard DLS 2020.1 to identify the chemical names to be searched for in the Danish Medicines Agency's product descriptions and the Danish Medicines Agency's list of permitted medicinal products in Denmark. The substances below were identified in DLS 2020.1. The remaining substances were not found, and it is thus assumed that they are not used in medicinal products.

- BHT — indicated using the name "butylhydroxytoluene"
- BHA — indicated using the name "butylhydroxyanisole"
- Parabens — propyl- and butylparaben are listed under the following names:
    - "Propyl parahydroxybenzoate" (propylparaben)
    - "Butyl parahydroxybenzoate" (butylparaben)

Therefore, BHT, BHA, and propyl- and butylparaben were searched for in the Danish Medicines Agency's lists of approved medicinal products and product summaries. The results of

[9]Personal correspondence with Anette Harbo Dahl, Danish Colourant and Adhesive Industry Association, April 2020

these searches are presented in section 3.2.7 "The Danish Medicines Agency's lists of medicinal products permitted in Denmark".

The Danish Medicines Agency was not available to contribute to the survey in this project due to the COVID-19 situation during the period when the survey was conducted. However, they later commented on the report to confirm that the product summaries contain information about all inactive ingredients contained in the individual medicinal products approved in Denmark. According to the Danish Medicines Agency, addition of preservatives is allowed only in those cases where they cannot be omitted due to the risk of microbial contamination and/or deterioration of the medicinal product. The amount added must be documented. Certain medicinal products are not permitted to contain preservatives, such as sterile, single-use medicinal products formulations. In general, there are strict requirements for inspection and labelling of preservatives in medicinal products.

3.1.6 The Danish Veterinary and Food Administration

The Danish Veterinary and Food Administration (FVST) is participating in the advisory group of the project. In this role, it forwarded the studies and information it has on the selected substances. These are partly studies of the content of some of the selected substances in foods and food contact materials (FCMs) as well as toxicological effects for the substances. The latter information is primarily described in the section on literature and in chapter 2 ”Health effects”. Analysis results from the Danish Veterinary and Food Administration's surveys of food and FCMs are presented below in TABLE 4.

The results below cover a total of 6 studies which investigated bisphenols, BHA, BHT, and siloxanes in reports from 2014 to 2019, the year of the most recent study. Bisphenols have primarily been studied in FCMs of metal (such as cans) and of plastic. However, one project studied BPA in cardboard packaging made from recycled cardboard, though it did not identify BPA above the limit of detection (Danish Veterinary and Food Administration, 2018). Bisphenols other than BPA have only been investigated in more recent projects, from 2016 onwards. For this reason, results from bisphenol studies prior to 2016 are not presented, as only BPA was studied previously. Neither siloxanes nor BHA and BHT were studied before 2014.

TABLE 4. The Danish Veterinary and Food Administration's studies on bisphenols (primarily BPAF and BPA)

Study (reference)	What was studied?	BPAF	BPA	Other bisphenols
Bisphenols in FCMs (Danish Veterinary and Food Administration, 2019)	Coated metallic packaging (cans), thermos flasks, reusable water bottles, biscuit tins; i.e., FCMs 24 products in all Migration analyses	*Not analysed*	Identified in 13 out of 24 products. Levels between 0.003 and 0.051 mg/kg food product.	Bisphenol B Bisphenol E Bisphenol F Bisphenol S No identification above the level of detection, 0.001 mg/kg food product.

Study (reference)	What was studied?	BPAF	BPA	Other bisphenols
Bisphenols in FCMs and migration to meat (Danish Veterinary and Food Administration, 2016a)	Plastic containers, plastic drinking glasses, and plastic blender jars (FCMs). Contamination of meat by bisphenols in meat trays.	*Not analysed*	Not identified in 13 out of 13 FCM products, and not identified in 28 out of 28 meat products. No identification above the detection limit, 0.006 mg/kg food product.	Bisphenol B Bisphenol E Bisphenol F Bisphenol S No identification above the level of detection, 0.006 mg/kg food product.
Bisphenols — migration from FCMs (Danish Veterinary and Food Administration, 2015b)	Cans, plastic drink bottles	*Not analysed*	Identified in 6 out of 15 FCMs. Levels between 0.006 and 0.150 mg/kg food product.	Bisphenol B Bisphenol E Bisphenol F Bisphenol S No identification above the level of detection, 0.005 mg/kg food product.

TABLE 5. The Danish Veterinary and Food Administration's studies on BHA and BHT

Study (reference)	What was studied?	BHA	BHT
Contamination of dry food products by BHA and BHT from FCMs (Danish Veterinary and Food Administration, 2015a)	Printed and unprinted wrapping film. Plastic/aluminium laminate, printed and unprinted	Not identified in 18 out of 18 samples Limit of detection: 0.015 mg/kg food product	Not identified in 18 out of 18 samples Limit of detection: 0.005 mg/kg food product
Migration of BHA and BHT from FCMs (Danish Veterinary and Food Administration, 2014)	Wrapping films, plastic bags, plastic films	Not identified in 28 out of 28 samples Limit of detection: 0.02 mg/kg food product	Not identified in 28 out of 28 samples Limit of detection: 0.02 mg/kg food product

TABLE 6. The Danish Veterinary and Food Administration's studies on D4 (siloxanes)

Study (reference)	What was studied?	D4	Siloxanes D3-D8
Siloxanes in FCMs (Danish Veterinary and Food Administration, 2016b)	Parchment paper, muffin moulds, feeding bottle nipples, etc. made from silicone	*D4 was not identified individually, but as the sum of D3 through D8*	Identified in 15 out of 25 samples in quantities from 0.09 to 63 mg/kg. Highest value is in a product from China.

3.2 Searches in various databases

Searches were performed in various materials databases and other relevant databases to obtain more detailed knowledge of the products in which the selected substances are used. Searches were performed in the following databases:

- The ECHA's database of registered substances
- The Danish EPA's database of chemical substances in consumer products
- The UL Prospector materials database
- The ECHA's plastic database
- The EU database on permitted food additives
- The Danish Medicines Agency's list of medicinal products permitted in Denmark
- The Danish Consumer Council Tænk Kemi's "Kemiluppen" database
- The Danish registry of products
- The Swedish registry of products

3.2.1 The ECHA's database of registered substances

The ECHA's database of registered substances specifies the amounts of each substance used annually (tonnage band for usage). The size of the total tonnage band per year for the selected substances can provide an idea of the usage levels of these substances in the manufacturing of products in the EU. Imported products containing these substances are not included. The total tonnage band; i.e., the sum of the tonnage bands for individual registrations, is presented in TABLE 7.

TABLE 7. Tonnage bands for REACH registration in the EU for the selected substances

Substance name	CAS no.	Total tonnage band	No. of registrants
BPAF	1478-61-1	100-1000 tonnes/year	10
BPA	80-05-7	100,000-1,000,000 tonnes/year	> 64
BPS	80-09-1	10,000-100,000 tonnes/year	12
4-MBC	36861-47-9	10-100 tonnes/year	1
Butylparaben	94-26-8	10-100 tonnes/year	2
Propylparaben	94-13-3	100-1000 tonnes/year	4
BHA	25013-16-5	100-1000 tonnes/year	4
BHT	128-37-0	10,000-100,000 tonnes/year	24
D4	556-67-2	100,000-1,000,000 tonnes/year	> 42

TABLE 7 shows that BPAF is used to a lesser extent than BPS, and that BPA is clearly far more widely used than other bisphenols. Butylparaben does not appear to have been used to a particularly great extent (10-100 tonnes/year), whereas propylparaben is used more (100-1000 tonnes/year).

Out of the selected substances, BHT and D4 appear to be used at the highest annual tonnages, by far.

3.2.2 The Danish EPA's database of chemical substances in consumer products

The Danish EPA has established a database of the chemical substances identified in consumer products in the course of performing surveys and/or chemical analyses in the Danish EPA's consumer projects[10]. A search was performed in this database for the individual substances. The results are presented below in TABLE 8. Only results in which levels above the

[10] https://mst.dk/kemi/kemikalier/forskning-og-kortlaegning/kortlaegning-af-forbrugerprodukter/

limit of detection were identified are presented. BPAF, 4-MBC, and nitromethane do not appear in the Danish EPA's database of chemical substances in consumer products. These substances are therefore not listed in TABLE 8 below.

TABLE 8. Search result for the selected substances in the Danish EPA's database of chemical substances in consumer products

Substance name	CAS no.	No. of hits	Product type (in X out of Y products studied)	References
BPA	80-05-7	20	Dummies for babies (in one out of 2 and in one out of 9) Vibrator (sex toy) (in one out of 9) Car seat (in one out of 10) Cash register receipts (in nine out of 12) Toys (in one out of 27) Thermal paper (in 12 out of 24) Mobile phone covers (in six out of 10) Pizza boxes (in five out of five)	Tønning et al., 2009a Lassen et al., 2011 Nilsson et al., 2006 Kjølholt et al., 2015 Lassen et al., 2011 Heckmann et al., 2015 Kristensen et al., 2019 Andersen et al., 2012 Larsen et al., 2017
BPS	80-09-1	5	Thermal paper (in six out of 24)	Kristensen et al., 2019
Butylparaben	94-26-8	7	Pet care products (in one out of 12) Cleaning wipes for cars (in one out of two) Slime toys (migration) (in three out of 14) Identified in hand soap, holiday make-up / face paints, dandruff shampoo, and sex crèmes, but no analyses performed	Nylén et al., 2004 Tønning et al., 2009b Svendsen et al., 2006
Propylparaben	94-13-3	8	Slime toys (in one out of 2) Pet care products (in one out of 12) Slime toys (migration) (in nine out of 14) Identified in holiday make-up / face paints, hand soap, dandruff shampoo, and ceramic paints, but no analyses performed	Poulsen & Nielsen, 2016 Nylén et al., 2004 Svendsen et al., 2006
BHA	25013-16-5	5	Body oil (in one out of three)	Larsen et al., 2017
BHT	128-37-0	75	Toys (flower) (one) Eraser (one product) Leather cleaner for cars (in one out of 14 car care products) Exterior fabric of children's jackets and mittens (in one and two out of five) Strap for zip closure (in two out of four) Nappies (elastics, stretch closures, printing on front of nappy, inside of waistband) Balloons (in four out of four) Paper pocket tissues (in one out of five)	Pors, 2006 Pors, 2006 Tønning et al., 2009b Tønning et al., 2009a Tønning et al., 2009a Tønning et al., 2009a Nilsson, 2007 Abildgaard et al., 2003

Substance name	CAS no.	No. of hits	Product type (in X out of Y products studied)	References
			3D printing material (in one out of four materials) Car seats (in two out of ten) Ceramic paints (in three out of 10) Christmas decorations (in one out of six) Changing pads (in one out of two) Shoe care products (in one out of two) Textile dyes (in one out of five) Sanitary napkins (in two out of eight) Identified in holiday make-up / face paints, gel pens, erasers, acrylic nails, gel nails, printed matter, dandruff shampoo, body lotion, sunscreen, body oils, deodorants, facial crèmes, and camping tents, but no analyses performed. Migration of BHT from various sex toys, neoprene waders, camping tents, erasers, squishy toys, pencil cases, toy bags, toothbrushes, computers, mobile phones, monitors, transformers, electronics, floor rugs, and artificial grass (no quantitative analyses performed)	Jacobsen et al., 2017 Kjølholt et al., 2015 Mikkelsen et al., 2005 Eurofins, 2003 Tønning et al., 2008 Engelund & Sørensen, 2005 Egmose & Pors, 2005 Pors & Fuhlendorff, 2002
D4	556-67-2	6	Toys and childcare articles Shoe care products (in 5 out of 8) Body lotion/crème, sunscreen, and stomach crème for pregnant women Plus emissions from rubber figures and energy-saving bulbs	Glensvig and Pors, 2006 Engelund & Sørensen, 2005 Andersen et al., 2012

3.2.3 The UL Prospector materials database

The Prospector® database from UL is a materials database that contains information about raw materials and ingredients in such items as plastics and metals. The database contains technical information for more than 10,000 products from global suppliers, and searches can be made for materials or ingredients. Some of the industrial areas the database covers include plastics, plastic additives, food additives, and household products.

A search was performed for the selected substances to obtain knowledge regarding the use of these substances in plastic materials especially. The results are presented below in TABLE 9. Searching by CAS number is not possible, so searches for numerous variants of the chemical names of the substances were performed. BPAF, 4-MBC, butylparaben, propylparaben, and nitromethane do not appear in the UL Prospector materials database. These substances are therefore not listed in TABLE 9 below.

TABLE 9. Search results for the selected substances in the UL Prospector materials database

Substance name	CAS no.	No. of search hits in database	Relevant descriptions in database
BPA	80-05-7	196	BPA appears used alone or in combination with bisphenol F in epoxy-based plastic. Epoxy is stated to be used for e.g. adhesives, laminates, floors, surface treatments (coatings). Contained in polycarbonate (PC). A polyester-based material is described as produced from hydrogenated BPA. The polyester material is used for synthetic fibres, synthetic rubber, and in medicinal products. Numerous search results also describe BPA-free raw materials.
BPS	80-09-1	5	Not relevant, the material is stated to be made without the use of BPA and BPS.
BHA	25013-16-5	2	BHA and BHT are used as antioxidants in plastics, elastomers and raw oils (lubricants, grease, and wax).
BHT	128-37-0	150	BHT has broad applications as an antioxidant in polymerised materials; i.e., in plastics and elastomers, as well as in raw oils (lubricants, grease, and wax) and in food products. BHT is also used as a stabiliser to inhibit the autopolymerisation of organic peroxides. BHT is a chemical antioxidant for food products, cosmetic products and medicinal products. BHT is recommended for use in rubber materials (EPDM*, natural rubber, synthetic rubbers including polyisoprene, polychloropene). BHT is an effective antioxidant in many types of plastic: ABS, EVA, PP, LDPE, HDPE, HIPS, polyamide, polycarbonate, and polyurethane. BHT is also used in waxes, insecticides, synthetic lubricants, and paints. Furthermore, BHT is used as an antioxidant in adhesives, printing inks, fragrances, and perfumes. BHT is also listed as a UV protection additive (photostabiliser). For SBR (styrene-butadiene rubber), a BHT concentration of 0.25-0.5% in the rubber material is listed. Many of the search results describe materials in which BHT is used, but just as many describe BHT-free materials.
D4	556-67-2	11	The results of the search are primarily additives for use after D4 has been used, or additives for use in combination with D4. These additives are recommended for use in synthetic rubber (polyisoprene, polychloroprene), TPE, TPV, and TPU. Or, they may be recommended for use as textile softeners.

3.2.4 The ECHA's plastic database

In 2016, the ECHA began their work on mapping the use of plastic additives together with numerous industry organisations. This work was published in December 2018 under the title

"Plastic Additives Initiative". The work resulted in a list of more than 400 additives used in large quantities in plastics; that is, additives used in quantities of more than 100 tonnes per year in Europe.

The ECHA states that their plastics database should not be taken to be exhaustive, as the following conditions apply (ECHA, 2019a):

- The database contains only the most widely used additives; that is, only those chemical substances which are registered in the REACH system and have a tonnage of more than 100 tonnes per year
- The database contains only information about registered chemical substances

It is possible to search the plastics database on the ECHA's website, and it is possible to see which additives are used for which polymer types if this information is available. The ECHA divides the additives into different types, such as heat stabilisers, antioxidants and softeners.

A search was performed in the ECHA's plastics database for the selected substances. The result was that only BHT was found in the ECHA's plastic database, described as an antioxidant. There is no information regarding the typical polymer types BHT is used in, nor at which concentrations. That BHT appears in the database proves, however, that the substance is used in Europe for the production of plastics and is used in large quantities in Europe (though these large amounts may be due to uses for BHT other than plastics).

3.2.5 The EU database on permitted food additives

EU regulation no. 1333/2008 on food additives contains Annex II, which is the EU's list of food additives approved for use in foods and the conditions for their use. Annex II is available on the EU's website as a database of permitted food additives[11]. This database was searched to investigate which of the selected substances are permitted for use in food products. Of the substances listed in section 1.4 "Scope", only BHA and BHT are permitted as food additives in the EU. BHA is also known by the E number E320, while BHT has the E number E321.BHA and BHT are permitted for use in a variety of food products, such as fats and oils, nut products, chewing gum, breakfast items, spices, sauces, dietary supplements, etc. Further details are provided in chapter 5 "Legislative requirements".

3.2.6 The EU list of permitted substances for food contact materials made of plastic

EU regulation no. 10/2011 on plastic materials and articles intended for contact with food contains Annex I, which is a list of substances permitted for use in manufacturing of plastic materials and plastic articles that will come into contact with food. This regulation was searched to investigate which of the selected substances are permitted for use in food contact materials (FCMs).

Of the substances listed in section 1.4 "Scope", only BPA and BPS may be used as monomers for the manufacture of plastic food contact materials. BPAF may not be used according to the regulation (EU Regulation 10, 2011). Specific migration limit values for BPA and BPS are provided. These limit values must be adhered to in the manufacture of plastic products for food contact (see Appendix 2). In addition, the use of propylparaben is permitted as additive in plastic materials for food contact, while the use of butylparaben is not. BHA and BHT may also be used in plastic food contact products, but common for all substances allowed in plastic for food contact is that they must be in compliance with specific migration limits (see Appendix 2) is required. BPAF, 4-MBC, butylparaben, and nitromethane are not allowed in food contact plastics.

[11] https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS

3.2.7 The Danish Medicines Agency's lists of medicinal products permitted in Denmark

The Danish Medicines Agency has published the following lists of medicinal products in Denmark which are searchable online:

- The Danish Medicines Agency's list of medicinal products permitted in Denmark
- The Danish Medicines Agency's product summaries for medicinal products in Denmark

The list of "product summaries" contains more detailed information than the list of permitted medicinal products, which primarily contains information about active ingredients. Product summaries constitute approved product information aimed at healthcare professionals. Therefore, they often contain information about all additives, including antioxidants and preservatives.

The Danish Medicines Agency's list of medicinal products permitted[12] in Denmark lists active ingredients, but not necessarily additives like BHT and BHA (antioxidants), as well as parabens (preservatives). The search results are therefore limited. There are no results for BHA and BHT, and a search for the parabens returns just three hits, out of 13,818 medicinal products. These three products are all provocation test patches for allergic reactions for such substances as parabens.

The Danish Medicines Agency's search database of "product summaries" appears to provide more information, as all additives appear to be listed in the product summaries. This information is listed below in TABLE 10. It should be noted that several of the medicinal products are for animal use (for example, flea products). Examples of medicinal products listed below are primarily for humans.

TABLE 10. Results for BHT, BHA, and parabens in medicinal products

Substance name	CAS no.	No. of hits	Examples medicinal product types and concentrations (if specified)
BHT Butylhydroxytoluene (E321)	128-37-0	196	Nicotine gum (0.43-0.5 mg per chewing gum) Pain relief fluid for inhalation (0.01%) Scabies treatment Treatment for male hypogonadism (1 mg/g) Anti-inflammatory treatment (0.2 mg/g) Psoriasis treatment (0.05-0.16 mg/g) Herpes treatments Treatment for sun damage to skin (2.0 mg/g) Treatments for vaginal oestrogen deficiency (0.008 mg / vaginal suppository) Treatment for vitamin D deficiency Dandruff shampoo Skin treatment (anti-biotic) (against infections in the skin) Plasters for allergy testing Hydrocortisone Treatments for urination problems ADHD medicines Prostate treatment medicines

[12] https://laegemiddelstyrelsen.dk/da/godkendelse/godkendelse-af-medicin/lister-over-godkendte-og-afregistrerede-laegemidler/saadan-bruger-du-listen-over-godkendte-laegemidler/

Substance name	CAS no.	No. of hits	Examples medicinal product types and concentrations (if specified)
BHA Butylhydroxyanisole	25013-16-5	97	Skin treatment (anti-biotic) (against infections in the skin) (0.04 mg/g) Plastics for allergy testing Hydrocortisone Acne treatments Cream for skin infections Cholesterol treatment medicines
Butylparaben Butyl parahydroxybenzoate	94-26-8	9	Hydrocortisone Herpes treatments Psoriasis treatments
Propylparaben Propyl parahydroxybenzoate	94-13-3	173	Hydrocortisone Herpes treatments Treatment for sun damage to skin (0.2 mg/g) Epilepsy medicine (0.18 mg/ml - 3 mg/5 ml) Creams for eczema Post-circumcision analgesic gel Allergy medicine (oral drops) (0.04-0.2 mg/ml) Treatments for blood potassium deficiency Mucolytic cough medicines Treatments for acid reflux / heartburn (6 mg / 10 ml) Vaginal flora treatments (0.2 mg/g) Scabies treatment Nasal spray (for smoking cessation) Painkillers for severe pain Treatment for frequent urination (0.2 mg/ml) Acne treatments Plasters for pain treatment (7 mg/plaster) Anti-inflammatory medicines (0.2 mg/ml) Urinary tract infection treatment Sore throat treatments (0.24 mg/dose) Ear drops for otitis media (0.3 ml/ml)

The conclusion from this search is thus that BHA and BHT are used to some extent in medicinal products in Denmark, and that propylparaben is used far more than butylparaben, which is used only in a select few products.

3.2.8 The Danish Consumer Council Tænk Kemi's "Kemiluppen" database

The Danish Consumer Council Tænk Kemi (English: Think Chemistry) has developed an app called “Kemiluppen” which offers ratings (A, B and C) of cosmetic products based on the Danish Consumer Council's assessment of the ingredients declared on the product. The app does not permit searches for ingredients, but the database behind Kemiluppen contains information about all of the ingredients declared in the approx. 12,600 products that Kemiluppen contains (as of April 2020), all of which are available on the Danish market. The project group therefore contacted the Danish Consumer Council, which extracted data on which and how many products contain the selected substances. The result of the search for the selected substances is presented in TABLE 11 below (the percentage of the total number of products is given in parentheses).

BPAF, BPA, BPS, 4-MBC, and nitromethane were not identified in any of the cosmetic products in the Danish Consumer Council's database of cosmetic products. These substances are therefore not listed in TABLE 11 below.

TABLE 11. Data extracted from the Danish Consumer Council Tænk Kemi's "Kemiluppen" database regarding the use of the selected substances in cosmetic products in Denmark

Substance name	No. of products in Kemiluppen (% of total no. of products in Kemiluppen)	Used primarily in the following types of products (no. of products of this type)	Limit values according to legislation
Butylparaben	108 (0.9%)	Facial care (21) — including facial crèmes (9) Hair care (10) Foundation/powder (34) Concealer/corrector (7) Mascara (10) After-sun lotion (1)	Max. concentration 0.14%
Propylparaben	444 (3.5%)	Facial care (70) — including facial crèmes (26) Lip balm (8) Hair care (59) — including waxes/sprays (30) Blush/highlighter (17) Foundation (32) Mascara (27) Powder (39) Eye shadow (26) Body lotion (86) Hand crème (21) Sunscreen / after-sun lotion (12) Toothpaste (2)	Max. concentration 0.14%
BHA	14 (0.1%)	Powder (5) Lipstick / lip balm (2) Hair mousse (1) Foot cream (1) Salve (1) Eye shadow (2) Mascara (1) Nail polish (1)	-
BHT	898 (7.1%)	Facial care (200) — including facial crèmes (73) and lip balms (48) Baby perfume (2) Women's shaving / hair removal (44) Hair care (107) — including waxes/sprays (24) Foundation/powder (50) Lipstick / lip gloss (25) Perfume (34) Body lotion (40) Hand crème (15) Body oil (8) Sunscreen / after-sun (18)	-

Substance name	No. of products in Kemiluppen (% of total no. of products in Kemiluppen)	Used primarily in the following types of products (no. of products of this type)	Limit values according to legislation
		Deodorant (191)	
D4	9 (0.1%)	Hair care - cream/conditioner/serum/oil (6) Foundation (3)	Recently prohibited*

* D4 was recently prohibited (in the latter half of 2019). Therefore, according to the Danish Consumer Council Tænk Kemi, products containing the substance may appear in Kemiluppen because they were added to the database before the ban came into effect.

As can be seen from the Danish Consumer Council Tænk Kemi's extracted data, BHT is clearly the most widely used of the selected substances and occurs most frequently in deodorants. It should be noted that 25% of all deodorants in Kemiluppen contain BHT. BHT also occurs in a number of other products, such as body lotion, foundation, women's shaving products, and sunscreens. Two products which are baby perfumes contain BHT.

Propylparaben is more frequently used in cosmetic products than butylparaben, but butylparaben is nonetheless used in approx. 100 products (or approx. 1% of the scanned products), and primarily in products for facial care and in foundations.

The use of BHT is not entirely consistent with the information received from manufacturers in the industry. The messages from them are that BHT is on the verge of being phased out. This could be the product of information in the Danish Consumer Council's database being older, depending on when the ingredient list of each product was last updated. It could also be due to the fact that more companies not using BHT chose to respond to the questionnaire.

Four years ago, similar data was extracted by the Danish Consumer Council Tænk for one of the Danish EPA's survey projects. In the roughly four years that have passed between these two data extractions from the Danish Consumer Council Tænk Kemi's "Kemiluppen" database, there has been an increase in the number of products containing both BHA and BHT relative to the first study. The increase is from 11 to 14 products for BHA and from 560 to 898 products for BHT; however, after those four years, the number of products in the Danish Consumer Council Tænk Kemi's database has also roughly doubled, meaning that percentage-wise, there has been a slight decrease.

3.2.9 Data extracted from the Danish registry of products

The registry of products is a shared registry on the use of hazardous substances and materials administered by the Danish Working Environment Authority. All companies which import or manufacturer hazardous chemical products for professional use in Denmark in quantities over 100 kg per year (Stat. Order 1794 2015) must report these products to the product registry. Among other items, this reporting requirement applies to substances and materials classified as hazardous, or which contain 1% or more of substances classified as hazardous (Stat. Order 1794, 2015). The product registry contains such information as the trade names of the substances and materials, their compositions, hazard labelling, manufactured/imported quantity, use, and function type, as well as the sector in which the substances or materials are used (Danish Working Environment Authority, 2020).

This means that a search in the product registry includes only chemical products both labelled as hazardous and sold for professional use. In other words, information obtained here primarily concerns the use of paints, joint fillers, and similar products.

The Danish EPA ordered a search for the selected substances in the Danish registry of products (administered by the Danish Working Environment Authority). Data is kept confidential if there is only a small number of uses. Therefore, to anonymise the data, the numbers of products are given in intervals in TABLE 12 below. Only some of the examples from the entire extract are reproduced here. It was decided to focus on products that could also be sold to consumers. The extracted data does not contain information about quantities (as it is confidential), so it is not possible to assess which uses are most widespread. Applications exclusively for industrial use are not included in the table.

BPAF, 4-MBC, and butylparaben were not identified in any of the chemical products listed in the Danish registry of products. These substances are therefore not listed in TABLE 12 below.

TABLE 12. Data extracted from the Danish registry of products for the selected substances

Substance name	Product type	No. of products	Max. conc. (%)
BPA	Building material protectors (PT10)	1-5	0.02
	Joint-free flooring	6-10	4.00
	Other flooring materials	1-5	11.00
	Solvent-based adhesives	1-5	0.0001
	Paint, water-dilutable, active biological effect, interior	1-5	0.16
		1-5	0.22
	Paint, water-soluble, decorative, interior	1-5	0.08
	Paint, volatile org. solvent, decorative	1-5	0.02
	Sealants		
BPS	Adhesive, organic solvent, for industrial use	1-5	0.05
	No uses for consumers		
Propylparaben	Air fresheners / odour removers	1-5	0.18
	Disinfectants (PT2)	1-5	0.20
	Veterinary hygiene (PT3)	1-5	0.10
	Insecticides / other pesticides for use on plants	1-5	0.10
	Wood preservatives	1-5	0.001
	Paint, water-soluble, decorative, interior	1-5	0.02
	General cleaning agents incl. concentrates	1-5	28.80
	Other cleaning agents	1-5	0.10
	Other polishing agents	1-5	0.08
BHA	"In-can" preservatives (PT6)	1-5	0.35
	Food additives	1-5	24.0
	Antioxidants (industrial application?)	6-10	100
BHT	Air fresheners / odour removers	1-5	0.40
	Antifreeze fluids	1-5	0.30
	Hygiene for humans (PT1)	1-5	0.10
	Disinfectants (PT2)	1-5	0.0006
	"In-can" preservatives (PT6)	1-5	0.02
	Rodenticides (PT14)	1-5	0.15
	Anti-fouling agents (PT21)	1-5	0.0001
	Insecticides / other pesticides for use on plants	1-5	1.00
	Car care products, general	11-15	0.16
	Joint-free floors	31-35	0.1
	Textile impregnation agents	1-5	0.0008
	Cement/concrete/mortar	6-10	0.003
	Adhesive, water-dilutable, for individual use	1-5	0.06
	Solvent-based adhesives	1-5	1.00

Substance name	Product type	No. of products	Max. conc. (%)
	Other adhesives	1-5	0.22
	Paint, water-dilutable, active biological effect, interior	1-5	0.004
	Paint, water-soluble, decorative, interior	26-30	0.0027
	Paint, volatile org. solvent, decorative	6-10	0.0028
	Rust removers	1-5	0.45
	Degreasers	1-5	0.10
	General cleaning agents	6-10	1.00
	Glass and window cleaner	1-5	0.06
	Hard water deposit removers	1-5	0.0037
	Stain removers	1-5	0.02
	Carpet cleansers	1-5	0.20
	Other anti-rust agents	16-20	1.00
	Motor oil	81-85	1.00
	Fillers	1-5	0.11
	Putty	6-10	0.005
D4	Anti-fouling agents (PT21)	1-5	0.03
	Car care products, general	11-15	0.19
	Joint-free floors	1-5	0.01
	Textile impregnation agents	1-5	0.01
	Wood preservatives	1-5	0.0001
	Cement/concrete/mortar	1-5	0.0004
	Other adhesives	1-5	0.30
	Paint, water-dilutable, active biological effect, interior	1-5	0.01
	Paint, water-soluble, decorative, interior	16-20	0.15
	Paint, water-soluble, decorative, exterior	16-20	0.03
	Floor wax and other polishes for floors	6-10	0.003
	General cleaning agents (incl. concentrates)	6-10	0.13
	Car shampoo	6-10	0.15
	Glass and window cleaner	1-5	0.02
	Stain removers	1-5	0.01
	Other cleaning agents	1-5	0.52
	Fillers	31-35	0.60
	Sealants	26-30	3.00

As can be seen from the data extracted from the Danish registry of products, only propylparaben, BHA, BHT, and D4 have registered uses in the registry of products that could also be purchased and used by individual consumers.

For virtually all uses, there is only a single business or a small number of businesses that have registered products containing these substances. There are, however, a few uses that stand out, in which a slightly larger number of products is registered. These are as follows:

- Car care products – containing both BHT and D4
- Joint-free flooring – containing BHT
- Cement/concrete/mortar – containing BHT
- Paint, water-soluble, decorative, for indoor use - containing both BHT and D4
- Paint, water-soluble, decorative, for outdoor use - containing D4
- General cleaning agents – containing both BHT and D4
- Floor wax and other polishes for floors – containing D4
- Rust protection agents - containing BHT
- Motor oil - containing BHT

- Joint fillers - containing D4
- Sealants - containing D4
- Putty - containing BHT

3.2.10 Data extracted from the Swedish registry of products

The Swedish registry of products is structured slightly differently from the Danish one, allowing for searches at the level of individual products. The Danish EPA ordered extraction of data on the selected substances in the Swedish registry of products, which collected the information on a more general, anonymised level. The result of the search in the Swedish registry of products is presented below in TABLE 13. BPAF, BPS, and 4-MBC were not identified in any of the chemical products listed in the Swedish registry of products. These substances are therefore not listed in TABLE 13 below.

TABLE 13. Results of the search for some of the selected substances in the Swedish registry of products

Substance name	CAS no.	Total amount used annually	Comments
BPA	80-05-7	200 kg	Paint/varnish and lubricants
Butylparaben	94-26-8	<10 kg	
Propylparaben	94-13-3	300 kg	Cleaning agents and adhesives
BHA	25013-16-5	<10 kg	
BHT	128-37-0	3000 kg	Lubricants, hydraulic fluids, and fabric softeners
D4	556-67-2	370 kg	Colourants, etc.

3.3 Literature/internet search

Beyond data and knowledge retrieved and obtained from the above, a literature search was performed to survey the products containing the selected substances, and to discover previous studies on the substances in products. This literature search was conducted exclusively on the internet, as follows:

- A general Google search for each substance to discover in which products it is found
- A search for articles on each substance using Science Direct. The individual searches for the substances were combined with keywords like "consumer products" to limit the number of hits
- A search on the Swedish EPA's website (KEMI) for studies on the substances
- A search on the Norwegian Environment Agency's website (Miljødirektoratet) for studies on the substances
- Searches with various testing organisations regarding studies of the substances in products, such as the Danish Consumer Council Tænk, Stiftung Wahrentest, and Öko-test

Information for each of the selected substances and for the individual reports/articles is described briefly below. The information has been gathered into a concise form in overview tables, TABLE 14 through TABLE 19. Some of the Danish EPA's survey reports from TABLE 8 appear in this section. This is because there is information about products for children or pregnant women that require more detailed investigation.

3.3.1 Bisphenols

In early 2020, the Danish Plastics Federation published a book on plastic production (Jensen et al., 2020). In it, the use of bisphenols as (a few among many) antioxidants is described. Antioxidants are substances added to plastics to avoid oxidation of the plastic that would lead to its gradual breakdown. Plastics become hard and brittle when exposed to light and/or heat, which may cause them to change colour and lose their strength.

The group of antioxidants known as phenols, to which bisphenols belong, is listed as the largest group of primary antioxidants. In polyolefin-based types of plastic (i.e., polyethylene (PE), polypropylene (PP), and polymethylpentene (PMP)), phenols are typically used at a concentration of 0.05 to 0.2% in the plastic, while a concentration as high as 2% may be necessary for unsaturated polymers like ABS, impact-resistant polystyrene, and synthetic rubber.

According to the The Danish Plastics Federation's book on plastic manufacturing (Jensen et al., 2020), BPA is used as a "building block" (a monomer) in bisphenol polyesters and in epoxy plastic (DGEBA, diglycidyl ether of epichlorohydrin and BPA). Because BPA is used to produce these types of plastics, the finished plastics will contain small residual amounts of unreacted BPA.

BPA is also used as a monomer in the production of polycarbonate (PC). In the Danish EPA's LOUS project on BPA (Møller et al., 2012), it is indicated that BPAF is a (fluorinated) alternative to BPA in polycarbonate. According to Møller et al. (2012), BPAF is used as a polycarbonate copolymer in high-temperature composite materials, gas-permeable membranes, and special polymer applications.

In the Danish Plastics Federation's book on plastic manufacturing, only BPA and, in a single case, bisphenol F, are named (Jensen et al, 2020). BPAF and other bisphenols are not described.

BPA is and has been used as a reactant in thermal paper (e.g., for cash register receipts), but the Danish EPA's survey project on the matter does not indicate that BPAF is used as an alternative here (Kristensen et al., 2019). As of January 2020, the use of BPA is no longer permitted in thermal paper in the EU (EU regulation no. 2235, 2016).

3.3.1.1 American study of feminine hygiene products

Gao and Kannan (2020) studied 77 women's hygiene products found in various New York supermarkets. These products are from 47 of the most popular brands in different price ranges, and were divided into various categories: panty liners, tampons, wet wipes, bactericidal creams, spray deodorants, and powders. Bisphenol F (BPF), BPA, and BPS are the bisphenols which were most commonly found in feminine hygiene products. BPF was commonly found in tampons (92%) and panty liners (69%) at median concentrations of 8.44 and 4.82 ng/g, respectively. BPA was found in powders (72%), panty liners (69%), tampons (92%), and wet wipes (75%). The highest concentration of BPA was found in panty liners (5.12 ng/g), followed by powders (2.77 ng/g), tampons (0.70 ng/g) and wet wipes (0.57 ng/g). The concentrations measured are very low. Only the outermost layer of the hygienic products was measured, and it is not stated whether the conversion subsequently performed was based on the weight of the entire product. The source of bisphenols in tampons and panty liners may be polymers, which may contain these chemicals as additives or impurities. Another finding of the study was that BPAF occurs rarely in feminine hygiene products (< 20%). No separate analysis results for bisphenol AF are presented in the article.

3.3.1.2 Chinese study of bisphenols in cosmetic products

Lu et al. (2018) studied a total of 150 cosmetic products (so-called PCPs — personal care products) purchased in China. Analyses were performed for a total of seven bisphenols, including BPAF. BPAF was identified in 38.7% (i.e., 58 out of 150) of the products studied. The highest total concentration of the seven bisphenols tested was identified in a face mask with a concentration of 78 ng/g (equivalent to 0.078 mg/kg) and in a hand sanitiser with a concentration of 87 ng/g. In other words, these are low concentrations (trace amounts).

3.3.1.3 Survey of endocrine disruptors in toys and articles for children, Norwegian Environment Agency

The Norwegian Environment Agency has performed two studies that encompassed bisphenols in toys. In a study from 2016 (Norwegian Environment Agency, 2016), 58 samples of toys and other articles for children were analysed for endocrine disruptors, including bisphenols. In a study from 2017 (Norwegian Environment Agency, 2017), 26 samples of toys and other articles for children were analysed. Some of the endocrine disruptors were detected in a few samples, while none of the substances were identified in the majority of the samples analysed.

In the 2017 project, only BPA was detected, in 8 samples which included pencil cases, goggles, sunglasses, and a jacket. In the 2016 project, BPA was identified in significant quantities in eight out of 58 soft polymer (PVC or PU) samples analysed.

- Box (57 mg/kg)
- Apron (16 mg/kg)
- Horn (bell) for bicycle (160 mg/kg)
- Pendant (160 mg/kg)
- Pendant (140 mg/kg)
- Pencil case (2.6 mg/kg)
- Purse (30 mg/kg)
- Zip on windcheater (87 mg/kg)

Analyses for BPAF and BPS (as well as a number of other bisphenols) were also performed in both studies, but only BPA was identified.

3.3.1.4 BPA in children's socks (Freire et al., 2019)

96 pairs of children's socks from Spain were analysed for BPA content. BPA was identified in 91% of all children's socks. The quantities of BPA identified were small, in the range from 4 ng/g to 3739 ng/g (equivalent to up to 3.7 mg/kg).

3.3.2 4-MBC

4-MBC, a UV filter, has long been the subject of discussion due to its endocrine-disruptive properties. As early as 2001, the Danish EPA entered into a voluntary agreement with Danish industry prohibiting the use of 4-MBC in products for children under 12 years of age[13]. For this reason, 4-MBC is apperently not used in cosmetic products in Denmark. This is supported by the study below, by the data extracted by the Danish Consumer Council Tænk (see section 3.2.8), and by information received from the industry. However, 4-MBC may be used in cosmetic products at a maximum concentration of 4% (according to the regulation on cosmetic products, (EU regulation no. 1223, 2009)), so it may be used in products outside of Denmark that are then imported into Denmark. According to the industry, 4-MBC is no longer used. However, no information was received from the industry regarding its use outside the EU. According to Xiongfeng et al. (2016), the use of 4-MBC is prohibited in cosmetic products (sunscreens) in both the USA and Japan. In China, use of concentrations up to 4% is permitted, as

[13] https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-produkter/kosmetik/ansvarlig-person/danske-saerregler/

in European regulations on cosmetic products. There may thus be products on the Chinese market containing 4-MBC, but whether or not it is used is unknown.

3.3.2.1 Rigshospitalet's study of Danish kindergarten children's exposure to UV filters

Rigshospitalet (a specialised hospital in Denmark) has studied Danish kindergarten children's exposure to a number of sun filters. The study was performed by examining the children's urine in the summer and winter for the presence of a number of UV filters typically used in sunscreens. The study showed that 4-MBC was not detected in any of the urine samples studied above the limit of detection, 0.87 ng/ml. The sun filters detected in children's urine were predominantly of other types, such as benzophenones (Krause et al., 2017).

3.3.3 Butylparaben and other parabens

Parabens are used as preservatives. Methylparaben is the most commonly used preservative (at least in cosmetic products (Danish Consumer Council Tænk, 2020)), but butylparaben is also used in cosmetic products today (Danish Consumer Council Tænk, 2020). No parabens are approved as active ingredients, according to the ECHA's database of active ingredients in biocides. This means that they may not be used in biocides or so-called "in-can preservatives"; i.e., as preservatives for preserving chemical products. However, a number of areas are exempt from the EU's biocide regulation (EU Regulation 528, 2012), meaning that the use of parabens (including butylparaben) is permitted in these areas. These areas are:

- Cosmetic products
- Toys
- Medicinal products
- Pet food
- Food additives (food for humans) – in the EU, however, neither butylparaben nor propylparaben are permitted for use

The use of parabens in food products, medicinal products, and cosmetic products is described in greater detail in section 3.2.5 "The EU database on permitted food additives", section 3.2.7 "The Danish Medicines Agency's lists of medicinal products permitted in Denmark", and section 3.2.8 "The Danish Consumer Council Tænk Kemi's "Kemiluppen" database".

The use of parabens has been reduced over the last few years in cosmetic products due to restrictions in regulations on cosmetic products (see chapter 5 ”Legislative requirements”). Information received from the industry suggests that butylparaben and propylparaben are also used outside the EU.

Knowledge on the use of butylparaben and other parabens in toys is limited. Individual studies, described below in greater detail, have been identified.

3.3.3.1 Study of parabens in teething rings (Potouridis et al., 2019)

This article describes a paraben migration study involving four teething rings. It states that parabens have previously been identified in the gel which the teething rings contain, so the purpose was to study whether parabens migrate from the material in teething rings. All the teething rings studied were filled and consisted of ethylene-vinyl acetate (EVA). Four teething rings were studied for migration of methyl-, ethyl-, and propylparaben. The highest migrated concentrations identified were of methylparaben, which migrated from all four teething rings (both from the gel and plastic material), while ethylparaben was found to have migrated from one product, and propylparaben migrated from three out of four teething rings (both from the gel and plastic material).

3.3.3.2 Assessment of butylparaben in products (Hessel et al., 2019)

In 2019, the Dutch RIVM conducted a risk assessment of butylparaben in various products, including cosmetic products, food products, medicinal products, and such other sources as clothing and childcare articles (teething rings). However, cosmetic products, food products, and medicinal products are considered to be the most significant sources of butylparaben exposure, for which reason only these were assessed in the report. Additionally, because of a lack of data on medicinal products, this group was not included in the calculations.

Hessel et al. (2019) states that butylparaben is only seen in food products in the USA and China. The use of butylparaben as an additive in food products is prohibited in the EU (see section 3.2.5). More than 99% of exposure comes from cosmetic products, while less than 1% comes from food products. The report concludes that a tendency was observed wherein butylparaben is used to a lesser extent than previously. Exposure calculations based on old data should thus be taken with caution. The report indicates that there is a lack of knowledge on the use of butylparaben in other types of consumer products (e.g., toys).

3.3.3.3 Parabens in children's socks (Freire et al., 2019)

96 pairs of children's socks in Spain were analysed for paraben content (methyl-, ethyl-, propyl-, and butylparaben, plus total paraben content). Ethylparaben was found in all the children's socks, while propylparaben was identified in about 44% of them, butylparaben was not identified above the limit of detection, 0.5 ng/g. The total paraben content was also measured, but the article does not indicate whether any parabens apart from those listed (methyl-, ethyl-, propyl-, and butylparaben) were identified. The quantities of propylparaben identified were low, within the range 0.74 to 2.45 ng/g (corresponding to as much as 0.00245 mg/kg).

3.3.3.4 Preservatives in toys (Poulsen & Nielsen, 2016)

In one of the Danish EPA's previous survey projects, the use of preservatives in toys was studied. Individual chemical analyses of toys were performed. In them, out of the selected parabens, only propylparaben was identified in two of the slime toy products analysed.

Additionally, information gathered from manufacturers in the survey shows that the selected parabens were used in the following types of chemical toys:

- Butylparaben:
    - Modelling clay (at a concentration of 20 mg/kg)
    - Holiday make-up / face paints
    - Glitter glue
    - Slime toys (seen in a previous study from 2006)
    - Soap bubble liquid (at a concentration of 10 mg/kg)
- Propylparaben:
    - Modelling clay (at a concentration of 20 mg/kg)
    - Holiday make-up / face paints
    - Glitter glue
    - Slime toys (at a concentration of 20 mg/kg)
    - Soap bubble liquid (at a concentration of 10 mg/kg)

Foreign studies (from 2010) are also referenced, in which it was found that finger paints contained parabens. However, which parabens were identified in the foreign studies is not indicated.

3.3.4 BHA

BHA is used as an antioxidant in such products as cosmetic products, medicinal products, and food products., However, the use of BHA is not as widespread as that of BHT (Danish Consumer Council Tænk, 2020).

3.3.4.1 Danish EPA project on small children's combined exposure to chemical substances

In a previous Danish EPA survey project (Larsen et al., 2017), cosmetic products were studied and analysed for their BHA content. The products were selected using information from the Danish Consumer Council Tænk and data extracted from their Kemiluppen database (launched in 2016).

In the project (Larsen et al., 2017), a product with BHA content was chosen for chemical analysis, and the concentration of the contents was determined to be 0.0039% (39 mg/kg).

3.3.4.2 Turkish study of BHA and BHT in chicken steaks

Sacriban & Yilmaz performed a study (2014) finding that both BHA and BHT are used as antioxidant additives in chicken steaks in order to prevent rancidification, delay the development of flavourings, as well as to improve colour stability.

3.3.4.3 Levels of BHA in food products

In an EFSA (European Food Safety Authority) opinion, it is stated that there is only little data regarding the current BHA use levels in food products. According to the EFSA (2011), it is stated that BHA is either not used or occurs at levels lower than the detection limit of 10 mg/kg of food product. The EFSA (2011) indicates that the Danish Veterinary and Food Administration examined a total of 122 sauces or fruit and vegetable mixtures (such as chutney, tomato paste, and similar items) without finding the presence of BHA at detectable levels.

The allowed levels of BHA in foods according to the EU legislation as well as the types of foods where BHA is allowed are described in Appendix 3.

3.3.5 BHT

According to the ECHA's plastic database (see section 3.2.4 ”The ECHA's plastic database”), BHT is used as an antioxidant. Since BHT appears in the ECHA's plastics database, this means that BHT is registered in REACH in larger quantities (more than 100 tonnes per year). However, BHT is not described in the Danish Plastics Federation's new book on plastic technology (Jensen et al., 2020). This may suggest that the use of BHT in plastics (at least in Denmark) is not particularly widespread, and the remaining quantity in the REACH system may be associated with uses other than plastics. For example, BHT is permitted as an antioxidant in a wide variety of foods, as well as in cosmetic products.

According to the UL Prospector materials database, BHT is used as an antioxidant in many plastic materials to protect against the effects of heating and oxidation in drying processes. BHT inhibits the oxidation process in plastic.

Information from the cosmetics and cleaning industry shows that BHT is included as a raw material in perfumes; i.e., the majority of products to which BHT has been added are scented products.

3.3.5.1 Danish EPA project on small children's combined exposure to chemical substances

In the Danish EPA project described above (Larsen et al., 2017), 24 products with a content of BHT were selected for chemical analysis, and the content concentration was determined to be between 0.0002% (2 mg/kg) in a body lotion and 0.32% (3200 mg/kg) in a sunscreen.

3.3.5.2 American study of dental sealing products

Wang et al. (2016) examined 63 tooth sealing products[14] purchased on the US market and identified BHT in all of them at a maximum concentration of 1020 mg/kg. The median value for all products examined was 56.8 mg/kg. Wang et al. (2016) indicate that BHT is probably used in these dental sealing products to inhibit the oxidative reaction and inhibit potential polymerisation; i.e, BHT helps to prolong the lifetime (storage time) of the products.

3.3.5.3 Danish EPA project on squishies

A survey project from the Danish EPA (Klinke et al., 2018) studying and assessing the risk from chemical substances in squishy toys (consisting of PU foam, a kind of plastic), BHT was found to be present in five out of eight products, at concentrations between 23 and 91 mg/kg. Additionally, BHT emissions were measured from three out of 10 products in an emission chamber, at concentrations between 6 and 10 µg/m^3 both after 1 hour and after 3 days.

3.3.5.4 Danish EPA project VOC emissions from PU foam

A survey project from the Danish EPA on VOC emissions from consumer PU foam products (Poulsen et al., 2020) studied emissions of chemical substances from head pillows, mattresses, folding mattresses, and similar products purchased in Denmark, the greater EU, and outside the EU. In the project, 20 PU foam products were placed in an emission chamber, and the emissions were subsequently analysed after 1 hour and after 3 days. Two out of the 20 products (a baby mattress and a tumbling mat purchased on the Danish market) emitted BHT at concentrations of 2.2 and 10 µg/m^3, respectively. Emissions were highest after 3 days. The total amount of VOCs emitted from the 20 products varied from 10 to 1900 µg/m^3, so the amount of BHT emitted is relatively small.

The project describes a source (Hillier et al., 2003) which studied emissions of a large number of VOCs from different products over a period of 5 years. The authors conclude that emissions of some VOCs were significantly reduced (including BHT). The authors conclude that this is due to the industry transitioning to less volatile antioxidants in manufacturing PU foam. This was confirmed when after 5 years, trace amounts of less volatile antioxidants began to be identified instead of high concentrations of BHT.

3.3.5.5 Levels of BHT in food products

In an EFSA opinion, it is stated that there is only little data regarding the current BHT use levels in food products. The EFSA (2012) indicates that the Danish Veterinary and Food Administration examined a total of 122 sauces or fruit and vegetable mixtures (such as chutney, tomato paste, and similar items) without finding the presence of BHT at detectable levels. The EFSA (2012) also refers to a Danish study on BHT in chewing gum, describing that chewing gum can be produced without the use of BHT, since one out of 28 products contained BHT in a quantity of 200 mg/kg food product, while the remaining products did not contain BHT. The EFSA (2012) states that the industry, in preparing this EFSA opinion, indicated that BHT is used at levels up to 100 mg/kg of food product (equal to the permitted limit) in fats and oils, lard, fish oil, and fats from beef, poultry, and lamb.

The allowed levels of BHT in foods according to the EU legislation as well as the types of foods where BHT is allowed are described in Appendix 3.

3.3.6 D4

As indicated by the Danish Colourant and Adhesive Industry Association, D4 is used as a building block for the production of silicone polymers. D4 can thus occur as small residues in

[14] Tooth sealing products are e.g. a kind of lacquer that can be spread over teeth to seal incipient holes.

products that contain silicone. D4 was previously allowed in cosmetic products but was prohibited by a restriction adopted in 2019 (EU Regulation 1223, 2009). In March 2019, it was proposed to further limit the use of D4, at which time the ECHA presented a proposed restriction (ECHA, 2019b). In December 2019, an opinion from the RAC and SEAC was tabled, whereupon the proposed restriction was listed and went out for consultation (ECHA, 2019c). The proposal contains a restriction on D4 (as well as D5 and D6) in chemical mixtures (limit value 0.1%), but not in articles. This means that D4 may occur in articles composed of silicone or with added silicone, but it will be limited in e.g. paints and joint fillers.

3.3.6.1 Danish EPA project on squishies

A survey project from the Danish EPA (Klinke et al., 2018) studying and assessing the risk of chemical substances in squishy toys (consisting of PU foam, a kind of plastic) identified emissions of D4 in an emission chamber test for five out of five products, at concentrations between 1 and 7 µg/m^3 both after 1 hour and after 3 days.

3.3.6.2 Danish EPA project on VOC emissions from PU foam

A survey project from the Danish EPA on emissions of VOCs from consumer PU foam products (Poulsen et al., 2020) identified emissions of D4 from six out of 20 products (a baby mattress, two folding mattresses, and three mattresses for adults / older children; two products purchased in Denmark, two in the greater EU, and two outside the EU) at concentrations between 11 and 150 µg/m^3. Emissions of D4 were only measured after 1 hour, not after 3 days.

3.3.6.3 Risk assessment of D4 in consumer products (Gentry et al., 2017)

In 2017, a number of Americans conducted a risk assessment for D4 in consumer products (Gentry et al., 2017). Here, it was mentioned that children may be exposed to D4 from the following types of products:

- Cosmetic products (prohibited in the EU today according to the EU regulation on cosmetic products (EU regulation no. 1223, 2009))
- Some processed foods (prohibited in the EU according to the EU database on permitted food additives (see section 3.2.5))
- Bottle nipples (silicone) and feeding bottles
- Straws made of silicone polymers

In the article, they conclude that consumers face no significant risk of health effects from exposure to D4 through food products, consumer products, or the environment, since the MoS (margin of safety) has been calculated at over 1000.

3.3.6.4 German test of menstrual cups (Öko-Test, 2020b)

The German consumer magazine Öko-test recently identified D4 in a menstrual cup made of silicone. D4 was not identified in any of the other 15 products tested (made of other materials), (Öko-Test, 2020b).

3.4 Summary of information about the selected substances

This section summarises the information received from industry associations, from data extracted from various databases, and identified via searches through various literature. The information is summarised in TABLE 14 to TABLE 19 below. A table is given for each substance (group of substances).

TABLE 14. Overview of the use of bisphenols

Cosmetic products	Other consumer products	Food products / food contact materials	Medicinal products/dietary supplements
Bisphenols in general			
Products ("personal care products") such as face masks, hand sanitisers - but at low concentrations (Lu et al., 2018)	Plastic: Bisphenols are used as antioxidants in such plastics as PE, PP, and PMP at a concentration of 0.05 to 0.2%. Used at a concentration of up to 2% in e.g. ABS, impact-resistant polystyrene, and synthetic rubber. Bisphenols are used as monomers (raw materials) for the production of epoxy plastics and polycarbonate Products for babies: Toys, dummy chains, pram chains, dummies and gripping toys (Test.de, 2017)	Coatings in metal cans for food products (Danish Plastics Industry Federation, 2020; Danish Veterinary and Food Administration studies)	Not observed to be used in medicinal products
BPAF			
Hair products (Helm et al., 2018) Toothpaste, make-up and body shampoo (ChemTrust, 2018) Products ("personal care products") such as face masks, hand sanitisers - but at low concentrations (Lu et al., 2018)	Women's hygiene products - but seen only rarely (Gao & Kannan, 2020) Products for children: Pencil cases, goggles, sunglasses (Norwegian Environment Agency, 2017) Other products: Plastic containers, iPhone covers, aprons, bicycle horns, purses, hairbrushes, balls, zip pendants, braces on rain pants (Norwegian Environment Agency, 2016)	Not studied in the Danish Veterinary and Food Administration's studies of sealings inside metal containers. Other bisphenols studied, but BPA identified.	Not observed to be used in medicinal products
BPA			
Products ("personal care products") such as face masks, hand sanitisers - but at low concentrations (Lu et al., 2018) Powders (Gao & Kannan, 2020)	Plastic: Used as a monomer in bisphenol polyesters, epoxy plastic (DGEBA) and polycarbonate plastic, such that a residual amount (unreacted) may be present. Products: Women's hygiene products: panty liners, tampons and wet wipes (Gao & Kannan, 2020) Products for children: Pencil cases, goggles, sunglasses (Norwegian Environment Agency, 2017). Boxes, aprons, bicycle bells, pendants, pencil cases, purses and zips (Norwegian Environment Agency, 2016)	Coatings for metal cans for food products (Danish Veterinary and Food Administration studies) BPA is allowed in plastic as a monomer	Not observed to be used in medicinal products
BPS			
Products ("personal care products") such as face masks, hand sani-	Only a few applications identified for industrial use	Not identified in FCMs (Danish Veterinary and	Not observed to be used in medicinal products

Cosmetic products	Other consumer products	Food products / food contact materials	Medicinal products/dietary supplements
tisers - but at low concentrations (Lu et al., 2018)		Food Administration), but is allowed in FCMs of plastic	

TABLE 15. Overview of the use of 4-MBC

Cosmetic products	Other consumer products	Food products / food contact materials	Medicinal products/dietary supplements
(Previously) used as a UV filter in crèmes, lip balms, sunscreens, sun oils (ECHA, 2020b) Max. permitted conc 4%. Not used in products for children under 12 years (Danish EPA, 2020b) Not seen in cosmetic products in Denmark (Danish Consumer Council Tænk, 2020) Not used according to industry	No identified uses	Not permitted in food	Not observed to be used in medicinal products

TABLE 16. Overview of the use of parabens

Cosmetic products	Other consumer products	Food products / food contact materials	Medicinal products/dietary supplements
Parabens generally			
Used in a wide range of cosmetic products (Danish Consumer Council Tænk, 2020) Body lotion (test.de, 2018), facial crèmes (Ökotest.de, 2014)		-	Used in a wide range of medicinal products
Butylparaben			
Max. permitted conc 0.14%. Prohibited in products for children under three years in Denmark. Used in some products, but not as prevalent as other parabens. Used in foundation/powder, concealers, fa-	No identified uses	Not approved in FCMs made of plastic Not approved as a food additive	Used, but not as prevalent as other parabens. Medicinal products (Hessel et al., 2019)

cial crèmes, hair care products, mascara, etc. (Danish Consumer Council, 2020) Sunscreen (DTU, 2016)			
Propylparaben			
Max. permitted conc 0.14%. Prohibited in products for children under three years in Denmark. Is far more prevalent than butylparaben, but not as widespread as methylparaben. Used in body lotion, wax/hairspray, hand crème, facial crème, foundation/powder, mascara, sunscreens, etc. Facial crème (Ökotest.de, 2019)	Childcare articles: Teething rings (Potouridis et al., 2019)	Approved for use as an additive in FCMs made of plastic Not approved as a food additive	Used in a wide range of medicinal products.

TABLE 17. Overview of the use of BHA

Cosmetic products	Other consumer products	Food/FCMs	Medicinal products/dietary supplements
Limited to a few products, such as body oils, powders and hair products (Larsen et al., 2017) In few products, such as powders (Danish Consumer Council Tænk, 2020)	Can be used as an additive in plastic products. However, its use in plastics does not appear to be particularly widespread (BHT is far more prevalent).	Permitted as a food additive according to the EU database on permitted food additives, in an amount of 200 mg/kg in: Dehydrated milk Lard and oil Nut butters Processed potato products (25 mg/kg) Breakfast items Pastries Processed meat Soups and broths Sauces Processed nuts Potato-, cereal-, flour-, and starch-based snacks Chewing gum (Danish Consumer Council Tænk, 2015) Lard, beer, dessert mixes, chicken steaks (Saricoban & Yilmaz, 2014)	Used in medicinal products, but not as broadly as BHT. Vitamin pills (Danish Consumer Council Tænk, 2016)

TABLE 18. Overview of the use of BHT

Cosmetic products	Other consumer products	Food/FCMs	Medicinal products/dietary supplements
Sunscreen, body lotion, deodorant, lip balm (Larsen et al., 2017) In many products, especially deodorants, body lotion, foundation, facial crèmes, sunscreen (Danish Consumer Council Tænk, 2020) Appears to be used primarily with scented substances (perfume) (UL Prospector database)	Plastic: Used as an antioxidant primarily in plastic films, but is effective in many different types of plastics: ABS, EVA, PP, LDPE, HDPE, HIPS, polyamide, polycarbonate, and polyurethane Recommended for use in rubber materials (EPDM*, natural rubber, synthetic rubbers including polyisoprene, polychloropene). Also used in waxes, insecticides, synthetic lubricants, and paints. Products: Waders, erasers, sport bandages, masks, nappies, balloons, gloves, paper pocket tissues, car seats, changing pads, sanitary napkins, toys (MST database) Car care products, waxes and polishes (ECHA, 2020b). Dental sealants (Wang et al., 2016) Baby mattress and tumbling mat made of PU foam (Poulsen et al., 2020). Squishy toys (made of PU foam) (Klinke et al., 2018) Used as an antioxidant in adhesives, printing inks, fragrances, and perfumes. Car care products (the Danish registry of products) Paint (the Danish registry of products) Cleaning agents (the Danish registry of products) Putty (the Danish registry of products)	Allowed as a food additive at a particular concentration in certain food products. Lard and oil (Wang & Kannan, 2019) Chewing gum (Danish Consumer Council Tænk, 2015)	Used in a wide range of medicinal products. Vitamin pills (Danish Consumer Council Tænk, 2016)

TABLE 19. Overview of the use of D4

Cosmetic products	Other consumer products	Food/FCMs	Medicinal products/dietary supplements
Not permitted in cosmetic products as of 2020 EU regulation no. 1223, 2009). Body lotion, stomach crème (for pregnant women), sunscreen (previously observed).	Silicone polymers: D4 is a monomer in the production of a variety of silicone polymers. There will be small residues of D4 left after production. Silicone products:	Not permitted in food products	Not used in medicinal products

Cosmetic products	Other consumer products	Food/FCMs	Medicinal products/dietary supplements
In foundation, hair conditioner and other hair products before the ban came into force (Danish Consumer Council Tænk, 2020). Shampoo and conditioner, body lotion, face cream and anti-wrinkle cream (Ökotest.de, 2020)	FCMs made of silicone (baking moulds, straws), silicone dummies / feeding bottles <u>Other products:</u> Restriction discussed for wax, polishes, and washing/cleaning products, etc. Washing and cleaning products, waxes and polishes, car care products, paints (ECHA, 2020b) Rubber figures, emissions from energy-saving light bulbs (MST database) Mattresses, folding mattresses and baby mattresses made of PU foam (Poulsen et al., 2020). Squishy toys (made of PU foam) (Klinke et al., 2018) Used in sealants and in some paints (Danish registry of products). Floor wax/polish (Danish registry of products). Car care products (the Danish registry of products) Cleaning agents (the Danish registry of products) Menstrual cup (Ökotest.de, 2020)		

3.5 Suggestion for relevant consumer products for chemical analysis

Based on the results of the survey, the table below with suggestions for relevant consumer products that would be relevant to carry out screening analyses on, was produced (see TABLE 20). The focus has been on consumer products and products for the target group (children and pregnant), as well as the products where a possible exposure to the selected substances is assumed to be highest.

TABLE 20. Consumer products used by the target group with highest exposure

Product type	Relevant selected substances	Expected exposure	Comments	Priority
Dummies made of PC (shields of dummies)	BPAF BPA Perhaps BHT	Low Skin contact	Primarily by skin contact with shield. Small amount in the plastic, unknown how much that will migrate.	Yes Knowledge is missing
Dummies made of silicone (the part in the mouth)	D4	Medium Oral	Long exposure time, but content expected to be low, and amount expected to migrate is low.	Yes Knowledge is missing

Product type	Relevant selected substances	Expected exposure	Comments	Priority
Mobile covers of silicone or PC	D4 BPAF BPA Perhaps BHT	Low Skin contact	Long exposure time, but content expected to be low, and amount expected to migrate is low.	Yes Knowledge is missing
Other products made of silicone or PC	D4 BPAF Perhaps BHT	Low Skin contact?	Small amount in the products and small amount is expected to migrate.	Perhaps
Toys (chemical), like: Slime Modelling clay Finger paint Soap bubble liquid	Butylparaben Propylparaben	Medium Skin contact (leave-on?)	Small amount in the products, but direct skin contact during play. Other preservatives are also used. The use of these preservatives is unknown.	Yes Limited knowledge
Squishy toys	BHT	Low Skin contact	Small amount in the products, and small amounts are expected to migrate from the products.	No Few data available in the squishy project
Cosmetic products, e.g.: Deodorants Facial cream Foundation Face powder Body lotion Hand cream Suntan lotion Body oil Baby perfume	BHT Butylparaben (4-MBC)	High Skin contact (leave-on)	Small amount in the products but applied directly on the skin. Focus on products for babies and pregnant as well as leave-on products. Content is listed on the products in the EU. BHT and butylparaben in cosmetics have earlier been reviewed. 4-MBC is not used in DK, EU, USA and Japan, but knowledge is missing for non-EU products from e.g. China.	Perhaps Knowledge is available for DK (and EU) products, men not for non-EU products
Packaging material for cosmetic products Metal cans e.g. toothpaste packaging or make-up	BPAF BPA	Low Skin contact	Small amount in the packaging material and small amount that migrates into the cosmetic product which is applied on the skin	Perhaps Knowledge is limited
Wet wipes	BPAF	Low Skin contact (leave-on)	Leave-on product. Very small amount that perhaps migrates from the plastic packaging material and into the wet wipe? Only data from new investigation in the USA.	Perhaps Limited knowledge
Zipper strap of plastics for jackets	BHT Perhaps D4 Perhaps BPAF Perhaps BPA	Low Oral	Small amount in the products, and small amount that migrates from the products. Only exposure when children are having the straps in their mouth when wearing the jacket.	Perhaps
Changing pads	BHT	Low Skin contact	Small amount in the products, and small amount that migrates from the products.	Perhaps

Product type	Relevant selected substances	Expected exposure	Comments	Priority
Teething rings	Butylparaben Propylparaben Perhaps D4 (for silicone) Perhaps BHT (for plastic)	Medium Oral	Small amount in the products, and small amount that migrates from the products. The amount that migrates is directly ingested. Only propylparaben (and methyl- and ethylparaben) investigated. No knowledge on use of butylparaben.	Yes Knowledge is missing
Swim rings Water wings	Perhaps BPAF Perhaps BPA	Low Skin contact (diluted by water)	In Norwegian survey, BPA has been found in products of soft plastic material. But low content, and small amount that migrates from the products – and is diluted by water.	No Knowledge is missing
Children socks and other textiles	Propylparaben BPA BPAF	Low Skin contact	Content of BPAF is not listed by Freire et al. (2019), but the amount of paraben and BPA is in general very small. Low content and small amount that is migrating from the products. Long exposure time. Small children may put the textiles in their mouth.	Yes Limited knowledge

4. Prioritisation of substances and product types

Chapter 3 “Survey” has provided input on a wide range of products that may contain the selected substances (see TABLE 20 above). In this chapter, a prioritisation is made of both product types, but also of the selected substances since it is not possible to investigate everything in the subsequent screening analyses.

Based on the chosen prioritisation of substances and product types, a selection of products purchased for the screening analyses was made. Both the prioritisation of substances and product types are described in more detail in this chapter. The selected substances (i.e. the Danish EPA's initial list of endocrine disruptors or substances suspected of being endocrine disruptors that were selected as the focus of this project) are therefore further prioritised based on the results of the survey and the possibilities for chemical analyses (see Appendix 4 regarding discussion of possible analysis methods). The final list of substances for which screening analyses are carried out in this project is the so-called "prioritised substances”.

4.1 Reasons for prioritisation of substances and product types

The selected substances and product types were prioritised using the following aspects:

- The focus was exclusively on consumer products
- The focus was on products for children and pregnant women
- The focus was on products with high exposure - both in terms of exposure time, but also expected content in the products or accumulated exposure from different consumer products or accumulated exposure from different endocrine disruptors with the same endpoint/critical effect
- The focus was primarily on substances that are considered to be endocrine disruptors, i.e. clear evidence for endocrine disruptive effects

In this project, the focus was exclusively on consumer products, since medicinal products and medical equipment belong under the Danish Medicines Agency, and food and food contact material belong under the Danish Veterinary and Food Administration and were therefore not investigated further in a project under the Danish EPA. As mentioned in the introduction, children, and pregnant women in particular are sensitive to endocrine disruptors, which is why the focus was on products used by this target group. In addition, there was a focus on substances and products where the highest accumulated exposure is expected. In other words, products used daily by the target group (e.g. cosmetic products, nappies, and dummies) were given higher priority than products used only occasionally (e.g. cleaning products). Substances that are part of many different consumer products are also interesting, as the accumulated exposure can be high even though the individual exposure from a single product is not necessarily problematic. Finally, there are some selected substances where there is stronger evidence of endocrine disruptive effects than others. In addition, substances with the same effect on the same target organ were prioritised.

4.2 The prioritised substances and product types for the screening

This project is a screening project, and the aim has been to gain as much knowledge as possible about the presence of selected or suspected endocrine disruptors. However, it is not possible within the framework of the project to conduct screening analyses of all the above-mentioned substances for all the above-mentioned consumer products. For this reason, it was therefore decided in collaboration with the Danish EPA to focus on the following of the selected substances. The following substances are thus the substances that are prioritised for the screening analyses and are therefore referred to as "the prioritised substances":

- BHT, since the substance is used in many different consumer products.
- BHA has the same application as BHT, but a major use of the substance in relation to BHT is not expected, and this we wish to confirm or disprove through screening analyses.
- D4, since the substance like BHT seems to have a wide use.
- Butylparaben and propylparaben, since there is limited knowledge about their use in some product types (chemical toys), and since there is recent knowledge about their prevalence in consumer products for children and pregnant women, which are used every day (including textiles).
- BPA, since there is more recent knowledge about the prevalence of the substance in consumer products for children and pregnant women, which are used every day (textiles).

Based on the above and TABLE 20 from the previous chapter, which shows consumer products used by the target group with the highest expected exposure – as well as the selection of the prioritised substances, focus on the following consumer products in the screening analyses was decided on in collaboration with the Danish EPA. The prioritised substances that are analysed through the screening analyses are indicated in parentheses:

- Mobile phone covers made of plastic (BHT and BHA)
- Plastic toys with a focus on rattles, teething rings, or toys for very young children, i.e. products that can be expected to be put in the mouth (BHT and BHA)
- Teething rings/teething toys made of silicone (D4, BHT and BHA)
- iPad and tablet covers made of silicone (D4, BHT and BHA)
- Dummies with nipple made of silicone and/or shield made of plastic (D4, BHT and BHA)
- Finger paints (butylparaben and propylparaben)
- Soap bubble liquid (butylparaben and propylparaben)
- Socks made of cotton for both children and adults (butylparaben, propylparaben and BPA)
- Briefs or special maternity underwear made of cotton (butylparaben, propylparaben and BPA)

The above products were selected as they are all consumer products that have a daily or frequent use, where there is close skin contact, or where it is products that are put in the mouth (products for children). Here, both finger paints and soap bubble liquid are products that are not necessarily used on a daily basis, but it is an area where there is a lack of knowledge about the use of the prioritised preservatives. The textile products (socks and underwear) were selected primarily because completely new studies show a content of parabens and BPA in cotton products, but there is limited knowledge about the prevalence.

Overall, there are four different materials that were selected for analysis:

1. Products made of silicone (dummies, iPad and tablet covers, teething rings, rattles/toys)
2. Products made of plastic (mobile phone covers, rattles, teething rings, other toys)
3. Chemical mixtures (soap bubble liquid and finger paints)
4. Textiles (socks and briefs made of cotton)

4.3 Description of the procedure for selection and procurement of products

A search was made for examples of consumer products in the four above-mentioned categories (products made of silicone, plastic, and textiles, as well as chemical mixtures, respectively). Based on this search, a document was created consisting of more than 170 different consumer products. There were some challenges in selecting the examples of consumer products, including:

- It was not possible in all cases to see information about the material of the products on the websites. Thus, examples were primarily selected where the indication of the material was available.
- Similarly, for the chemical mixtures, there were only a few products where it was actually stated on the website whether the product contained parabens. When such information appeared on the website, it was typically information such as “does not contain parabens” or an indication of the specific preservatives used (e.g. methylparaben and phenoxyethanol). Use of butylparaben and propylparaben was not identified through any websites. Products where this type of information appeared on websites were deliberately not selected, but for some products there was information on the content of the preservatives on the packaging once they arrived (although the information did not appear on the website). It was decided that these products should be analysed anyway.
- It was not possible in all cases to see information about the manufacturer or which country the product was manufactured in.
- We had a schedule of approx. 40 days from order until the first analyses were to commence. Therefore, purchasing of products with an indication of a longer delivery time than this was deliberately not selected. However, not all websites indicated the delivery time.

The products were selected for purchase so that they covered:

- Purchases from Denmark (DK), non-EU countries (N-EU), and EU countries other than Denmark (EU)
- Different types of products within the relevant categories
- Products at different price levels
- Products from different manufacturers

Based on this list of examples of consumer products (of plastic, silicone, textiles and chemical mixtures, respectively), a total of 85 products were selected in collaboration with the Danish EPA, which were ordered/purchased for a total of 78 planned analyses. The planned analyses are presented below in TABLE 21 compared to the actual number of analyses that ended up being conducted. Additional products were deliberately purchased in case there were products that did not arrive on time (before the screening analyses were commenced).

TABLE 21. The number of planned and actual analyses performed for the four different types of materials

Type of material	Purchased in	Number of planned analyses	Number of actual analyses performed	Total number
Plastic products	DK	6	6	
	EU	6	6	18
	N-EU	6	6	
Silicone products	DK	6	6	
	EU	6	7	18
	N-EU	6	5	

Type of material	Purchased in	Number of planned analyses	Number of actual analyses performed	Total number
Textile products	DK	7	7	
	EU	7	7	21
	N-EU	7	7	
Chemical mixtures	DK	7	9	
	EU	7	7	21
	N-EU	7	5	
Total		78	78	78

DK = products purchased in Denmark or from companies with a Danish CVR number
EU = products purchased from websites in the EU, but not from Denmark
N-EU = products purchased from websites outside the EU

The vast majority of products were purchased via the Internet, as this phase of the project took place during the Corona outbreak in Denmark (May 2020). Only six products were bought at physical stores in Denmark. Despite the fact that the first products were ordered 48 days before the last products were sent for analysis, there were still products that did not arrive before the date of the commencement of the analyses. This is generally due to long delivery times from websites such as wish.com, amazon.com, ebay.com and aliexpress.com, but may also be due to extra delivery time caused by the ongoing Corona pandemic. As a result, there are some product categories for which it was not possible to secure enough products from non-EU countries (N-EU) in order to achieve an equal distribution among the products from DK, the EU and N-EU. In these cases, extra Danish products have primarily been purchased, or where it has been possible, some products that contain e.g. both plastic and silicone have been examined both under the category of plastic products and under the category of silicone products. Similarly, a single toy containing soap bubble products for blowing soap bubbles was also chosen as a plastic product for analysis. A total of 73 products arrived and were selected for analysis, i.e. a total of five products are analysed in two of the four above-mentioned categories.

4.4 General overview of the selected products for analysis

Appendix 5 contains an overview of the 73 consumer products in total that were selected for a total of 78 material analyses (screening analyses). It should be noted that the products are named (“Lab no.”) after where they were purchased, which does not mean that they were manufactured in the same place. I.e.

- 27 “DK” products were purchased via Danish websites (with Danish CVR number) or were purchased at Danish stores in the Copenhagen area (only six products)
- 25 “EU” products were purchased from EU countries (excl. Denmark), i.e. for example, on Amazon.de, but also directly from German, Swedish websites, as well as some websites from other EU countries, where it was possible to have the products shipped to Denmark
- 21 “N-EU” products were purchased from non-EU countries, i.e. typically on Amazon.com, Wish.com, eBay.com or Aliexpress.com

There are some “gaps” in the order of the labelling (especially for the N-EU products), which is due to the fact that these products were removed after labelling/naming of the products, or it was because the products did not arrive before the commencement of the analyses.

TABLE 22 below contains an overview of the types of products purchased for the screening analyses.

TABLE 22. Overview of distribution of types of analysed consumer products divided into the different categories. The number in parentheses is the number of products of this type that were analysed.

Main category	Amount from DK	Amount from EU*	Amount from N-EU	Target groups
Silicone products	Teething rings/teething toys (2) iPad/tablet covers (2) Dummies (2)	Teething rings/teething toys (2) iPad/tablet covers (1) Dummies (2) Toys (2)	Teething rings/teething toys (2) iPad/tablet covers (2) Dummies (1)	Children Children/pregnant women Children Children
Plastic products	Mobile phone covers (2) Dummies (1) Plastic toys (3)	Mobile phone covers (3) Dummies (1) Plastic toys (2)	Mobile phone covers (1) Dummies (1) Plastic toys (4)	Pregnant women Children Children
Chemical mixtures	Soap bubble liquid (5) Finger paints (4)	Soap bubble liquid (3) Finger paints (4)	Soap bubble liquid (3) Finger paints (2)	Children Children
Textile products	Underwear (2) Adult socks (2) Children's socks (3)	Underwear (2) Adult socks (2) Children's socks (3)	Underwear (2) Adult socks (2) Children's socks (3)	Pregnant women Pregnant women Children
Total ** distributed to the target group	**Children (22)** **Pregnant women (8)**	**Children (20)** **Pregnant women (8)**	**Children (18)** **Pregnant women (7)**	**Children (60)** **Pregnant women (23)**

* EU means EU except Denmark

** The products for both children and pregnant women here are included in both places

Overall, this means that 55 consumer products for children have been analysed in this project (plus five products that are analysed as both plastic and silicone products), as well as 23 consumer products for pregnant women (maternity underwear, adult socks, mobile phone covers, and iPad and tablet covers). The products for children that are analysed are plastic toys (primarily rattles), dummies, iPad and tablet covers, teething rings/teething toys, finger paints, soap bubble liquid and children's socks. In this count, the five iPad and tablet covers are included in both places as a product that is for both children and pregnant women. Mobile covers, on the other hand, are exclusively used as a product for pregnant women.

5. Legislative requirements

This chapter briefly describes the legislative requirements that exist for the prioritised substances (BHA, BHT, D4, butylparaben and propylparaben, as well as BPA) in the selected product types.

Legislative requirements for cosmetic products are also included in this section, as the data extract from the Danish Consumer Council Tænk provides a very good overview of the use of the prioritised substances on the market in Denmark. The legislative requirements are illustrated in TABLE 23 below and are elaborated in the text below the table in cases where there is applicable legislation or possibly legislation on its way.

Overall, it appears from TABLE 23 that, with the exception of cosmetic products, the regulations that apply to the prioritised substances in the selected product types are very limited. This is a requirement in the toy standard EN 71-7 for the parabens, but requirements in standards should not be construed as regulatory requirements (see section 5.2.3 “Butylparaben and propylparaben”). For the other product types, it will thus be a chemical safety assessment of the product that is crucial. However, this is not within the scope of this project.

TABLE 23. Overview of the legislative requirements for the prioritised substances for the selected product types, as well as cosmetic products. Fields with a green background are the product types that have been investigated for the listed substances in this project.

Substance Product type	BHA / BHT	D4*	Butylparaben/ propylparaben	BPA
Teething ring/teething toy	No regulation	No regulation	No regulation	Toys: SML*** = 0.04 mg/l
Plastic toys	No regulation	No regulation	No regulation	Toys: SML*** = 0.04 mg/l
Dummies	No regulation	No regulation	No regulation	No regulation
Mobile phone covers	No regulation	No regulation	No regulation	No regulation
iPad and tablet covers	No regulation	No regulation	No regulation	No regulation
Finger paints	No regulation	No regulation	0.14%**	Toys: SML*** = 0.04 mg/l
Soap bubble liquid	No regulation	No regulation	No regulation	Toys: SML*** = 0.04 mg/l
Textiles	No regulation	No regulation	No regulation	No regulation
Cosmetic products	No regulation	May not be used	EU: Max 0.14%, may not be used in leave-on products for the diaper area DK: May not be used in products for children under the age of three.	May not be used

* For D4, there is a restriction proposal, which has not yet been considered by the Commission (see section 5.2.2 on D4 for more details)
** Requirements according to standard EN 71-7, which should not be regarded as a legislative requirement
*** SML stands for Specific Migration Limit

5.1 Legislation in general

Danish Act on Products and Market Surveillance (ACT no. 799.2020) implements parts of EU regulation no. 95/2001 on product safety in general. According to the Danish Act on Products and Market Surveillance, products that comply with the regulations of the Act and do not pose a risk are only permitted to be made available on the internal market. The composition of the product and thus the content of chemical substances also play a role in relation to an assessment of whether a product poses a risk. Thus, if a risk assessment of an ingredient in a product is carried out that constitutes a risk to the consumer when used, it means that the product is illegal to market according to the Danish Act on Products and Market Surveillance.

The Danish Act on Products and Market Surveillance does not apply to the safety aspects where other specific legislations have already laid down provisions regarding safety.

5.2 Legislation for the individual substances

Below is an explanation of which legislation is in force or on its way for the individual substances.

5.2.1 BHA and BHT

For BHA and BHT, no regulations have been laid down on their presence in products made of plastic (or silicone).

Areas where BHA and BHT are regulated, which are not relevant to the analysed products in this project, are:

- According to the EU Regulation on food contact materials made of plastic (EU regulation no. 10, 2011), BHA and BHT are permitted as additives or production aids, and a specific limit has been set for the migration of the substances (see Appendix 2)
- According to the EU database of approved food additives, BHA and BHT are permitted as food additives in certain foods (see Appendix 3)

5.2.2 D4

For D4, a restriction proposal was submitted for the siloxanes D4, D5 and D6 in March 2019. In December 2019, the proposal was going out for consultation (ECHA, 2019c). There is an assessment from the expert committees RAC and SEAC on the restriction proposal (ECHA, 2020d; ECHA, 2020e). The proposal is for a fairly broad restriction on the use of D4 (as well as D5 and D6) in various products both for consumers but also within professional contexts. However, the restriction proposal has not yet been considered by the commission but is expected to be adopted in 2020 or early 2021.

Areas where D4 is regulated, which are not relevant to the analysed products in this project, are:

- According to Annex II of the EU Cosmetics Regulation (EU regulation no. 1223/2009), D4 is prohibited for use in cosmetic products

5.2.3 Butylparaben and propylparaben

For toys, there are generally no regulations regarding the content of parabens, except for finger paints, where according to standard EN 71-7 on finger paints it is stated that a concentration of butylparaben or propylparaben is permitted at a maximum concentration of 0.14%. The total concentration of parabens must not exceed 0.8%.

However, requirements in standards are not part of the legislation and should therefore not be regarded as legislative requirements for finger paints, but can be used for the purpose of presuming compliance with the directive in the case of harmonised standards referred to in the EU Official Journal, e.g. EN 71-7.

Areas where BHA and propylparaben are regulated, which are not relevant to the analysed products in this project, are:

- According to the EU Regulation on food contact materials made of plastic, propylparaben is permitted as an additive or secondary material in production (see Appendix 2)
- According to the EU Cosmetics Regulation (EU regulation no. 1223/2009), both butylparaben and propylparaben may only be used with a maximum concentration of 0.14% and may not be used in leave-on products for the purpose of being used in the diaper area for children under the age of three. The maximum permissible total concentration of all parabens is 0.8%
- In Denmark, the use of butylparaben, propylparaben and two other parabens in cosmetic products intended for children under the age of three is not only restricted, but completely prohibited via the statutory order banning the import, sale and use of certain parabens in cosmetic products for children under the age of three (Stat. Ord. no. 1217, 2013)

5.2.4 BPA

For toys (i.e. teething rings / teething toy, plastic toys, finger paints and soap bubble liquid), BPA is restricted in toys intended for use by children under the age of three or in other toys intended to be put in the mouth (according to Appendix II, Appendix C of the Danish Statutory Order on safety requirements for toys (Stat. Ord. 309, 2017)). BPA is restricted via a migration value of 0.04 mg/litre in accordance with the methods set out in EN 71-10 and EN 71-11 on organic chemical substances

Areas where BPA is regulated, which are not relevant to the surveyed products in this project, are:

- According to Annex II of the EU Cosmetics Regulation (EU regulation no. 1223/2009), BPA is prohibited for use in cosmetic products
- According to the EU Regulation on food contact materials made of plastic, BPA is permitted as a monomer, but a specific migration limit value has been set (see Appendix 2)
- According to REACH Annex XVII, BPA may not be used in thermal paper in concentrations exceeding 0.02%

6. Screening analyses

This chapter describes the screening analyses that were carried out in the project based on prioritisation of both substances and product types, as described in chapter 4 “Prioritisation of substances and product types”.

6.1 Planned screening analyses

As described in chapter 4 “Prioritisation of substances and product types”, a decision was made on having the following screening analyses conducted:

- 18 silicone products were analysed for the presence of D4, BHA and BHT
- 18 plastic products were analysed for the presence of D4, BHA and BHT
- 21 chemical mixtures were analysed for the presence of butylparaben and propylparaben
- 21 textile products were analysed for the presence of BPA, butylparaben and propylparaben

The distribution of products in the different product groups (DK, EU and N-EU) as well as the different product types (e.g. teething rings, iPad and tablet covers, dummies) is described in more detail in chapter 4.

The screening analyses are generally performed as single determinations and as a screening, i.e. a value for the content is not specified, but whether a content has been observed above or below the detection limit. It should be noted that the analyses for the textile products were performed as quantitative determinations (true double determinations), as the content here was expected to be low based on the descriptions in the literature (see chapter 3.3 "Literature/internet search"). However, for the other types of analyses, the purpose was only to perform screening analyses. The quantitative analysis results for the textile products are rendered in Appendix 6 “Quantitative analyses of textiles”, whereas this chapter only indicates whether the substances have been identified or not on an equal footing with the other screening analyses performed.

6.2 Analysis methods used

The different analysis methods for the different screening analyses (for textiles quantitative analysis) are specified in more detail below.

6.2.1 Analysis for D4, BHA and BHT in plastic and silicone

The screening analyses for D4, BHA and BHT in both plastic and silicone were conducted by the Danish Technological Institute.

Screening of the samples for content of the compounds D4, BHA and BHT is performed according to the analytical method by Danish Technological Institute OA 562: Determination of siloxanes and other organic compounds by GC-MS.

Sample preparation
Samples made of silicone are extracted with dichloromethane containing internal standard (add 1 g sample to 10 mL solvent).
Samples made of plastic are extracted with dichloromethane containing internal standard (add 1 g sample to 10 mL solvent).

Analytical method
Extracts are analysed by gas chromatography with mass spectrometric detection (GC-MS). The detected compounds are identified by comparison of MS spectra with reference standards. Calibration is performed by using reference standards of the three compounds in the measuring range from 0.5 µg/mL to 8 µg/mL corresponding to between about 5 and 80 ppm (µg/g) in the sample.

Detection limits
D4: 5 ppm (µg/g)
BHA: 10 ppm (µg/g)
BHT: 10 ppm (µg/g)

6.2.2 Analysis for butylparaben and propylparaben as well as BPA in textiles

The analyses for butylparaben and propylparaben, as well as BPA in textiles were conducted by Medico Kemiske Laboratorium ApS.

Sample preparation
0.5 g of sample is added 1.5 mL of acetone and 6 mL of dichlormethane, including isotopic labelled standards (D-16 BPA, C13-PP and C13-BP). The sample is extracted for 20 min using ultrasonic extraction. After extraction, the sample is filtered and evaporated to dryness.

Analytical method
The dried sample is re-suspended in 0.5 mL of methanol and subsequently analysed by LC-ESI-MS (Thermo Scientific™ Dionex™ UltiMate™ 3000 RSLC with ISQ EC Masspec.) in negative mode. The compounds are identified and quantified from the molecular ion (BPA = 227 m/z, butylparaben = 193 m/z, propylparaben =179 m/z). The content in the samples is calculated by use of certified standards. The added isotopic labelled standards are used to correct for loss during sample preparation and analysis. A control solution is analysed for a minimum every of 10th sample on the LC-MS. True double determinations were made for each sample.

Detection limits
BPA: 5 ng/g
Butylparaben: 0.5 ng/g
Propylparaben: 0.5 ng/g

6.2.3 Analysis for butylparaben and propylparaben in chemical mixtures

The screening analyses for butylparaben and propylparaben in chemical mixtures were conducted by FORCE Technology. The focus was on the identification of butylparaben and propylparaben, but in cases where other parabens (methylparaben and ethylparaben) or other preservatives were identified using the same method, this is also indicated.

Sample preparation
Approx. 0.1 g of sample was weighed and mixed with anhydrous sodium sulfate and Florisil until homogeneous. A glass pasteur pipette was filled with a little glass wool at the bottom, a little Florisil, and finally the sample mixture. It was eluted with ethyl acetate and the liquid was collected in a 1 ml volumetric flask which was finally filled with ethyl acetate to a volume of 1.00 ml.

Analysis technique
The eluates were analysed by GC-MS (gas chromatography with a mass spectrometry). Single determinations of samples, blind as well as standard addition for selected samples, and double determination of control samples were made. In addition, 2 x 6 standard additions were made for a selected sample at high and low concentration of the parabens, respectively. Calibration was performed using external calibration on both the total amount of detected ions (TIC) and on four ions specific for the two parabens (SIM). Parabens in the samples were identified using the mass spectra and retention times.

Detection limits
Butylparaben: 1 ppm
Propylparaben: 1 ppm

6.3 Results of the screening analyses

Results of the screening analyses are given in TABLE 24 to TABLE 27 below for respectively:

- Screening for presence of D4, BHA and BHT in silicone products
- Screening for presence of D4, BHA and BHT in plastic products
- Screening for presence of butylparaben, propylparaben and BPA in silicone products
- Screening for presence of butylparaben and propylparaben in chemical mixtures

6.3.1 Analysis results for the silicone products

The results of the screening analyses for the presence of D4, BHA and BHT in the silicone products are given in TABLE 24 below.

TABLE 24. Results of screening for presence of D4, BHA and BHT in the silicone products

Lab. no.	Description	D4	BHA	BHT
DK S 1	Teething ring/teething toy	++	-	-
DK S 2	iPad and tablet covers	-	-	-
DK S 3	iPad and tablet covers	+++	-	-
DK S 4 (DK P 4)	Dummy	-	-	-
DK S 5	Dummy	-	-	-
DK S 6	Teething ring/teething toy	-	-	-
EU S 1	Dummy	-	-	-
EU S 2	Teething ring/teething toy	++	-	-
EU S 3	iPad and tablet covers	+++	-	-
EU S 4 (EU P 7)	Dummy	-	-	-
EU S 5 (EU P 5)	Teething ring/teething toy Plastic toys	-	-	-
EU S 6	Teething ring/teething toy	+++	-	-
EU S 7	Teething ring/teething toy Plastic toys	-	-	-

Lab. no.	Description	D4	BHA	BHT
N-EU S 1	Teething ring/teething toy	++	-	-
N-EU S 2	iPad and tablet covers	++	-	-
N-EU S 3 (N-EU P 3)	Teething ring/teething toy Plastic toys	-	-	-
N-EU S 4 (N-EU P 7)	Dummy	-	-	-
N-EU S 6	iPad and tablet covers	+++	-	-

- indicates content less than the detection limit of 5 ppm (D4) or 10 ppm (BHA and BHT) respectively
+ indicates content just above the detection limit (5 ppm)
++ indicates content of the sample within the calibrated range (equivalent to between 5 and 80 ppm)
+++ indicates content in the sample that exceeds the calibrated range (i.e. > 80 ppm)

As shown in TABLE 24, neither BHA nor BHT has been identified in any of the silicone products. D4 has been identified in eight of the 18 silicone products analysed, but only in teething rings/teething toys (in four products) and in iPad and tablet covers (in four products). The general picture is that the concentration is highest in iPad and tablet covers.

The presence of D4, which probably occurs as residues, is distributed as follows depending on purchases from DK, EU, or N-EU respectively:

- Two out of six Danish products (33%) contain D4
- Three out of seven EU products (43%) contain D4
- Three out of five N-EU products (60%) contain D4

There are several products purchased outside the EU that contain D4, but as there are relatively few products of each category, it cannot be ruled out that it is due to coincidences.

6.3.2 Analysis results for the plastic products

The results of the screening analyses for the presence of D4, BHA and BHT in the plastic products are given in TABLE 25 below.

TABLE 25. Results of screening for presence of D4, BHA and BHT in the plastic products

Lab. no.	Description	D4	BHA	BHT
DK P 1	Plastic toys	-	-	++
DK P 2	Mobile phone covers	-	-	-
DK P 3	Plastic toys	-	-	-
DK P 4 (DK S 4)	Dummy	-	-	-
DK P 5	Mobile phone covers	-	-	-
DK P 6	Plastic toys	-	-	-
EU P 1	Mobile phone covers	-	-	-
EU P 3	Mobile phone covers	++	-	+++
EU P 4	Mobile phone covers	-	-	-
EU P 5 (EU S 5)	Plastic toys Teething ring/teething toy	-	-	-
EU P 6	Plastic toys	-	-	-
EU P 7	Dummy	-	-	-

Lab. no.	Description	D4	BHA	BHT
(EU S 4)				
N-EU P 1	Plastic toys	-	-	++
N-EU P 2	Mobile phone covers	-	-	-
N-EU P 3 (N-EU S 3)	Plastic toys Teething ring/teething toy	-	-	++
N-EU P 4	Plastic toys	-	-	-
N-EU P 6	Plastic toys	-	-	-
N-EU P 7 (N-EU S 4)	Dummy	-	-	-

- indicates content less than the detection limit of 5 ppm (D4) or 10 ppm (BHA and BHT) respectively
+ indicates content just above the detection limit
++ indicates content of the sample within the calibrated range (equivalent to between 5 and 80 ppm)
+++ indicates content in the sample that exceeds the calibrated range (i.e. > 80 ppm)

It appears from TABLE 25, that BHA has not been identified in any of the plastic products. D4 was not initially expected in any of the plastic products but is identified in one of the plastic products (a mobile phone cover). BHT was identified in four of the 18 products, three types of plastic toys and in a single mobile phone cover. The types of plastic products where BHT is identified are of two different plastic types ABS (plastic toys) and PC (mobile phone cover), which indicates that BHT is used in different plastic types.

The presence of BHT is distributed as follows depending on purchases from DK, EU, or N-EU respectively:

- One out of six Danish products (17%) contains BHT
- One in six EU products (17%) contains BHT
- Two out of six N-EU products (33%) contain BHT

There are several products purchased outside the EU that contain BHT, but as there are relatively few products of each category, it cannot be ruled out that it is due to coincidences.

6.3.3 Analysis results for the textile products

The results of the screening analyses for the presence of butylparaben, propylparaben and BPA are given in TABLE 26 below.

TABLE 26. Results of content analysis for butylparaben and propylparaben as well as BPA in Textile products

Lab. no.	Description (cotton content)	Butylparaben	Propylparaben	BPA
DK T 1	Children's socks (78 %)	-	-	-
DK T 2	Adult socks (77%)	-	-	-
DK T 3	Children's socks (79 %)	-	-	-
DK T 4	Adult socks (75 %)	-	-	-
DK T 5	Underwear (90 %)	-	-	-
DK T 6	Underwear (79 %)	-	-	-
DK T 7	Children's socks (75%)	-	-	-
EU T 1	Underwear (95%)	-	-	-
EU T 2	Underwear (95%)	-	-	-
EU T 3	Adult socks (24 %)	-	-	-

Lab. no.	Description (cotton content)	Butylparaben	Propylparaben	BPA
EU T 4	Children's socks (55 %)	-	++	-
EU T 5	Children's socks (73 %)	-	++	-
EU T 6	Adult socks (20 %)	-	-	-
EU T 8	Children's socks (unknown)	-	-	-
N-EU T 1	Underwear (unknown)	-	-	-
N-EU T 2	Adult socks (95 %)	-	-	-
N-EU T 3	Children's socks (72 %)	-	+	+
N-EU T 4	Children's socks (72 %)	-	-	++
N-EU T 5	Adult socks (90 %)	-	+	+
N-EU T 6	Underwear (95%)	-	-	-
N-EU T 8	Children's socks (70 %)	-	-	-

- indicates content less than the detection limit of 0.5 ng/g (butylparaben and propylparaben) or 5 ng/g (BPA) respectively
+ indicates content just above the detection limit
++ indicates the content of the sample within the calibrated range (i.e. between about 0.5 to 10 ng/g for butylparaben and propylparaben and between about 5 and 250 ng/g for BPA)
+++ indicates content in the sample that exceeds the calibrated range (i.e. > 10 ng/g for butylparaben and propylparaben and <250 ng/g for BPA)

It appears from TABLE 26, that butylparaben has not been identified in any of the textile products. Propylparaben was identified in four of 21 textile products (three children's socks and a pair of adult socks), and BPA in three of 21 textile products (two different children's socks and one adult sock).

The cotton content in the various products is written in parentheses in the table. There is no correlation between the presence of the prioritised substances and the presence of cotton in the products.

There is a predominance of products that contain residues of BPA in products purchased outside the EU, while the paraben content for products in the EU (not Denmark) and outside the EU is evenly distributed:

- None of seven Danish products (0%) contains propylparaben or BPA
- Two out of seven EU products (29%) contain propylparaben (none contains BPA)
- Two out of seven N-EU products (29%) contain propylparaben and three out of seven products (43%) contain BPA

6.3.4 Analysis results for the chemical mixtures

The results of the screening analyses for the presence of butylparaben and propylparaben in the chemical mixtures are given in TABLE 27 below.

TABLE 27. Results of screening for presence of butylparaben and propylparaben in the chemical mixtures

Lab. no.	Description	Butylparaben	Propylparaben	Other substances
DK KB 1	Finger paints	-	-	Methylparaben (+++)
DK KB 2	Finger paints	-	-	
DK KB 3	Finger paints	-	-	
DK KB 4	Soap bubble liquid	-	-	
DK KB 5	Soap bubble liquid	-	-	

Lab. no.	Description	Butylparaben	Propylparaben	Other substances
DK KB 6	Soap bubble liquid	++	++	Methylparaben (+++) Ethylparaben (+)
DK KB 7	Finger paints	-	-	
DK KB 8	Soap bubble liquid	-	-	
DK KB 9	Soap bubble liquid	-	-	
EU KB 1	Finger paints	-	-	
EU KB 2	Finger paints	-	-	Methylparaben (+++)
EU KB 3	Finger paints	-	-	
EU KB 4	Finger paints	-	-	
EU KB 5	Soap bubble liquid	-	-	
EU KB 6	Soap bubble liquid	-	-	
EU KB 7	Soap bubble liquid	-	-	
N-EU KB 2	Finger paints	-	-	
N-EU KB 3	Finger paints	-	-	
N-EU KB 4	Soap bubble liquid	-	-	
N-EU KB 5	Soap bubble liquid	+	+	Methylparaben (+++) Ethylparaben (+) Isobutylparaben (+)
N-EU KB 7	Soap bubble liquid	-	-	

- indicates content less than the detection limit of 5 ppm for butylparaben and propylparaben respectively
+ indicates content of the sample within the calibrated range of 50-250 ppm
++ indicates content in the sample within the calibrated range of 250-500 ppm
+++ indicates content in the sample that exceeds the calibrated range (i.e. > 500 ppm)

As can be seen from TABLE 27, the presence of butylparaben and propylparaben in only two of the 21 chemical mixtures has been identified. In both cases, they were soap bubble liquid. In the same products, both methylparaben and ethylparaben were also identified, as well as isobutylparaben in one of the soap bubble liquids. In the ten finger paints, neither butylparaben nor propylparaben were identified. However, methylparaben was identified in high concentrations in two of the products.

In the screening analyses, large amounts of the preservative 2-phenoxyethanol was also identified[15] in a high proportion within both soap bubble liquids and finger paints. The results show that the use of 2-phenoxyethanol appears to be more prevalent in finger paint than in soap bubble liquid. However, the content has not been determined or described in more detail in this report, as 2-phenoxyethanol is not suspected of being an endocrine disruptor and therefore has not been a focus in this project.

There is no clear pattern in the presence of butylparaben and propylparaben in the chemical mixtures, as the substances are only identified in two products (a DK product and a non-EU product).

- One out of nine Danish products (11 %) contains butylparaben and propylparaben
- None of seven EU products (0%) contains butylparaben and propylparaben
- One in five N-EU products (20 %) contains butylparaben and propylparaben

[15] 2-phenoxyethanol is considered, among other things, to be damaging to the liver (SCCS, 2016)

6.4 General overview of identification of prioritised substances

Overall, a total of 78 analyses were performed across the various main product categories for a total of six different prioritised substances. The results show that there is a tendency for the prioritised substances to be identified more often in products outside the EU than in Denmark or within the EU (not Denmark):

- Four out of a total of 28 Danish products (14%) contain at least one of the prioritised substances
- Six out of a total of 27 EU products (22 %) contain at least one of the prioritised substances
- Eight out of a total of 23 N-EU products (35%) contain at least one of the prioritised substances

7. Discussion of results

This chapter contains a discussion of the results of the project, i.e. of the survey and screening analyses of the selected product categories for the prioritised substances. In addition, suggestions have been given as to which substances and product types a possible project could focus on advantageously. Finally, this chapter discusses whether there are areas where there is a need for further knowledge about the exposure of the substances, i.e. whether there are product types and/or substances in this project that have been left out due to prioritisation, but which should be investigated further.

7.1 Discussion

In this screening project of selected endocrine disruptors and/or substances suspected of being endocrine disruptors (the so-called selected substances), a survey of the use of selected substances in consumer products, food, food contact materials and medicinal products was carried out. Based on the survey, a number of consumer products were proposed that could be relevant to investigate for some of the selected substances. Since this project is a screening project, it has not been possible to investigate everything, and therefore the following areas were selected and prioritised in the screening analyses:

- Silicone products were analysed for the presence of D4, BHA and BHT – dummies, iPad and tablet covers and teething rings/teething toys made of silicone were purchased
- Plastic products were analysed for the presence of D4, BHA and BHT – mobile phone covers, dummies (focus on the shield) and various plastic toys made of plastic (e.g. rattles) were purchased
- Textile products were analysed for the presence of BPA, butylparaben and propylparaben – underwear for pregnant women, adult socks and children's socks containing cotton were purchased
- Chemical mixtures were analysed for the presence of butylparaben and propylparaben – soap bubble liquid and finger paints were purchased

In addition, the data extract from the Danish Consumer Council Tænk Kemi's database on the use of substances in cosmetic products provides a very good overview of the prevalence of the prioritised substances in these products in Denmark.

7.1.1 Presence of the prioritised substances in the selected products

The overall results are presented in TABLE 28 below.

TABLE 28. Overview of the number of products in which the prioritised substances were identified in the selected four different product categories, as well as in cosmetic products. The green background colour indicates that no analysis has been carried out for the substance in question in the relevant product category.

Product category	D4	BHA	BHT	BPA	Butylparaben	Propylparaben
Silicone products (18 products in total)	8	0	0			
Plastic products (18 products in total)	1	0	4			
Textile products (21 products in total)				3	0	4

Product category	D4	BHA	BHT	BPA	Butylpara-ben	Propylpara-ben
Chemical mixtures (21 products in total)					2	2
Cosmetic products (12,600 products)*	9 (-**)	14	898	-	108	444

* Extract from the Danish Consumer Council Tænk Kemi's database, Kemiluppen – see more in section 3.2.8 in the survey
** D4 has recently been banned in cosmetic products, which is why some products may appear in the database from before the ban came into force.
- means that the substance may not be used in cosmetic products

As shown in TABLE 28 and in chapter 6 “Screening analyses”, BHA has not been identified in any of the silicone or plastic products examined. BHT was identified in four of 18 plastic products, but exclusively in plastic toys and mobile phone covers – not in the plastic shields in the three dummies studied. Both BHA and BHT are included in cosmetic products in the Danish Consumer Council Tænk Kemi's database Kemiluppen. However, BHT is far more prevalent than BHA in cosmetic products, where it is primarily used in perfumed products, such as deodorants.

D4 was identified in eight of 18 silicone products and exclusively in teething rings/teething toys and in iPad and tablet covers as well as a mobile phone cover made of plastic. No D4 was identified in any of the five dummies studied. Currently, D4 is not allowed to be used in cosmetic products.

Butylparaben was only identified in two of the chemical mixtures studied and only in soap bubble liquid – not in finger paints. Propylparaben was identified in two soap bubble fluids as well as in small amounts in four of the textile products studied (only in children's and adult socks, but not in underwear). Both parabens are used currently in a variety of cosmetic products, but propylparaben is more prevalent than butylparaben. Information from the industry indicates that the use of butylparaben is declining, as none of the companies that responded to the inquiry in the survey uses butylparaben.

BPA was identified in small amounts in three of the textile products studied – also here only in children's and adult socks, but not in underwear. BPA is not allowed to be used in cosmetic products.

For the textile products, it should be noted that the analyses were performed on the newly purchased, unwashed textile. Whether the content is just as high in textiles that have been washed e.g. one or more times, should be investigated further. For propylparaben, which is to some extent[16] soluble in water, it might be expected that the substance would be washed out of the fabric by washing the clothes, whereas BPA and butylparaben, which have a lower solubility in water[17], may be expected to remain in the washed textile to a greater extent. However, both parabens and BPA have a solubility that is defined as poorly soluble in water[18]. However, this should be investigated further, e.g. by performing washing tests and possibly subsequent quantitative content analyses as well as migration analyses.

[16] The solubility in water is approx. 500 mg/litre for propylparaben according to ECHA’s database of registered substances

[17] The solubility in water is approx. 300 mg/litre for BPA and approx. 200 mg/litre for butylparaben according to ECHA’s database of registered substances

[18] Defined as < 0.1 g per 100 g water (https://www.sigmaaldrich.com/united-kingdom/technical-services/solubility.html)

For cosmetic products, the extract from Kemiluppen from the Danish Consumer Council Tænk Kemi shows that BHT and propylparaben are used in 7.1% and 3.5% respectively of the over 12,000 cosmetic products that exist in Kemiluppen. However, butylparaben is not particularly used (0.9% of the products in Kemiluppen), and information from the industry (those who responded to the inquiry) indicates that Danish manufacturers do not use butylparaben.

In the screening analyses, the selected substances in some of the examined products were generally identified (in between 5 and 38% of the examined products) – with the exception of BHA, which was not identified above the detection limit. I.e. that the substances occur in the investigated product types, but there are also products on the market in which the substances do not occur or have not been identified at levels above the detection limit. However, it appears that the presence of D4 in silicone products is somewhat more widespread, as the substance was identified in almost 40% of the products studied.

Based on this screening study, it thus does not make sense in a possible follow-up project to focus on neither BHA in plastic and silicone products nor on butylparaben and propylparaben in finger paints. These substances do not seem to occur in the product types studied. For the other substances and the other product types, it will be relevant in a possible follow-up project to conduct quantitative content analyses followed by migration analyses to carry out a risk assessment of whether the quantities present in the products may constitute a health risk of endocrine disruptive effects. It will especially make sense to focus on e.g. the accumulated exposure to BHT, which appears to be used in a variety of consumer products (various plastic products, as well as various cosmetic products).

7.1.2 Differences between products purchased from DK, EU, or N-EU

In general, for each of the four product categories examined (silicone products, plastic products, textile products and chemical mixtures), there was a slight predominance of products purchased from N-EU compared to products purchased from DK and the EU, which contained the prioritised substances. However, there are generally few products (between five and nine) from each product category purchased from the various regions (DK, EU, and N-EU), so this could be a matter of coincidence. If you look at the overall picture across the various main product categories, where a total of 78 products have been examined for a total of six different prioritised substances, the results show that there is a tendency for the prioritised substances to be identified more often in products outside the EU than in Denmark or within the EU:

- Four out of a total of 28 Danish products (14%) contain at least one of the prioritised substances
- Six out of a total of 27 EU products (22 %) contain at least one of the prioritised substances
- Eight out of a total of 23 N-EU products (35%) contain at least one of the prioritised substances

7.1.3 Effects of the prioritised substances

For the prioritised substances identified in one or more of the product categories examined, the following substances have the same endpoint, i.e. same type of endocrine disruptive effect:

- Effects on the thyroid and reproductive system
    - BHT (suspected of these effects)
    - D4 (weak evidence for these effects)
- Oestrogen activity
    - D4 (clear evidence)
    - BPA (included on the Candidate List)
    - Butylparaben (clear evidence)
    - Propylparaben (suspected)

Since several of the substances have the same type of endocrine disruptive effects, there may be a risk that the use of several products at the same time (e.g. a child using an iPad and tablet cover made of silicone, children's socks and playing with soap bubble liquid) may constitute a risk of endocrine disruptive effects, even if the individual product itself does not pose a risk. It is therefore proposed that a possible follow-up project should also focus on the overall exposure and the risk of exposure to several of these endocrine disruptors and/or substances that are suspected to be endocrine disruptors from different sources of exposure. If, on top of this, contributions from previous studies of e.g. parabens in sunscreens and other cosmetic products (Larsen et al., 2017; Andersen et al., 2012), BHT in cosmetic products and foods (Larsen et al., 2017) and BPA in foods and consumer products (Larsen et al., 2017 ; Andersen et al., 2012) are added, it is worth examining the contribution of these substances and product types to the overall endocrine disruptive effects.

7.2 Suggestions for further work

Suggestions for further work, i.e. which product types and substances that a possible follow-up project should focus on, are two-part. On the one hand, it is relevant to examine the product types in more detail where the prioritised substances were identified, and on the other hand, it may be relevant to examine some of the product types and substances that were left out of this project, due to the fact that it was not possible to conduct analyses of all proposed product groups within the framework of the project.

7.2.1 Suggestions for further work for products analysed in this project

Based on the screening analyses carried out in this project, it will be relevant to proceed with quantitative analyses and subsequent migration analyses in the following product types and for the following substances:

- For babies:
  - D4 in teething rings/teething toys
  - BHT in plastic toys (rattles)
  - BPA in children's socks[19]
- For children:
  - D4 in iPad and tablet covers
  - BHT in plastic toys and mobile phone covers
  - BPA and propylparaben in children's socks[19]
  - Butylparaben and propylparaben in soap bubble liquids
- For pregnant women:
  - D4 in iPad and tablet covers
  - BPA and propylparaben in adult socks[19]
  - BHT in mobile phone covers

7.2.2 Suggestions for further work with other products

Of the product types (and substances) that were not selected for screening analyses in this project, it will initially be the following that will be most relevant (based on the survey results):

- BHT and propylparaben in cosmetic products (the use of butylparaben is minor)
- BPA and possibly BPAF in metal containers for cosmetic products
- BPA in consumer products made of polycarbonate
- D4 in other consumer products made of silicone
- Propylparaben and butylparaben in gel-filled teething rings (do the substances migrate from the gel into the teething ring and subsequently into the saliva?)

[19] For these products, quantitative analyses were carried out in this project, but knowledge of possible migration is missing as well as whether there is a difference in content before and after washing

- BHT in other consumer products made of plastic
- BHT, BHA and propylparaben in medicinal products
- 4-MBC in sunscreens and face creams from the Chinese market

Both BHT and propylparaben are used in cosmetic products on the Danish market today (according to Kemiluppen from the Danish Consumer Council Tænk Kemi). Both BHT and propylparaben are found in products that are relevant for both children and pregnant women, e.g. body lotions, sunscreen/after sun lotion, hand cream and facial care products, i.e. these are products that are used daily and several products on the same day. However, it should be noted that the extract from Kemiluppen is only representative of the Danish market. Some of the same products can probably be bought on the European market, but the picture of how widespread the prioritised substances are in cosmetic products on the European market is not known. In addition, there is a lack of knowledge about the use of the prioritised substances in cosmetic products outside the EU if Danish consumers purchase a significant amount of cosmetic products outside the EU.

When BHT is used as an antioxidant in plastics, a consideration could also be whether BHT from plastic could migrate into the cosmetic product. However, it must be assumed that an added amount directly to the cosmetic product, which the survey shows occurs for a number of cosmetic products on the Danish market today, will be greater than a possible migration from the plastic and into the cosmetic product.

According to the survey, BPAF does not appear to be used to any great extent compared to BPA. However, in a few recent studies, BPAF has been identified in e.g. some cosmetic products. One of the studies (ChemTrust, 2018) points out that the reason may be that BPAF, like BPA, is used in seals for metal containers or in metal coating for cosmetic products. Thus, this area could be interesting to investigate further, although the content of BPA and BPAF is not expected to be high (according to the studies identified in the survey).

BPA is also used as a monomer for the production of polycarbonate plastic (PC). According to the survey, BPAF is an alternative to BPA – also in polycarbonate plastic but is only used for special polymer materials. Thus, it is primarily expected to be BPA that is relevant to consumer products made of PC. Dummies and cash register receipts have been studied in previous projects (among others, Larsen et al., 2017; Tønning et al., 2009). It may be relevant to examine whether there are other relevant consumer products of PC that should be further analysed for the presence and migration of BPA.

D4 was identified in a large proportion of the silicone products studied (close to 40%). For this reason, the content of D4 in consumer products made of silicone is generally expected to be an area of interest. However, there is a restriction proposal on the way for D4 in consumer products. The proposal has not yet been adopted.

A recent study (Potouridis et al., 2019) has identified migration from gel-filled teething rings made from the material EVA. The study indicates that it is due to the fact that the gel inside the teething rings is preserved with parabens. Propylparaben was also identified in migratoin fluid. Whether this is a widespread phenomenon and what the risks are in that case could also be interesting to investigate further.

The screening analyses show that BHT is used in some plastic products (were identified in mobile phone covers made of PC and various plastic toys (primarily rattles) made of ABS). It could therefore be relevant to examine these product groups in more detail or other consumer products made of plastic or of this type of plastic, e.g. dummies with shields made of PC, changing pads or toys intended to be put in the mouth (e.g. musical instruments, etc.).

The review of the Danish Medicines Agency's databases of permitted medicinal products in Denmark shows that BHT and propylparaben in particular are included in a large number of medicinal products. In a number of cases, the concentration is even indicated for these substances. BHA is also used in a number of products, whereas the use of butylparaben is limited. In a possible follow-up project, it would therefore be relevant in a risk assessment to include the contribution from BHT, BHA and propylparaben from medicinal products. For some medicinal products there will be direct consumption, whereas, for instance, other medicinal products are intended for application on the skin.

The survey of the use of the prioritised substances in food and food contact materials shows that BPA is permitted to be used as a monomer for the production of plastic for food contact. BHA, BHT and propylparaben are allowed to be used as additives in food contact products made of plastic, but butylparaben is not allowed to be used. Common to substances that are permitted in plastic for food contact is that they must comply with specific migration limit values. The use of BPA, especially in the coating in metal cans, has already been a focus point to some extent, whereas the use of BHA, BHT and propylparaben in plastic for food contact has not been investigated. BHA and BHT may be used as the only prioritised substances as food additives in certain types of foods, but the use seems to be limited.

The survey has shown that the use of the UV filter 4-MBC is not used in cosmetic products on either the Danish or European markets. In addition, sources have been identified indicating that 4-MBC is not used in cosmetic products in the US or Japan. However, no information is available on the use on the Chinese market (other than that it is allowed in a concentration of up to 4%, as in the EU). It is not known how widespread the purchase of sunscreens and face creams directly from the Chinese market is for consumers in Denmark. If this occurs, it could be relevant to investigate the presence of 4-MBC in cosmetic products on the Chinese market.

8. References

Abildgaard et al., 2003. Survey of chemical substances in paper handkerchiefs and toilet paper. Abildgaard A, Mikkelsen SH, Stuer-Lauridsen F, COWI. Survey of chemical substances in consumer products no. 34 2003. https://eng.mst.dk/media/mst/69117/34.pdf

Andersen et al., 2012. Exposure of pregnant consumers to suspected endocrine disruptors. Andersen DN, Møller L, Buchardt Boyd H, DHI. Boberg J, Petersen MA, Christiansen S, Hass U, DTU Fødevareinstituttet. Poulsen PB, Strandesen M, Bach D, FORCE Technology. Survey of chemical substances in consumer products no. 117, 2012. https://mst.dk/service/publikationer/publikationsarkiv/2012/apr/exposure-of-pregnant-consumers-to-suspected-endocrine-disruptors/

Danish Working Environment Authority, 2020. Description of the product register on the web page of the Danish Working Environment Authority. The search was carried out in April 2020. https://at.dk/en/product-registry/

CeHos, 2012a. Evaluation of 22 SIN List 2.0 substances according to the Danish proposal on criteria for endocrine disrupters. Danish Centre on Endocrine Disrupters. https://mst.dk/media/mst/67169/SIN%20report%20and%20Annex.pdf

CeHos, 2012b. Evaluation of tebuconazole, triclosan, methylparaben and ethylparaben according to the Danish proposal for criteria for endocrine disrupters. Danish Centre on Endocrine Disrupters. https://mst.dk/media/mst/9106715/chemicalsreportandannex.pdf

CeHoS, 2018. List of endocrine disrupting chemicals. Final report, December 2017, some mainly editorial changes September 2018. Danish Centre on Endocrine Disrupters. http://www.cend.dk/files/DK_ED-list-final_2018.pdf. Inklusiv appendix 1 til rapporten: http://www.cend.dk/files/DK_ED-list-final_appendix1_2018.pdf

CeHoS, 2020. Text from web page of the Danish Center for endocrine disruptors (Center for hormonforstyrrende stoffer). Visited in April 2020. http://www.cend.dk/stoffer-og-virkningsmekanismer.html

Celeiro et al., 2014. In-Vial Micro-Matrix-Solid Phase Dispersion for the Analysis of Fragrance Allergens, Preservatives, Plasticizers, and Musks in Cosmetics. Celeiro M, Lamas JP, Llompart M, Garcia-Jares C. Cosmetics 2014, 1, 171-201. https://www.mdpi.com/2079-9284/1/3/171

ChemTrust, 2018. From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them. ChemTrust, March 2018. https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf

Danish Consumer Council Tænk, 2015. Tyggegummi indeholder hormonkemi (in Danish). Article in the Danish consumer magazine Tænk (Think) June 2015. https://taenk.dk/om-os/presserum/tyggegummi-til-boern-indeholder-hormonkemi

Danish Consumer Council Tænk, 2016. Sådan har vi testet vitaminpiller til børn (in Danish). Article in the Danish consumer magazine Tænk (Think) February, 2016.

https://taenk.dk/test-og-forbrugerliv/boern/vitaminpiller-til-boern/saadan-har-vi-testet-vitaminpiller-til-boern

Danish Consumer Council Tænk, 2020. Extract from the database Kemiluppen on cosmetic products – from the Danish Consumer Council Tænk (Think), April 2020.

Danish EPA, 2020a. Text from the website of the Danish EPA concerning endocrine disruptors. Viewed in April 2020. https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-stoffer/hormonforstyrrende-stoffer/hvorfor-er-vi-bekymrede-for-hormonforstyrrende-stoffer/

Danish EPA, 2020b. Text from the website of the Danish EPA concerning suntan lotion. Viewed in April 2020. https://mst.dk/kemi/kemikalier/saerligt-for-borgere-om-kemikalier/groenne-tips/din-personlige-pleje/solcreme/solcreme-baggrund/

Danish EPA, 2020c. Text from the website of the Danish EPA concerning endocrine disruptors. Viewed in April 2020. https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-stoffer/hormonforstyrrende-stoffer/kriterier-og-kriterieforslag/

Danish EPA, 2020d. Category 1 of the EU list of potential endocrine disruptors. Text from the website of the Danish EPA concerning endocrine disruptors. Viewed in April 2020. https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-stoffer/hormonforstyrrende-stoffer/identifikation-af-hormonforstyrrende-stoffer/kategori-1-paa-eus-liste-over-potentielt-hormonforstyrrende-stoffer/

Danish plastics industry, 2020. Personal correspondence with environmental manager in the Danish plastics industry, Christina Busk in April/May 2020.

Danish Veterinary and Food Administration, 2014. BHA og BHT dual use additiver i plast (2014). J. nr.: 2013-29-64-00542 (in Danish). *English title: BHA and BHT dual use additives in plastics*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2014/BHA%20og%20BHT%20dual%20use%20additiver%20i%20plast.pdf

Danish Veterinary and Food Administration, 2015a. Afsmitning fra plastemballage til tørre fødevarer (2015). J. nr.: 2013-29-64-00544 (in Danish). *English title: Migration from plastic packaging to dry foods*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2015/Afsmitning%20fra%20plastemballage%20til%20t%C3%B8rre%20f%C3%B8devarer.pdf

Danish Veterinary and Food Administration, 2015b. Bisphenol A i fødevarekontaktmaterialer, FKM (2015). J. nr.: 2010-20-64-00238 (in Danish). *English title: Bisphenol A in food contact materials*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2015/Bisphenol%20A%20i%20FKM.pdf

Danish Veterinary and Food Administration, 2016a. Bisphenol A i fødevarekontaktmaterialer, FKM (2016). J. nr.: 2010-20-64-00238 (in Danish). *English title: Bisphenol A in food contact materials*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2016/Bisphenol%20A%20i%20FKM.pdf

Danish Veterinary and Food Administration, 2016b. Siloxaner i bageforme, flaskesutter, mad- og bagepapir (2016). J. nr.: 2014-29-61-00177 (in Danish). *English title: Siloxanes in baking tins, feeding bottles and greaseproof paper*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2016/Siloxaner.pdf

Danish Veterinary and Food Administration, 2018. Kemiske stoffer i fødevarekontaktmaterialer af genbrugspapir (2018) J. nr.: 2017-29-61-00871, projektnummer 5055. Danish Veterinary and Food Administration (in Danish). *Englis title: Chemical substances in food contact materials of recycled paper.* https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2018/Genbrugspapir.pdf

Danish Veterinary and Food Administration, 2019. Bisphenoler i fødevarekontaktmaterialer (FKM) (2019). J. nr.: 2014-29-61-00124, projektnummer 5152. Danish Veterinary and Food Administration (in Danish). *English title: Bisphenols in food contact materials*. https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2019/Bisphenoler.pdf

DLS, 2020. Liste over råvarer, DLS 2020.1 / Ph. Eur. 10.1 (in Danish). *English title: List of raw materials*. https://laegemiddelstyrelsen.dk/da/godkendelse/kontrol-og-inspektion/standardisering-af-kvaliteten-af-laegemidler-i-europa/danske-laegemiddelstandarder/~/media/F38425479F4E41A48D1C600ED84D076B.ashx

DTU, 2020. Memorandum. DTU-DOCX journal no. 20/1013091. Update on literature for BHT from 2011 to 2020 dealing with endpoints relevant for endocrine disruptive effects. July, 2020. Memorandum from DTU to the Danish EPA.

ECHA, 2017a. Member State Committee Support Document for identification of 4,4'-isopropylinenediphenol (BPA, BISPHENOL A) as a substances of very high concern because of this endocrine disrupting properties which cause probable serious effects to human health which give rise to an equivalent level of concern to those of CMR and PBT/VPVB substances. Adopted on 14 June 2017.
https://echa.europa.eu/documents/10162/908badc9-e65d-3bae-933a-3512a9262e59

ECHA, 2017b. Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency). Doc: ED/30/2017. Helsinki, 06.07.2017. https://echa.europa.eu/documents/10162/eeed2c09-2263-25ad-49cd-a0926736c877

ECHA, 2019a. Plastic additives initiative. Supplementary Information on Scope and Methods. 15.02.2019. https://echa.europa.eu/documents/10162/13630/plastic_additives_supplementary_en.pdf/79bea2d6-8e45-f38c-a318-7d7e812890a1

ECHA, 2019b. Annex XV Restriction report proposal for a restriction. Substance Name(s): Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6). European Chemicals Agency. Version number 1.1. 20 March 2019.
https://echa.europa.eu/documents/10162/11f77453-8a0d-411b-38c3-7f992a136cca

ECHA, 2019c. Opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6). Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). Agreed, 5 December 2019. https://echa.europa.eu/documents/10162/562177be-2dac-8fa4-9086-7f3d65481cd5

ECHA, 2020a. Annex XV report. Proposal for Identification of a substance of very high concern on the basis of the criteria set out in REACH article 57. Substance Names: Butyl 4-hydroxybenzoate (Butylparaben).
https://echa.europa.eu/documents/10162/4b52d00f-e629-5746-904c-64ef318c92a4

ECHA, 2020b. Information on chemicals. ECHA's database over kemiske stoffer tilgået i april 2020. https://echa.europa.eu/da/information-on-chemicals

ECHA, 2020c. Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. Decision of the European Chemicals Agency. 18.6.2020. https://echa.europa.eu/documents/10162/9227ca75-c14c-29ab-81ff-ee86058dd7a7

ECHA, 2020d. Opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6). Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 28 November 2020) and SEAC's opinion (adopted 12 March 2020). https://echa.europa.eu/documents/10162/b2388eee-ca3e-d534-c11e-cce7e6ceab79

ECHA, 2020e. Background document to the opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6). Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). 12 March 2020. https://echa.europa.eu/documents/10162/b2388eee-ca3e-d534-c11e-cce7e6ceab79

EFSA, 2011. Scientific Opinion on the re-evaluation of butylated hydroxyanisole – BHA (E 320) as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2011;9(10):2392.

EFSA, 2012. Scientific Opinion on the re-evaluation of butylated hydroxytoluene BHT (E 321) as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2012;10(3):2588.

Egmose & Pors, 2005. Survey of chemical substances in textile colorants. Egmose K & Pors J, Eurofins. Survey of chemical substances in consumer products, No. 58 2005. https://mst.dk/service/publikationer/publikationsarkiv/2005/jun/survey-of-chemical-substances-in-textile-colorants/

Engelund & Sørensen, 2005. Mapping and health assessment of chemical substances in shoe care products. Engelund B, Sørensen H. Dansk Toksikologi Center. Survey of chemical substances in consumer products, No 52, 2005. https://eng.mst.dk/media/mst/69130/52.pdf

Environment Canada, 2010. Screening Assessment for the Challenge. Methane, nitro- (Nitromethane). Chemical Abstracts Service Registry Number 75-52-5. Environment Canada. Health Canada, July 2010.

EU Regulation 1333, 2008. Regulation No. 1333/2008 of the European Parliament and of the Council (EF) of 16 December 2008 on food additives. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:02008R1333-20200319&qid=1587622791269&from=EN

EU Regulation 1223, 2009. Regulation No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20191218&qid=1587896524978&from=EN

EU Regulation 10, 2011. Commission regulation (EU) no. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:02011R0010-20190829&qid=1587913393869&from=EN

EU Regulation 528, 2012. Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market on use of biocidal products. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:32012R0528

EU Regulation 2235, 2016. Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:32016R2235&qid=1591623562125&from=EN

EU Regulation 213, 2018. Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:32018R0213&qid=1591443793756&from=EN

Eurofins, 2003. Mapping and exposure of chemical substances in Christmas decorations. Eurofins Intecon Consultancy A/S. Survey of chemical substances in consumer products no. 37. 2003.

Freire et al., 2019. Concentrations of bisphenol A and parabens in socks for infants and young children in Spain and their hormone-like activities. Freire C, Molina-Molina J-M, Iribarne-Duran, Jimenez-Diaz I, Vela-Soria F, Mustieles V, Arrebola JP, Fernandez MF, Artacho-Cordon F, Olea N. Environment International, Volume 127, June 2019, p. 592-600. https://www.sciencedirect.com/science/article/pii/S0160412019307287

Gao & Kannan, 2020. Phthalates, bisphenols, parabens, and triclocarban in feminine hygiene products from the United States and their implications for human exposure. Gao CJ, Kannan K, Environment International 136, 2020.

Gentry et al., 2017. A global human health risk assessment for octamethylcyclotetrasiloxane (D4). Gentry R, Franzen A, Van Landingham C, Greene T, Plotzke K. Toxiclogy Letters 279 (2017), p. 23-41. https://www.sciencedirect.com/science/article/pii/S0378427417301935

Glensvig & Pors, 2006. Mapping of perfume in toys and children's articles. Glensvig D, Pors J, COWI A/S, Eurofins Danmark. Survey of chemical substances in consumer products no. 68, 2006. https://mst.dk/service/publikationer/publikationsarkiv/2006/mar/mapping-of-perfume-in-toys-and-childrens-articles/

Heckmann et al., 2015. CMR-substances in toys – Market surveillance and risk assessment. Heckmann L-H L, Tordrup SW, Bondgaard Nielsen I, Malmgren-Hansen B, Nilsson NH, Teknologisk Institut. Survey of chemical substances in consumer products no. 141, 2015. https://mst.dk/service/publikationer/publikationsarkiv/2015/okt/cmr-substances-in-toys-market-surveillance-and-risk-assessment/

Hessel et al., 2019. Review on butylparaben: exposure, toxicity and risk assessment. With a focus on endocrine disrupting properties and cumulative risk assessment. Hessel E.V.S, Boon P.E, den Braver-Sewradi S.P, Meesters J.A.J, Weda M, Brand W, RIVM Report 2018-0161, 2019.

Hillier et al., 2003. An Investigation into VOC Emissions from Polyurethane Flexible Foam Mattresses. Hillier K, Schupp T, Carney I. Cellular Polymers, Vol. 22, No. 4, 2003. http://www.polymerjournals.com/pdfdownload/896351.pdf

Jacobsen et al., 2017. Survey and danger and ressource assessment of 3D printers and 3D printed articles (in Danish). Risikovurdering af 3D-printere og 3D-printede produkter. Jacobsen E, Bondgaard Nielsen I, Schjøtt-Eskesen J, Holst Fischer C, Teknologisk Institut. Larsen PB, Andersen DN, DHI. Kortlægning af kemiske stoffer i forbrugerprodukter nr. 160, 2017. https://www2.mst.dk/Udgiv/publikationer/2017/05/978-87-93529-99-1.pdf

Jensen et al., 2020. Plast Teknologi, 3. Udgave (in Danish). *English title: Plastic technology, 3rd edition*. Jensen B, Johansen J, Karbæk K, Kjærsgaard P, Roth Nielsen C, Rasmussen AB, Rasmussen TB, Høst-Madsen B, Mose Henriksen L. Plastindustrien (Danish plastics industry). Januar 2020. https://plast.dk/wp-content/uploads/2020/03/Plastteknologi.pdf

Kjølholt et al., 2015. Chemical substances in car safety seats and other textile products for children. Kjølholt J, Warming M, Lassen C, Hagen Mikkelsen S, Brinch A, COWI. Bondgaard Nielsen I, Jacobsen E, Teknologisk Institut. Survey of chemical substances in consumer products no. 135, 2015. https://mst.dk/service/publikationer/publikationsarkiv/2015/apr/chemical-substances-in-car-safety-seats/

Klinke et al., 2018. Analysis and risk assessment of fragrances and other organic substances in squishy toys. Klinke HB, Winther Lund BL, Villadsen SR, Tordrup SW, Kristensen GT, Teknologisk Institut, Larsen PB, DHI. Survey of chemical substances in consumer products no. 164, August 2018, the Danish EPA. https://mst.dk/service/publikationer/publikationsarkiv/2018/aug/analysis-and-risk-assessment-of-fragrances-and-other-organic-substances-in-squishy-toys/

Krause et al., 2017. Exposure to UV filters during summer and winter in Danish kindergarten children. https://www.sciencedirect.com/science/article/pii/S0160412016307656

Kristensen et al., 2019. Survey and risk assessment of developers in thermal paper. Kristensen GT, Jepsen LH, Johannesen SA, Jacobsen E, Teknologisk Institut. Larsen PB, DHI. Survey of chemical substances in consumer products no. 178. https://mst.dk/service/publikationer/publikationsarkiv/2020/mar/survey-and-risk-assessment-of-developers-in-thermal-paper/

Larsen et al., 2017. Exposure of children and unborn children to selected chemical substances. Larsen PB, Mørk TA, Buchardt Boyd H, Andersen DN, DHI. Boberg J, Axelstadt M, Hass U, DTU Fødevareinstituttet. Poulsen PB, FORCE Technology. Survey of chemical substances in consumer products no. 158. https://mst.dk/service/publikationer/publikationsarkiv/2017/maj/exposure-of-children-and-unborn-children-to-selected-chemical-substances/

Lassen et al., 2011. Migration of bisphenol A from cash register receipts and baby dummies. Lassen C, Hagen Mikkelsen S, Brandt UK, COWI. Survey of chemical substances in consumer products no. 110 2011. https://mst.dk/service/publikationer/publikationsarkiv/2011/jun/migration-of-bisphenol-a-from-cash-register-receipts-and-baby-dummies/

Law nr. 799, 2020. Lov om produkter og markedsovervågning (in Danish). *English title: Law on products and market surveillance*. LOV nr. 799 af 9.6.2020. https://www.retsinformation.dk/eli/lta/2020/799

Lu et al., 2018. Estimation of intake and uptake of bisphenols and triclosan from personal care products by dermal contact. Lu S, Yu Y, Zhang X, Liu G, Yu Y. Science of the Total Environment, Vol. 621, 15 April, 2018, p. 1389-1396. https://www.sciencedirect.com/science/article/pii/S0048969717327912?via%3Dihub

Mikkelsen et al., 2005. Survey and assessment of chemcial substances in glass and porcelain colours. Mikkelsen SH, Havelund S, Mogensen AS, Stuer-Lauridsen F, COWI. Survey of chemical substances in consumer products, No. 59 2005. https://mst.dk/service/publikationer/publikationsarkiv/2005/aug/survey-and-assessmens-of-chemical-substances-in-glass-and-porcelain-colours/

Møller et al., 2012. Survey of Bisphenol A and Bisphenol-Adiglycidylether polymer. Part of the LOUS-review Environmental Project No. 1483, 2013. Møller L, Fotel FL, Larsen PB, DHI. https://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-14-8.pdf

Nilsson et al., 2006. Survey and health assessment of chemcial substances in sex toys. Nilsson NH, Malmgreen-Hansen B, Bernth N, Pedersen E, Pommer K, Teknologisk Institut. Survey of chemical substances in consumer products no. 77 2006. https://mst.dk/service/publikationer/publikationsarkiv/2006/sep/survey-and-health-assessment-of-chemicals-substances-in-sex-toys/

Nilsson, 2007. Analysis of chemical substances in balloons. Nilsson N, Teknologisk Institut. Survey of chemical substances in consumer products no. 89, 2007. https://mst.dk/service/publikationer/publikationsarkiv/2007/dec/analysis-of-chemical-substances-in-balloons/

Norwegian Environment Agency, 2016. Survey of endocrine disruptors in toys and articles for children. Analysis of selected groups of endocrine disruptors, report M-590, Norwegian Environment Agency, 2016. https://www.miljodirektoratet.no/globalassets/publikasjoner/M590/M590.pdf

Norwegian Environment Agency, 2017. Survey of bisphenol compounds in toys and other articles intended for children, report M-689, Norwegian Environment Agency, 2017

Nylén et al., 2004. Mapping of chemical substances in animal care products. Nylén D, Borling P, Sørensen H. Survey of chemical substances in consumer products, No. 44 2004. https://eng.mst.dk/media/mst/Attachments/Surveyno44.pdf

ÖKO-TEST, 2014. 21 Feuchtigkeitspflegecremes für da Gesicht im Test (in German). Viewed in April 2020. https://www.oekotest.de/kosmetik-wellness/21-Feuchtigkeitspflegecremes-fuer-das-Gesicht-im-Test_104331_1.html

ÖKO-TEST, 2019. Zu viele Problemstoffe: Bebe Intensive Pflege für trockene Haut enttäuscht im Test (in German). Viewed in April 2020. https://www.oekotest.de/kosmetik-wellness/Zu-viele-Problemstoffe-Bebe-Intensive-Pflege-fuer-trockene-Haut-enttaeuscht-im-Test-_10986_1.html

ÖKO-TEST, 2020a. Silikone: Was macht der Kunststoff in Kosmetik? (in German). Viewed in April 2020. https://www.oekotest.de/kosmetik-wellness/Silikone-Was-macht-der-Kunststoff-in-Kosmetik_10764_1.html

ÖKO-TEST, 2020b. Ruby Cup im Test: Wegen bedenklicher Inhaltsstoffe nur "ausreichend". Hentet i april 2020. https://www.oekotest.de/kosmetik-wellness/Ruby-Cup-im-Test-Wegen-bedenklicher-Inhaltsstoffe-nur-ausreichend-_11210_1.html

Petersen et al., 2002. Kortlægning af kemiske stoffer i fastelavns- og teatersminke (in Danish). *English title: Mapping of chemicals in shrovetide and stage make-up*. Kortlægning af kemiske stoffer i forbrugerprodukter nr. 5 2002. Miljøstyrelsen. https://www2.mst.dk/udgiv/publikationer/2002/Kortlaegning/005_Kortl%C3%A6gning_af_kemiske_stoffer_i_fastelavns-og_teatersminke.pdf

Pors & Fuhlendorff, 2002. Mapping of chemical substances in tampons. Pors J & Fuhlendorff R. MILJØ-KEMI. Survey of chemical substances in consumer products no. 12, 2002. https://eng.mst.dk/media/mst/69095/12.pdf

Pors, 2006. Mapping of perfume in toys and children's articles. Survey of chemical substances in consumer products no. 68, 2006. https://mst.dk/service/publikationer/publikationsarkiv/2006/mar/mapping-of-perfume-in-toys-and-childrens-articles/

Potouridis et al., 2019. Examination of paraben release from baby teethers through migration tests and GC–MS analysis using a stable isotope dilution assay. Potouridis T, Knauz A, Berger E, Püttman W. BMC Chemistry (2019) 13:70. https://bmcchem.biomedcentral.com/track/pdf/10.1186/s13065-019-0587-6

Poulsen et al., 2020. Survey and risk assessment of VOC in PU foam products. Poulsen PB, Strange M, Schmidt AC. Survey of chemical substances in consumer products no. X, 2020 (not published yet).

Poulsen & Nielsen, 2016. Survey and healt assessment of preservatives in toys, corrected version. Poulsen PB, Nielsen R. Survey of chemical substances in consumer products no. 124, 2016. https://mst.dk/service/publikationer/publikationsarkiv/2014/feb/survey-and-health-assessment-of-preservatives-in-toys/

Rud Larsen et al., 2006. Survey of liquid hand soaps, including health and environmental assessments. Rud Larsen J, Dansk Toksikologi Center; Andersen TT, Rasmussen D, DHI. Survey of chemical substances in consumer products no. 69 2006. https://mst.dk/service/publikationer/publikationsarkiv/2006/jun/survey-of-liquid-hand-soaps-including-health-and-environmental-assessments/

Saricoban & Yilmaz, 2014. Effect of thyme/cumin essential oils and butylated hydroxyl anisole/butylated hydroxyl toluene on physicochemical properties and oxidative/microbial stability of chicken patties. Saricoban C, Yilmaz MT, Poultry Science 93:456-463, 2014.

SCCS, 2016. SCCS Opinon on Phenoxyethanol. The SCCS adopted this opinion at its 2nd plenary meeting on 6 October 2016. SCCS/1575/16, Final version of 6 October 2016. https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf

Stat. Ord. 1217, 2013. Bekendtgørelse om forbud mod import, salg og anvendelse af visse parabener i kosmetiske produkter til børn under 3 år (in Danish). *English title: Statutory Order on import, sale and use of certain parabens in cosmetic products for children under the age of 3 years.* https://www.retsinformation.dk/eli/lta/2013/1217

Stat. Ord. 1794, 2015. Bekendtgørelse om særlige pligter for fremstillere, leverandører og importører m.v. af stoffer og materialer efter lov om arbejdsmiljø (in Danish). *English title: Statutory Order on special obligations for producers, suppliers and importers of substances and materials following the law on working environment*. https://www.retsinformation.dk/Forms/R0710.aspx?id=176598

Svendsen et al., 2006. Survey and release of chemical substances in ”slimy” toys. Svendsen N, Pedersen SF, Berth N, Pedersen E, Hanensen OC, Teknologisk Institut. Survey of chemical substances in consumer products no. 67, 2006. https://mst.dk/service/publikationer/publikationsarkiv/2006/mar/survey-and-release-of-chemical-substances-in-slimy-toys/

Technical University of Denmark (DTU), 2016. Butylparaben can have several endocrine disrupting effects. ScienceDaily. Science, 2016. https://www.kemifokus.dk/wp-content/uploads/sites/7/DAK042006s24-27.pdf

Test, 2017: Greiflinge, Schnullerketten und Kinderwagenketten im Test (in German). Viewed in April 2020. https://www.test.de/Test-Spielzeug-Babys-Schadstoffe-1063459-0/

Test, 2018**.** Körperlotionen für trockene Haut: 17 Lotions im Test (in German). Viewed in April 2020. https://www.test.de/Koerperlotion-im-Test-4128814-0/

Tønning et al., 2008. Survey, emission and health assessment of chemical substances in baby products. Tønning K, Pedersen E, Lomholt AD, Malmgren-Hansen B, Woin P, Møller L, Bernth N. Teknologisk Institut. Survey of chemical substances in consumer products, No. 90 2008. https://www2.mst.dk/udgiv/publications/2008/978-87-7052-717-0/pdf/978-87-7052-718-7.pdf

Tønning et al., 2009a. Survey and health assessment of the exposure of 2-year-olds to chemical substances in consumer products. Tønning K, Jacobsen E, Pedersen E, Teknologisk Institut. Strange M, Poulsen PB, FORCE Technology. Møller L, Buchardt Boyd H, DHI. Survey of chemical substances in consumer products no. 103, 2009. https://www2.mst.dk/udgiv/publications/2009/978-87-92548-81-8/pdf/978-87-92548-82-5.pdf

Tønning et al., 2009b. Survey and healt assessment of products for interior car care. Tønning K, Jacobsen E, Pedersen E, Teknologisk Institut. Poulsen PB, FORCE Technology. Survey of chemical substances in consumer products no. 105, 2009. https://mst.dk/service/publikationer/publikationsarkiv/2011/jan/survey-and-health-assessment-of-products-for-interior-car-care/

Wang & Kannan, 2019. Quantitative identification of and exposure to synthetic phenolic antioxidants, including butylated hydroxytoluene, in urine. Wang W, Kannan K, Environmental International 128, 24-29, 2019

Wang et al., 2016. Synthetic phenolic antioxidants, including butylated hydroxytoluene (BHT), in resin-based dental sealants. Wang W, Kannan P, Xue J, Kannan K. Environmental Research, Vol. 151, November 2016, p. 339-343. https://www.sciencedirect.com/science/article/abs/pii/S0013935116303334

WHO, 2013. State of the Science of Endocrine Disrupting Chemicals 2012. Summary for Decision-Makers. An assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme and World Health Organization. https://apps.who.int/iris/bitstream/handle/10665/78102/WHO_HSE_PHE_IHE_2013.1_eng.pdf?sequence=1

Xiongfeng et al., 2016. Determination of Sunscreen Agents in Sunscreen Cream. Xiongfeng H, Lvye L, Qun X, Roher J. Application Note 1118. Thermo Fisher Scientific, 2016. https://assets.fishersci.com/TFS-Assets/CMD/Application-Notes/AN-1118-LC-Sunscreen-Agents-AN71512-EN.pdf

Appendix 1. Survey of nitromethane

In this appendix, searches in various databases on nitromethane are listed. For an explanation behind the searches, refer to the respective sections in chapter 3 ”Survey”.

Appendix 1.1 The ECHA's database of registered substances

Tonnage bands for registration of nitromethane are given in TABLE 29 below. For a more detailed description and comparison with other selected substances, see section 3.2.1 ”The ECHA's database of registered substances”.

TABLE 29. Tonnage bands for REACH registration in the EU for nitromethane

Substance name	CAS no.	Total tonnage band	No. of registrants
Nitromethane	75-52-5	100-1000 tonnes/year	5

Appendix 1.2 Data extracted from the Swedish and Danish registries of products

The use of nitromethane according to the Danish and Swedish product register is stated in TABLE 30 below. For a more detailed description and comparison with other selected substances, see section 3.2.9 ”Data extracted from the Danish registry of products”.

TABLE 30. Data extracted from the Danish registry of products for nitromethane

Substance name	Product type	No. of products	Max. conc. (%)
Nitromethane	Degreasers	1-5	0.25

TABLE 31. Result of searching the Swedish registry of products for nitromethane

Substance name	CAS no.	Total amount used annually	Comments
Nitromethane	75-52-5	2400 kg	Fuel for miniature models

As shown by the data extracted from the Danish and Swedish product registries, only a single use is registered in each country: degreasers (Denmark) and model fuel (Sweden).

Appendix 1.3 Literature search for nitromethane

There is generally little information on nitromethane. Nitromethane appears to have been used in the past in cosmetic products and as a rust protector in spray cans, but is apparently no longer used (Danish Consumer Council Tænk, 2020; Environment Canada, 2010). The only use identified is fuel for miniature models (model cars, model ships and the like) and degreasers (information from the Danish and Swedish product register). It is not known whether the application as a degreaser is for professional use only.

Canadian survey, 2010

Environment Canada (2010) states that Canada's total use of nitromethane was between 100 and 1000 kg in 2006. In other words, this is not a substance that is used in large quantities.

According to the Environment Canada survey, use of nitromethane was only reported in two cosmetic products for professional use: a gel for removing adhesive from false eyelashes and a product for removing artificial nails. Historically, nitromethane has been used in aerosol hair spray products, but it is no longer used in this type of product.

Environment Canada (2010) studied the presence of nitromethane in food contact materials in 2009, but it did not identify any use of the substance.

Nitromethane is used as a chemical intermediate for producing medicinal products, so trace amounts may be present in medicinal products (Environment Canada, 2010).

According to this ten-year-old study, nitromethane is used as a stabiliser in solvents for dry-cleaning clothes, and Environment Canada indicates that there may therefore be residues left in cleaned textiles. Whether this use is still current is not known, but neither the Danish nor the Swedish product register has registered such a professional use of nitromethane.

Nitromethane is or has previously been used as an additive in rocket fuel and, together with methanol, as a fuel in cars for drag racing. As far as consumer products go, it is mentioned that nitromethane is used as fuel for such miniature models as cars, boats, and planes (Environment Canada, 2010).

In addition, a number of industrial applications which are not considered to have any significance relative to the content of consumer products are also described (Environment Canada, 2010).

Appendix 1.4 Summary for nitromethane

A summary of the use of nitromethane is given in TABLE 32 below.

TABLE 32. Overview of the use of nitromethane

Cosmetic products	Other consumer products	Food/FCMs	Medicinal products/supplements
May be used as a corrosion inhibitor at a max. conc. of 0.3% (EU regulation no. 1223, 2009). Use in soap (ECHA, 2020b) and aerosol hair spray products previously observed (Environment Canada, 2010) No longer used in cosmetic products for private use (Environment Canada, 2010)	Fuel for models (planes, cars, ships) Stabiliser in solvent in chemical cleaners (Environment Canada, 2010) Model fuel (Swedish registry of products) Degreasers (Danish registry of products)	Not present in FCMs (Environment Canada, 2010)	Not used in medicinal products. Residues may remain in medicinal product products (Environment Canada, 2010)

Appendix 2. Legislation on plastic for food contact

For the investigated substances in this project, BPA, BPS, propylparaben, BHA and BHT are permitted to be used in plastic material for food contact (EU regulation no. 10, 2011). Specific migration limit values have been set for these substances, which must be complied with when producing plastic products for food contact (see TABLE 33). However, there is no specific migration limit value for propylparaben. Concerning butylparaben, it is not permitted for use in plastic for food contact.

TABLE 33. Permitted substances for the production of plastic for food contact (according to EU regulation no. 10, 2011)

Substance	CAS no.	Allowed	Restrictions	Specific migration limit for the substance
BPA	80-05-7	Yes May be used as a monomer	Not to be used as an additive or a polymerisation aid. Not to be used for the manufacture of polycarbonate infant feeding bottles. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill-proof characteristics, are intended for infants and young children.	0.05 mg/kg
BPS	80-09-1	Yes May be used as a monomer	Not to be used as an additive or a polymerisation aid.	0.05 mg/kg
Propylparaben	94-13-3	Yes	Approved for use as an additive or polymerisation aid.	None
BHA	25013-16-5	Yes	Approved for use as an additive or polymerisation aid.	30 mg/kg
BHT	128-37-0	Yes	Approved for use as an additive or polymerisation aid.	3 mg/kg

Appendix 3. Additives for food

BHA and BHT are the only substances studied in this project that, according to the EU's database of permitted food additives[20] are allowed to be used as food additives. The foods where BHA and BHT may be added, as well as the permitted limit values are stated in TABLE 34 below.

TABLE 34. Foods where BHA and BHT are allowed for use as additives

Type of food	BHA (Maximum permitted quantity)	BHT (Maximum permitted quantity)
Dehydrated milk	200 mg/kg Only milk powder for vending machines	*Not permitted*
Fats and oils essentially free from water (excluding anhydrous milkfat)	200 mg/kg Only fats and oils for the professional manufacture of heat-treated foods; frying oil and frying fat (excluding olive pomace oil) and lard, fish oil, beef, poultry, and sheep fat	100 mg/kg Only fats and oils for the professional manufacture of heat-treated foods; frying oil and frying fat (excluding olive pomace oil) and lard, fish oil, beef, poultry, and sheep fat
Other fat and oil emulsions including spreads and liquid emulsions	200 mg/kg Only frying fat	100 mg/kg Only frying fat
Nut butters and nut spreads	200 mg/kg Only processed nuts	*Not permitted*
Processed potato products	25 mg/kg Only dehydrated potatoes	*Not permitted*
Chewing gum	400 mg/kg	400 mg/kg
Breakfast cereals	200 mg/kg Only pre-cooked cereals	*Not permitted*
Pre-cooked or processed cereals	200 mg/kg Only pre-cooked cereals	*Not permitted*
Fine bakery wares	200 mg/kg Only cake mixes	*Not permitted*
Non-heat-treated processed meat	200 mg/kg Only dehydrated meat	*Not permitted*
Seasoning and condiments	200 mg/kg	200 mg/kg
Soups and broths	200 mg/kg Only dehydrated soups and broths	*Not permitted*
Sauces	200 mg/kg	*Not permitted*
Potato-, cereal-, flour- or starch-based snacks	200 mg/kg Only cereal-based snack foods	*Not permitted*
Processed nuts	200 mg/kg	*Not permitted*

[20] https://webgate.ec.europa.eu/foods_system/main/?sector=FAD&auth=SANCAS

Type of food	BHA (Maximum permitted quantity)	BHT (Maximum permitted quantity)
Food supplements supplied in solid form including capsules and tablets and similar forms, excluding chewable forms. Excluding food supplements for infants and young children.	400 mg/kg	400 mg/kg
Food supplements supplied in liquid form. Excluding food supplements for infants and young children.	400 mg/kg	400 mg/kg
Food supplements supplied in a syrup-type or chewable form. Excluding food supplements for infants and young children.	400 mg/kg	400 mg/kg

Appendix 4. Method of analysis

This chapter describes which analysis methods can be used for screening analyses for the presence of the selected substances in consumer products. The section also describes analysis techniques that can be used for quantitative content analysis. Possible analysis methods are described below for the individual substances.

Appendix 4.1 Methods of analysis for the selected substances

In general, GC-MS (gas chromatography with mass spectrometry) is the most useful analysis method as a screening method, as a large number of substances can be detected, which can subsequently be identified (via NIST library). Analysis techniques such as LC-MS (liquid chromatography with mass spectrometry) and HPLC-UV (high performance liquid chromatography with UV spectroscopy) are better suited for quantitative analyses of predetermined ingredient substances. However, GC-MS can also be used as a quantitative content analysis.

BPA and BPAF (and possibly other bisphenols)

BPAF has a comparable structure/properties with the other bisphenols and is therefore expected to be able to be analysed through the same analysis method (HPLC-UV), which is used for BPA, BPF and BPS, in the survey project on "Exposure of children and unborn children to selected chemical substances." (Larsen et al., 2017). Another option is a GC-MS analysis of the extract that was also used in the same project or an LC-MS analysis of the extract.

BHA and BHT

Quantitative content determination of BHA and BHT has previously been made in cosmetic products in the survey project on "Exposure of children and unborn children to selected chemical substances" (Larsen et al., 2017). The method of analysis here was a GC-MS analysis. The same method, i.e. GC-MS analysis after extraction of the material with an organic solvent is expected to be applicable to solid materials such as e.g. plastics in which BHA and BHT are primarily expected to occur.

Butylparaben (and possibly other parabens)

Butylparaben (and possibly other parabens) in cosmetic products is expected to be able to be analysed via the same method as specified for BHA and BHT, i.e. through GC-MS. Similarly, parabens are expected to be able to be analysed through GC-MS in e.g. other chemical mixtures, such as chemical toys. In addition, LC-MS can be used to determine parabens.

D4

D4 should also be able to be analysed through GC-MS. According to the Danish Veterinary and Food Administration's study on "Siloxanes in baking tins, bottle teats…" (Danish Veterinary and Food Administration, 2016b), D4 in silicone products can be determined by an extraction with ethyl acetate of finely divided silicone product and analysis through GC-MS. This method should also be able to be used as a screening method.

4-MBC

4-MBC can be analysed by the same method as the other substances above in cosmetic products, i.e. GC-MS.

Appendix 4.2 Possible analysis methods for the screening analyses

The above descriptions provide overall these various possible analysis techniques:

1. GC-MS - should be applicable for:
   - BHA and BHT
   - Parabens
   - 4-MBC
   - D4
   - BPA and BPAF
2. HPLC-UV is expected to be applicable for:
   - BPA, BPAF and possibly other bisphenols
3. LC-MS - should be applicable for:
   - BPA
   - Parabens

Appendix 4.3 Discussion of the analyses

A selection of the above analysis methods is primarily performed as screening analyses in this project. The same analysis methods and all the above analysis methods can be used in a possible follow-up project for quantitative determination of the presence of the substances.

For GC-MS analysis (screening) for BHT and BHA in cosmetic products, a detection limit of 2 ppm is expected according to previous studies (Larsen et al., 2017). The detection limit for BHT in plastic products is expected to be slightly higher, depending on the volume of extraction liquid used. For BPAF, it is expected that the substance has approximately the same sensitivity as BPA and that the detection limit is around 3-10 ppm when using GC-MS. The detection limit of D4 in silicone products or cosmetic products using GC-MS is not known and it will depend on the volume of extraction liquid used as well as the sensitivity of the substance, but it is estimated that the detection limit will be around 5 to 10 ppm.

It is unknown whether the expected detection limits for BPA, BPAF and D4 will be low enough in relation to the actual levels of these substances in plastic and silicone products respectively. BPA, BPAF and D4 are all used as monomers to make polymers, and it is therefore expected that only small residues of un-reacted monomers remain in the polymer. Measured levels of BPA in dummy shields in the project by Tønning et al. (2009a) was above 1000 ppm, but it is not known whether the level of a possible presence of e.g. BPAF will be at the same level.

Appendix 5. Overview of analysed products

This appendix contains an overview of the total of 73 consumer products that were selected for in all 78 material analyses (screening analyses). It should be noted that the products have been named ("Lab no.") after where they have been purchased. However, this does not mean that the products are produced in the same region. This appendix contains four tables in all – one for each type of material that has been analysed. The price apiece has been calculated as the price for each pair of socks or the price per pot of finger paint even though it may be sold in a six-pack.

TABLE 35. Names and description of the total of 18 silicone products

Lab no.	Product type	Produced in*	Price apiece excl. cargo
DK S 1	Teething ring/teething animal	No information	29 DKK
DK S 2	iPad and tablet cover	USA	473 DKK
DK S 3	iPad and tablet cover	China	249 DKK
DK S 4 (DK P 4)**	Soother	Thailand	15 DKK
DK S 5	Soother	UK	24 DKK
DK S 6	Teething ring/teething animal	Denmark	119 DKK
EU S 1	Soother	Sweden	20 DKK
EU S 2	Teething ring/teething animal	Belgium	120 DKK
EU S 3	iPad and tablet cover	China	83 DKK
EU S 4 (EU P 7)**	Soother	Germany	15 DKK
EU S 5 (EU P 5)**	Plastic toy (Teething ring/teething animal)	France?	22 DKK
EU S 6	Teething ring/teething animal	Portugal	15 DKK
EU S 7	Plastic toy (Teething ring/teething animal)	China	315 DKK
N-EU S 1	Teething ring/teething animal	No information	0 DKK (only paid for cargo)
N-EU S 2	iPad and tablet cover	UK	75 DKK
N-EU S 3 (N-EU P 3)**	Plastic toy (Teething ring/teething animal)	China?	30 DKK
N-EU S 4 (N-EU P 7)**	Soother	China	25 DKK
N-EU S 6	iPad and tablet cover	No information	76 DKK

*"?" in the column "Produced in" means that the company name written on the product is situated in this country, but there is no information about where the product has been produced.

** means that the same product also was analysed as a plastic product, as the product contains both plastic and silicone. Lab. no. for the corresponding plastic analysis is listed in brackets.

TABEL 36. Names and description of the total of 18 plastic products

Lab no.	Product type	Produced in*	Price apiece excl. cargo
DK P 1	Plastic toy (building set)	Denmark	180 DKK
DK P 2	Mobile covers	South Korea	149 DKK
DK P 3	Plastic toy (stacking rings)	No information	79 DKK
DK P 4 (DK S 4)**	Soother	Thailand	15 DKK
DK P 5	Mobile covers	China	199 DKK
DK P 6	Plastic toy (soap bobble pistol)	Germany	99 DKK
EU P 1	Mobile covers	China	36 DKK
EU P 3	Mobile covers	No information	61 DKK
EU P 4	Mobile covers	China	68 DKK
EU P 5 (EU S 5)**	Plastic toy (Teething ring/teething animal)	France?	22 DKK
EU P 6	Plastic toy (rattle)	China	5 DKK
EU P 7 (EU S 4)**	Soother	Germany	15 DKK
N-EU P 1	Plastic toy (rattle)	China?	21 DKK
N-EU P 2	Mobile covers	UK	59 DKK
N-EU P 3 (N-EU S 3)**	Plastic toy (Teething ring/teething animal)	China?	30 DKK
N-EU P 4	Plastic toy (rattle)	China	94 DKK
N-EU P 6	Plastic toy (rattle)	China	18 DKK
N-EU P 7 (N-EU S 4)**	Soother	China	25 DKK

*"?" in the column "Produced in" means that the company name written on the product is situated in this country, but there is no information about where the product has been produced.

** means that the same product also was analysed as a silicone product, as the product contains both plastic and silicone. Lab. no. for the corresponding silicon analysis is listed in brackets.

TABEL 37. Names and description of the total of 21 chemical mixtures

Lab no.	Product type	Produced in*	Price apiece excl. cargo
DK KB 1	Finger paint (25 g)	Italy	20 DKK
EU KB 1	Finger paint (unknown amount)	Sweden	17 DKK
DK KB 2	Finger paint (80 ml)	No information	20 DKK
DK KB 5	Soap bubble fluid (500 ml)	Italy	20 DKK
DK KB 4	Soap bubble fluid (400 ml)	Poland	49 DKK
DK KB 6	Soap bubble fluid (120 ml) incl. pistol	Germany	99 DKK
EU KB 5	Soap bubble fluid (60 ml)	Germany?	7 DKK
EU KB 2	Finger paint (40 ml)	Italy	8 DKK
N-EU KB 4	Soap bubble fluid (60 ml)	China or USA?	21 DKK
N-EU KB 2	Finger paint (473 ml)	Mexico	20 DKK
N-EU KB 5	Soap bubble fluid (300 ml)	USA	16 DKK
N-EU KB 3	Finger paint (30 ml)	China	8 DKK

Lab no.	Product type	Produced in*	Price apiece excl. cargo
N-EU KB 7	Soap bubble fluid (10 ml conc.)	China	3 DKK
EU KB 3	Finger paint (35 ml)	Germany	10 DKK
EU KB 6	Soap bubble fluid (60 ml)	China	5 DKK
EU KB 4	Finger paint (150 g)	Germany	10 DKK
EU KB 7	Soap bubble fluid (70 ml) incl. blowing horn	Germany	40 DKK
DK KB 3	Finger paint (35 ml)	No information	5 DKK
DK KB 7	Finger paint (75 ml)	China	20 DKK
DK KB 8	Soap bubble fluid (58 ml)	China	10 DKK
DK KB 9	Soap bubble fluid (225 ml)	China	15 DKK

*"?" in the column "Produced in" means that the company name written on the product is situated in this country, but there is no information about where the product has been produced.

TABEL 38. Names and description of the total of 21 textile products

Lab no.	Product type	Produced in*	Price apiece excl. cargo
DK T 5	Briefs (pregnant)	Sweden	26 DKK
DK T 4	Socks (adults)	Pakistan	14 DKK
DK T 3	Socks (children)	Turkey	12 DKK
DK T 1	Socks (children)	No information	4 DKK
EU T 1	Briefs (pregnant)	China	36 DKK
DK T 6	Briefs (pregnant)	Turkey	80 DKK
EU T 2	Briefs (adults)	No information	53 DKK
EU T 6	Socks (adults)	China	70 DKK
EU T 5	Socks (children)	Turkey	28 DKK
EU T 4	Socks (children)	China	20 DKK
DK T 2	Socks (adults)	Turkey	20 DKK
N-EU T 6	Briefs (pregnant)	No information	35 DKK
N-EU T 2	Socks (adults)	No information	30 DKK
N-EU T 5	Socks (adults)	Pakistan	21 DKK
N-EU T 3	Socks (children)	China	10 DKK
N-EU T 4	Socks (children)	China	16 DKK
N-EU T 8	Socks (children)	Pakistan	12 DKK
N-EU T 1	Briefs (adults)	UK	123 DKK
EU T 8	Socks (children)	Pakistan	40 DKK
EU T 3	Socks (adults)	Vietnam	18 DKK
DK T 7	Socks (children)	Sweden	10 DKK

Appendix 6. Quantitative analyses of textiles

In this appendix the values for quantitative content analyses performed for the textile products are listed. These analyses have been performed by Medico Kemiske Laboratorium ApS (in Denmark). True duplicate determinations have been carried out. The uncertainty of the analyses is 20% but may be up to 50% in the area just above the detection limit.

TABLE 39. Results of the quantitative content analyses for butyl- and propylparaben as well as BPA in the textile products. The two columns represent the results of the first and second duplicate determination respectively.

Lab. no.	Description (content of cotton)	Butylparaben (ng/g)		Propylparaben (ng/g)		Bisphenol A (ng/g)	
DK T 1	Children's socks (78 %)	-	-	-	-	-	-
DK T 2	Adult's socks (77 %)	-	-	-	-	-	-
DK T 3	Children's socks (79 %)	-	-	-	-	-	-
DK T 4	Adult's socks (75 %)	-	-	-	-	-	-
DK T 5	Briefs (90 %)	-	-	-	-	-	-
DK T 6	Briefs (79 %)	-	-	-	-	-	-
DK T 7	Children's socks (75 %)	-	-	-	-	-	-
EU T 1	Briefs (95 %)	-	-	-	-	-	-
EU T 2	Briefs (95 %)	-	-	-	-	-	-
EU T 3	Adult's socks (24 %)	-	-	-	-	-	-
EU T 4	Children's socks (55 %)	-	-	**1.5**	**1.5**	-	-
EU T 5	Children's socks (73 %)	-	-	-	-	-	-
EU T 6	Adult's socks (20 %)	-	-	**0.8**	**1.2**	-	-
EU T 8	Children's socks (unknown)	-	-	-	-	-	-
N-EU T 1	Briefs (unknown)	-	-	-	-	-	-
N-EU T 2	Adult's socks (95 %)	-	-	-	-	-	-
N-EU T 3	Children's socks (72 %)	-	-	**0.6**	**0.8**	**30**	**38**
N-EU T 4	Children's socks (72 %)	-	-	-	-	**252**	**235**
N-EU T 5	Adult's socks (90 %)	-	-	**0.7**	**0.5**	**17**	**21**
N-EU T 6	Briefs (95 %)	-	-	-	-	-	-
N-EU T 8	Children's socks (70 %)	-	-	-	-	-	-

- indicates content less than the detection limit of 0.5 ng/g (butyl- and propylparaben) or 5 ng/g (BPA) respectively

Survey of selected endocrine disruptors

The purpose of this project was to investigate the use of selected endocrine disruptors and/or suspected endocrine disruptors in products which children and pregnant women use. It was also investigated if whether differences exist in the content of selected endocrine disruptors and/or suspected endocrine disruptors depending on where the purchased products originate from (Denmark, within the EU and outside of the EU).

A total of 78 consumer products were investigated for content of BHT, BHT and D4 in products of plastic and/or silicone materials, BPA, butyl- and propylparaben in textiles and butyl- and propylparaben in chemical toys-mixtures. The products covers teething rings, dummies, socks, soap bubbles and covers for mobiles and iPads/tablets.

The results were that, BHT was identified in four out of the 18 examined plastic products, propylparaben and BPA were identified in in socks (but not in underpants) and butyl- and propylparaben were both identified in two of the examined soap bubble liquids, but not in any of the examined finger paints. Furthermore, D4 was identified in eight out of the 18 examined silicone products and one plastic product.

In total, four out of 28 products (14 %), six out of 27 products (22 %) and eight out of 23 products (35 %) from Denmark, within the EU and outside of the EU had a content of at least one of the six investigated substances.

The Danish Environmental
Protection Agency
Tolderlundsvej 5
DK - 5000 Odense C

www.mst.dk